

**TOXIC SUBSTANCES CONTROL ACT AND THE  
CHEMICALS MANAGEMENT PROGRAM AT EPA**

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**HEARING**

BEFORE THE

**COMMITTEE ON  
ENVIRONMENT AND PUBLIC WORKS  
UNITED STATES SENATE**

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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August 2, 2006  
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# **TOXIC SUBSTANCES CONTROL ACT AND THE CHEMICALS MANAGEMENT PROGRAM AT EPA**

**WEDNESDAY, AUGUST 2, 2006**

U.S. SENATE,  
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,  
*Washington, DC.*

The committee met, pursuant to notice, at 9:30 a.m. in room 406, Dirksen Senate Office Building, Hon. James Inhofe (chairman of the committee) presiding.

Present: Senators Inhofe, Jeffords, Lautenberg, Carper, Thune, Warner, Boxer.

## **OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA**

Senator INHOFE. The hearing will come to order.

Because of a development, we are going to change the order of things a little bit from what we had planned. We are going to go ahead and proceed with opening statements from the panel and then questions, and then the next panel, opening statements and questions. Because we have to recess this hearing at 11 o'clock to reconvene at the event we are not concluded at that time at 3 o'clock today in the same place.

So why don't we go ahead and start. We are actually going to defer any opening statements also until 3 o'clock.

If you would like to go ahead and start, Mr. Gulliford, now that Senator Jeffords is here, begin with your opening statement.

[The prepared statement of Senator James M. Inhofe follows.]

### STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Good morning. Today's hearing is a very important one. The Committee has not held a hearing on the chemicals management program at EPA in more than 10 years.

There are many people who come to this hearing with a preconceived notion that the U.S. chemicals management program is broken and that Congress needs to completely rewrite the Toxic Substance Control Act (TSCA). I do not come into this hearing with that assumption and I look forward to hearing from the witnesses how they believe the statute and the program are working. However, it is important to take a look at how our environmental statutes are being put into practice, which is why shining light on EPA implementation of TSCA with this hearing is so important. Government bureaucracies only work well when there is Congressional oversight.

The chemical industry is a crucial part of the U.S. economy. The United States is the number one chemical producer in the world, generating \$550 billion a year and putting more than 5 million people to work. More than 96 percent of all manufactured goods are directly touched by chemistry.

Chemicals are the essential building blocks of products that safely and effectively prevent, treat and cure disease; ensure the safest and most abundant food supply in the world; purify our drinking water and put out fires. They are the foundation for life-saving vaccines, child safety seats, bicycle helmets, home insulation, and Kevlar vests. Innovations in chemistry have helped to increase energy efficiency and to make planes, fighter jets, satellites and space shuttles safer and more secure. We are also on the cusp of new and exciting chemical advances in the form of nanotechnology. These tiny chemicals have the potential to cure cancers, clean up pollution, and make cars stronger and lighter than ever before. To say that chemicals are vital is an understatement.

There are those that suggest the mere presence of chemicals in our bodies is cause for alarm. However, the Centers for Disease Control in its biennial report on Human Exposure to Environmental Chemicals states, "just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease. The toxicity of a chemical is related to its concentration in addition to a person's individual susceptibility."

This is not to say that we should ignore human health and environmental risks if they do, based on scientific evidence, exist. For nearly 30 years, chemical products have been among the most thoroughly evaluated and regulated, covered by more than a dozen Federal laws, including TSCA. These statutes are centered on the concept of regulating substances based on risk. I do not believe American chemicals innovation should be stifled by Government regulation without the clear identification of risk. We need to ensure that we regulate chemicals based on demonstrated risk not the just the perception or assumption of it. That "precautionary" concept is one that I cannot support.

In reviewing the statute and its legislative history it appears that the Congress was very deliberate in the powers it granted EPA under TSCA and appropriately balanced them with burdens on the private sector. For example, TSCA gives EPA the power to limit or prohibit the manufacture and distribution of a substance if it is found to pose an unreasonable risk. Chemical product makers are required to submit information on all newly developed chemicals BEFORE they are even manufactured. If EPA has concerns, it has the power to mandate testing and then to control or ban it. In nearly 30 years, EPA estimates that 20,000 new chemicals have gone into commercial production by going through the new chemicals review process and never over the objection of EPA.

EPA has also created effective new programs to ensure that we have chemical safety data on those existing chemicals that are produced or imported in the United States in large quantities. This program is called the High Production Volume (HPV) Challenge program and covers approximately 95 percent of current U.S. chemical production and use by volume. Through the program, seventeen types of information are being collected, including physical-chemical properties, environmental fate, and human and aquatic organism toxicity. This information is identical to the internationally-agreed upon Screening Information Data Sets, established by the 30 nations of the Organization for Economic Cooperation and Development.

There is no shortage of strong feelings when it comes to chemicals and how they are regulated and managed. I look forward to hearing from our witnesses today regarding the success of the chemicals program at EPA and its principal statute. And perhaps we will uncover implementation problems that this committee, exercising its oversight, can encourage the Agency to rectify.

**STATEMENT OF JAMES B. GULLIFORD, ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY**

Mr. GULLIFORD. Thank you, Mr. Chairman, Senator Jeffords. I want to thank you for the opportunity to appear today, but I also want to thank you for your support during my recent confirmation process. As I said during that process, I am committed to working with each of you to fully understand the issues, to seek solutions, to facilitate change and collaborate on the challenges that we face.

I would also like to thank John Stephenson and his staff at GAO for their engagement in the work of my office. While we may not always agree on a specific path, we share the same goal of implementing our laws in the most efficient and effective ways possible.

I want to assure you that EPA takes very seriously its commitment to protect human health and the environment from the adverse effects of chemicals. I believe that TSCA has been used effectively over the past three decades to provide those vital protections for the American people and the environment. It is a statute that has broad ranging authorities, and it has allowed us to use the right tool for the right job. It is a statute that is science-based, recognizes the role that social and economic factors have in common sense regulation, and is flexible enough to work in harmony with other statutes and other risk management approaches. It gives us the authority and the flexibility that we need to effectively manage both new and existing chemicals as well as producers of biotechnology and nanotechnology. As the environmental challenges that we have faced have evolved, so too has our use of TSCA.

Leveraging our authorities under TSCA with the principles of environmental stewardship, pollution prevention and innovation, I believe that we have developed and maintained a successful and comprehensive regulatory framework for chemicals management. Let me share a few of our accomplishments.

The TSCA New Chemicals program has been recognized nationally and internationally as a model regulatory program for assuring the safety of new chemicals as they enter the marketplace. Since 1979, the program has received and reviewed over 45,000 new chemical notices. Using both regulatory and voluntary approaches, the United States has been in a leadership position worldwide in identifying and managing risks associated with existing chemicals.

For example, while we are not yet a part to the POPS treaty, although as you know we are working very diligently to get there, the United States has already banned or severely restricted all of the original 12 POPS chemicals before the treaty was even drafted. Under TSCA authorities, as well as innovative partnership approaches, the United States has developed an extensive and publicly available data base on chemical hazard information. We have developed sophisticated modeling programs to predict the chemical's toxicity, as well as peer-reviewed models to identify chemicals that may be persistent and bioaccumulative.

We have made these programs available to industry to use in the design and development of safer and greener new chemicals. We are seeing that shift take place as well.

Innovative partnership programs, such as the HPV program, have considerably increased the pace of environmental progress. We have worked to ensure that pollution prevention is the tool of first choice for our Nation. Stopping pollution before it starts is clearly the most sustainable approach that we can pursue.

Let me cite some additional accomplishments. The voluntary stewardship programs are very important. EPA, working cooperatively with the chemical industry and the environmental community, launched the High Production Volume (HPV) challenge program. This program sought commitments from chemical manufacturers to make basic health and safety data publicly available on about 2,800 chemicals produced in the United States at more than 1 million pounds annually. These HPV chemicals account for more than 93 percent of the production volume from the chemicals that

we track on the inventory. Under the Bush administration, data has been submitted on 97 percent of the HPV chemicals.

The Agency has in turn met its commitment to making that information publicly available. We launched the HPV public information system in March of this year, and will further engage the public in a December data use conference. The HPV program is now being extended by industry to develop these same health and safety data on an additional 500 HPV chemicals. There is no denying that these are real results and will lead to both greater understanding of chemicals and better protection of public health and the environment.

For new chemicals, when TSCA was passed in 1976, there were 62,000 chemicals placed on the TSCA inventory. Since that time, EPA has reviewed more than 45,000 new chemical submissions. Twenty thousand, roughly, have been added to the inventory, but only after detailed review by EPA.

For existing chemicals, from Section 8 requirements, the Agency has the ability to require record keeping and reporting on a wide range of data, including production volume information, health and safety data and substantial risk information. This is critical information in developing risk assessments.

We recently amended the inventory update reporting rule to obtain exposure data on HPV chemicals to help inform the risk-based assessments on these chemicals. In this area, more than 50,000 health and environmental studies have been submitted to the Agency. This information is also helpful to EPA, but also a number of other Federal agencies that use this data.

EPA has also received industry submissions under TSCA Section 8 of substantial risk information, which alerts EPA to critical new test data. This test data has been highly valuable in identifying chemicals for information.

In closing, let me say we are most appreciative of today's opportunity for the hearing, the ongoing interest of the Committee in TSCA and the work of GAO. There are many dedicated engineers, chemists, biologists, toxicologists, economist, statisticians, attorneys and other civil servants who work directly on TSCA issues for EPA. I am proud of their achievements and proud to support their work today.

Thank you.

Senator INHOFE. Thank you, Mr. Gulliford. It is an excellent statement.

Mr. STEPHENSON.

**STATEMENT OF JOHN B. STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE**

Mr. STEPHENSON. Thank you, Mr. Chairman, and members of the Committee. I am pleased to be here today to discuss our work on EPA's implementation of the Toxic Substances Control Act.

Tens of thousands of chemicals are currently in commercial use in the United States, and over 700 new chemicals are introduced in commerce every year. Although these chemicals are unquestionably essential to produce important goods and services that we all enjoy, some may be toxic and may adversely affect human health



and/or the environment. It was in this context that Congress enacted TSCA in 1976, authorizing EPA to obtain information on risk of chemicals and to control those that pose an unreasonable risk.

My testimony today is based on a report that we issued last year, but also on past and ongoing work we have done on TSCA. In summary, our work has shown that TSCA's authorities for collecting data on existing chemicals do not facilitate EPA's review process, primarily because the costly and time-consuming burden of producing chemical risk data is on EPA rather than the chemical industry. As a result, EPA has used its authorities to require chemical companies to develop data for only about 200 of the 62,000 chemicals in commerce since TSCA was enacted in 1976.

In addition, EPA has had difficulties in using TSCA to control the risks of specific chemicals. For example, in order to withstand judicial scrutiny, a TSCA rule to control chemical risk must be supported by substantial evidence that a given chemical presents not just a substantial risk, but an unreasonable risk to human health and the environment. In our view, this is such a high legal standard that it inhibits EPA's ability to ban or restrict the manufacture or use of chemicals. In fact, EPA has issued regulations under the Act to ban or limit the production of only five chemicals in the 30 years since TSCA was passed.

Recognizing the need for additional information on existing chemicals, EPA implemented the High Production Volume challenge program, as you just heard, in the late 1990's. Under this program, chemical companies agree to voluntarily provide test data on chemicals produced or imported in amounts of 1 million pounds or more per year. While the HPV challenge program is a laudable effort and has resulted, as you heard in EPA receiving information on 2,800 additional chemicals, EPA has not yet fully determined how useful the information it has obtained will be or what additional information may be required.

Even with this additional data, EPA still needs to meet TSCA's lofty standard of demonstrating in a costly and time-consuming rulemaking that a given chemical possesses unreasonable risk before it can take action. Similarly, EPA's processes for reviewing new chemicals is cumbersome. TSCA does not require chemical companies to test new chemicals before notifying EPA of their intent to manufacture a chemical. And companies generally do not voluntarily perform such testing.

To compensate for this general lack of data, EPA uses sophisticated scientific models to predict the potential exposure and toxicity level of new chemicals. However, these models are not always accurate predictors of risk. Additionally, estimates of the chemical's production volume and anticipated use can change substantially after EPA completes its review. But the estimates do not have to be amended by companies unless EPA promulgates a significant new use rule.

Mr. Chairman, while EPA's efforts are commendable in encouraging companies to voluntarily provide data on existing chemicals, the Agency's ability to manage its chemical review program and assess chemical risks are severely inhibited by TSCA's cumbersome authorities. EPA could review substantially more chemicals in less time if some of the burden for assuring the risks of chemicals was

shifted from EPA to chemical manufacturers. In that regard, we have made several recommendations over the years for improving TSCA, such as giving EPA additional authority under Section 4 to require companies to develop test data based on production volumes and the potential risk of the chemical. EPA has begun to address some of our recommendations, but others require amendments to TSCA.

Mr. Chairman, that concludes my summary of my statement. I will be happy to answer questions.

Senator INHOFE. Thank you, Mr. Stephenson.

Let me ask you a question. At the very last of your statement, you talked about the recommendation that you make to shift more responsibility back to the companies. When you make recommendations like that, do you take into consideration the costs that would be involved to the ultimate consumer of the chemicals?

Mr. STEPHENSON. We do. And, we think the recommendations we have made fall in the modest category. I would say, that we would not require the chemical industry to produce data on all chemicals, only the few that aren't the greatest risk. We subscribe to a risk-based approach, based on the volume of the chemical produced and other risk factors.

Senator INHOFE. But you do consider that, then?

Mr. STEPHENSON. Yes.

Senator INHOFE. In a recent congressional staff briefing, the GAO stated that companies can claim any information they want as confidential business information and therefore be protected from public view. Yet the Section 8 requires companies to immediately submit information that reasonably supports the conclusion that a substance presents "a substantial risk of injury or health and the environment." Do you see a conflict there?

Mr. STEPHENSON. We think CBI claims are mostly legitimate. They are protecting proprietary information of the company. What we are subscribing is a broader use of even CBI information beyond EPA to other valid users. For example, the States may have valid reasons for seeing that data. Right now, it is not easily provided to them or other legitimate users because of limitation in TSCA.

Senator INHOFE. I see.

Mr. Gulliford, I took some notes at the very last of your statement. Because I didn't get that from your submitted statement. Is it correct, you said since 1968, well, in 1968 there were some 62,000 identified chemicals?

Mr. GULLIFORD. That is the number of the chemicals that were immediately put on the list as existing chemicals.

Senator INHOFE. As existing chemicals. Now it is almost, well, it is up another 45?

Mr. GULLIFORD. We reviewed 45,000 new submissions. Roughly 20,000 of those have gone onto the list.

Senator INHOFE. Some people believe that TSCA is broken and that it doesn't provide EPA the needed authority to gather the information necessary to adequately evaluate and regulate the harmful chemicals. You said it was very effective in your opening statement. Very briefly, I would just like to have you restate that, because I want to make sure we understand what your feeling is about their effectiveness.

Mr. GULLIFORD. We think TSCA is a very effective statute. It does give us the ability to assess the likelihood of risk during the introduction of chemicals into manufacturing or commercial processes here in this Country. We get good information. We have excellent models that allow us to determine whether or not there is a likelihood of an increased risk. TSCA gives us the authority to go to the companies and require additional information if we feel it is appropriate. We also have the authority, if the chemical appears to be a very safe chemical, to allow it to proceed immediately, which is good for industry and it is good for the environment.

Senator INHOFE. Good. Just last week, the American Bar Association's environment section released a paper that indicated the organization's belief that TSCA currently provides sufficient legal authority to regulate nanoscale chemicals. Does EPA believe it has the authority it needs to address these chemicals? This is something people are concerned with today.

Mr. GULLIFORD. We have examined the authorities very carefully, and we do believe and we agree that TSCA has and provides the authorities necessary to review both new and existing nanoscale materials for use in this Country. We are pleased that the American Bar Association came to the same conclusion.

Senator INHOFE. All right, that is good.

Let me at this point, I understand that Senator Lautenberg has to depart shortly. If it is all right with you, Senator Jeffords, we can go to him for his questions.

Senator LAUTENBERG.

Senator LAUTENBERG. I appreciate that very much, Mr. Chairman, and I know that you have a commitment that you must keep.

What I wanted to get square, Mr. Gulliford, is whether or not, in your remarks you talked about the number of new things that have come up and have been reviewed. But since the passage of TSCA, only 2 percent of the chemicals that were in use at that time have been evaluated by the EPA. And only five of those have been regulated. In other words, we are talking about a base of 62,000 chemicals. Are my statements, do they reflect the real condition?

Mr. GULLIFORD. What the Agency has done is, we have looked at the number of chemicals that are in use in this Country, those that are used in the highest volume. And we went to the industry and asked for additional data on those high production volume chemicals. And in doing so, we have data actually on 93 percent of these actual chemicals that are in use or produced and used in this Country. And again, industry was very responsive.

Senator LAUTENBERG. You are talking about a base of 62,000?

Mr. GULLIFORD. That is right. Of those 62,000 chemicals, many of those chemicals are used in large volumes. Those are the ones that we went to, I believe it was 2,800 of those that are actually responsible for 93 percent of the chemistry or the chemicals that are produced in this Country. Those are the ones that we went to with the HPV challenge to get information, additional information on those chemicals.

We have received that. In fact, we have received already to date 97 percent of the information that was requested. We have reviewed those studies and are looking now on how to proceed for-

ward to use that information. We have also made that information available for public on the web to allow any users access to that information.

Senator LAUTENBERG. Fundamentally you are saying you cutoff your review at a particular volume of use? Does that include the toxicity of these things as well? Whether or not it is high volume or low volume, if it is terribly dangerous material, then even a low volume might—

Mr. GULLIFORD. We have opportunities to look at low volume chemicals, too, as I think was pointed out. Through the Section 8(e) requirements of TSCA, if an industry becomes aware that there are toxicity problems with the chemical, they must report that immediately. That has happened. We have had good examples of that. The PFOS reports that came to us.

Senator LAUTENBERG. Are you satisfied with the progress that we have made since TSCA was put into law?

Mr. GULLIFORD. Yes, I am.

Senator LAUTENBERG. You really are? There are 82,000 chemicals currently in commerce. Are they all safe?

Mr. GULLIFORD. There are different toxicities related to those chemicals. The information that we have States that in their production and in their use, the risks to the human health and environment is acceptable.

Senator LAUTENBERG. Now, that, so you make that analysis regardless of what age the person who is exposed might be? I mean, if it is an infant or a child, doesn't that cause a little more intensity of review?

Mr. GULLIFORD. Yes, it does. In fact, we have a pilot program looking at the effect of chemicals on infants and children. We looked at 20 chemicals that were specifically chosen for their potential access to those chemicals to children. We are just now getting the data from that. We have been reporting it. We are about to issue a Federal Register notice asking for an evaluation of the information that we have learned about those chemicals.

So we do have the ability to look specifically at chemistry, that is, specific to children.

Senator LAUTENBERG. How many of these materials would you say that you have had a thorough enough review—how many have you discarded because of low volume of use, do you know?

Mr. GULLIFORD. It is not our approach to discard any of the chemicals.

Senator LAUTENBERG. I use the term loosely. Ignore.

Mr. GULLIFORD. Well, in terms of new chemicals, as we review them, roughly 10 percent of the chemicals that come in are either voluntarily not chosen to be brought into production because the industry understands the risks associated, that our models have identified. We also place restrictions on a lot of the chemicals that have come.

With respect to existing chemicals, again, we looked at those in the highest volumes of production, because again, they are likely then to either have manufacturing exposures associated with them or exposures in the actual use of those chemicals. So that is why we chose those as the appropriate first steps.

Senator LAUTENBERG. Mr. Chairman, with appreciation for the time, I would just like to ask that my full opening statement be included in the record.

Senator INHOFE. Yes.

Let me ask you, Senator, are you going to be able to come back at 3 o'clock and participate, in the event that the panelists are not through?

Senator LAUTENBERG. Lord willing.

[Laughter.]

Senator INHOFE. I think the Lord is willing.

[Laughter.]

Senator LAUTENBERG. Thank you.

Senator INHOFE. Your entire statement will be made a part of the record.

[The prepared statement of Senator Lautenberg follows:]

STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM  
THE STATE OF NEW JERSEY

Mr. Chairman, in 1962, a scientist named Rachel Carson published a book called *Silent Spring*. *Silent Spring* was a wake-up call to the American people. It warned us that many chemicals that were in widespread use at that time including DDT posed threats to our health, our environment, and to wildlife. In the aftermath of its publication, some dangerous substances, like DDT, were banned.

And in 1976, Congress passed the Toxic Substances Control Act to protect us from dangerous chemicals in everyday consumer products. Unfortunately, since the passage of that law 30 years ago, we still don't have adequate information about thousands of chemicals to which we and our children are exposed every single day.

The American people should have a right to that information. But court rulings have limited the effectiveness of TSCA, and tied the hands of the EPA in its ability to evaluate the danger of chemicals in our environment. Since the passage of the TSCA, only two percent of the chemicals that were in use at the time have even been evaluated by the EPA. And only five toxic substances have been regulated. Meanwhile, we are constantly exposed to thousands of other chemicals that might or might not be safe.

Last year the CDC issued a report evaluating the U.S. population's exposure to 148 chemicals. In samples of blood, urine and fat tissue, they found traces of all but two of those chemicals. Other studies have found hundreds of industrial chemicals in the umbilical cord blood of babies born in the United States.

Clearly, the health of our children is still at risk from exposure to industrial chemicals. That's why I have introduced the Kids Safe Chemical Act, to update and strengthen the TSCA. Senators Jeffords and Boxer are co-sponsors. My bill would protect children by requiring manufacturers to provide health information to the Government before they distribute a chemical in consumer products. It would establish special safety standards for children, because they are especially vulnerable to toxic exposures. And it would say that if we aren't certain that a chemical is safe we shouldn't use our children as guinea pigs.

I hope we can have a hearing on the Kids Safe Chemicals Act before Congress adjourns for the year, or early in the next session of Congress. The American people have already waited 30 years for this information. The time for delay is past. Now it is time for meaningful action.

Thank you Mr. Chairman.

Senator INHOFE. Senator Jeffords.

Senator JEFFORDS. Mr. Gulliford, on March 6th, 2006, Donald Elliott, former EPA general counsel, appeared before the House Committee on Energy and Commerce. Mr. Elliott testified that EPA can no longer use TSCA Section 6 as a useful tool for regulating chemicals, because of the high evidentiary standard. Mr. Elliott stated, if after thousands of deaths from asbestos exposure EPA could not regulate asbestos under Section 6, it is virtually impossible for EPA to regulate any chemical under Section 6.

Is this correct?

Mr. GULLIFORD. I am not familiar with that testimony, but Section 6 remains a very important portion of the TSCA statute to us. It clearly serves as a backstop to a lot of the work that we do and a lot of the interaction that we have with industry. The numbers are correct, and the decision on the Fifth Circuit Court did not sustain EPA's position on the regulation of asbestos. Still, the presence of that statute, and we have initiated actions under that portion of the statute, has been very helpful in allowing us to come to agreement on voluntary actions on the part of industry to either remove chemicals from production or change the way that those chemicals are used.

Senator JEFFORDS. Mr. Gulliford, in your testimony you discuss the High Production Volume initiative as a voluntary mechanism for getting health and safety data on chemicals that are produced at quantities over 1 million pounds annually. Yet the President's proposed budget would cut \$2.2 million from this program and dramatically restricts EPA's ability to review the data voluntarily provided.

What steps are you taking to ensure that this voluntary information is expeditiously reviewed, so that potential public health dangers can be quickly identified?

Mr. GULLIFORD. Several things. First of all, one of the best things we did was we made all of this information public. So not only does the Agency have access to it, but so do any other organizations in Government or the private sector will have, certainly, input from them as to how they interpret the information that is there, as well as their own scientists' review of it. I think the information will get a very careful screening and it will allow us to again select from that, on the basis of that, any chemicals that we believe are appropriate to follow up with in more detail.

Senator JEFFORDS. Mr. Stephenson, in EPA's statement, the Agency emphasized that they have initiated voluntary programs, such as the High Production Volume challenge program, in order to gather information on chemicals that generally were already in commerce when TSCA was enacted. Will the program be effective in assisting the Agency in its regulatory rule?

Mr. STEPHENSON. We are supporters of the HPV or any other voluntary program, because it provides additional data which would otherwise be difficult to get under the TSCA authorities. The problem is that it is basic screening level data.

Now, I just heard today that they have asked for additional exposure data, which is a good thing. But we don't think the data is sufficient enough to do the analysis to determine the risk of chemicals at this point. There is a lot of analysis that needs to be going on. While this HPV program came into place in 1990, data is still coming in. There is still data on 250 plus chemicals that has not come in.

So it is too soon to tell how useful this information will be. This does not negate the need for making TSCA easier to use, in our opinion.

Senator JEFFORDS. Thank you.

Senator INHOFE. Senator Carper, would you like to be recognized for questions?

Senator CARPER. Not at this time, thanks.

Senator INHOFE. We are about through with this panel.

Senator CARPER. Let's let them go.

Senator INHOFE. All right. I have one last question, Mr. Gulliford. As we all know, the testing for pesticides and food additives are in a different statute. Would you kind of explain the reason behind that and the different types of testing that you have under TSCA, as opposed to the statutes that regulate pesticides and food additives?

Mr. GULLIFORD. Yes, thank you, Mr. Chairman. The TSCA and the FIFRA statutes are two fundamentally different statutes, fundamentally different approaches to regulation. In fact, FIFRA acts as a licensing agent or a licensing process for pesticides, which we generally assume to have active ingredients and to be biologically active.

Therefore, we ask for the information necessary to determine what the likely impacts of those actions might be on biological communities or human health, as well as the environment. So we do ask for very specific data to enable us to make those judgments, make those decisions relative to FIFRA and pesticides.

TSCA, on the other hand, deals with industrial chemicals. They are not designed for food purposes or food uses. So we place in effect through TSCA an assessment process to measure the potential risk that those chemicals may have, either through their manufacture or through their use in commerce. Then we use that information to determine whether or not there is a probable risk to human health or the environment. And then given when we find that, we can take an action then to appropriately either gain additional information necessary to regulate those uses or to regulate on the basis of the information that we have.

So they are very fundamentally different statutes for very different purposes.

Senator INHOFE. Thank you for that distinction.

Mr. Gulliford, Mr. Stephenson, thank you very much for being here. Let me just say that there will be questions for the record. Also there will be statements, opening statements, that will be submitted for the record for those that didn't have a chance to do it. We would ask that you review those when you receive them. Thank you very much for your appearance.

We will call up the second panel. Before we do, I would like to recognize Cori Lucero. Cori, stand up, hold your hand up there, let them see who you are. This is going to be her last hearing. She has been with us for a couple of years now. We were expecting she would be here a lot longer than that, but she has better things to do, I guess.

[Laughter.]

Senator INHOFE. She has done a great job, and she is going to be replaced by Steve Chapman over here. Steve, you smile too much for that job. You have to be mean.

[Laughter.]

Senator INHOFE. Cori, you have done a great job, you really have. It has been a joy having you around. Thank you.

Senator Carper, we checked with staff, there was an unfortunate death and the funeral takes place at 11 o'clock today. So we had

planned to go ahead with our witnesses and then come back at 3 o'clock, take a recess at 11 o'clock and come back at 3 o'clock. If you would be able to do that, in your schedule, that would be great. We will see how far along we get between now and 11 o'clock.

Senator CARPER. We have a markup in my Banking Committee at 10 o'clock, and they have asked us to come, so I am going to slip out for a while, but I will come back.

Senator INHOFE. Yes. All right. I understand that.

Our next panel is William Rawson, the Chair, Environment, Land and Resources Department, partner in Latham and Watkins; Lynn Goldman, Johns Hopkins University, Bloomberg School of Public Health; Michael Walls, Managing Director of Regulatory and Technical Affairs, American Chemistry Council; Michael Wilson, Center for Occupational and Environmental Health, School of Public Health, University of California, Berkeley; and Gail Charnley, President, HealthRisk Strategies.

So in that order, we will start with opening statements, with you, Mr. Rawson. And we would like to ask you to try to stay within your timeframe, all five of you. Then we will proceed to questions. Your entire statements will be made part of the record.

Mr. RAWSON.

**STATEMENT OF WILLIAM K. RAWSON, PARTNER AND CHAIR OF THE ENVIRONMENT, LAND AND RESOURCES DEPARTMENT, LATHAM AND WATKINS**

Mr. RAWSON. Mr. Chairman, distinguished members of the Committee, and staff, good morning.

I would like to begin by thanking you for giving me the opportunity to speak this morning and to contribute to the public discourse on the Toxic Substances Control Act. I hope that my written and oral testimony will prove useful.

The question before the Committee today, at least in part, is whether the provisions of TSCA give EPA the authority it requires to meet the objectives set forth in the Act. I believe the answer to that question is yes. In my judgment, TSCA is a well crafted statute that has stood the test of time well.

My written testimony focuses on three sections of the statute, Section 5, pertaining to the review, testing and control of new chemicals, Section 4, pertaining to the testing of existing chemicals, and Section 6, pertaining to the regulation of existing chemicals. In my oral testimony, I will just speak briefly to a few key points.

Before I do that, I would like to express my personal strong support for EPA's mission. I have worked with many EPA managers and staff over the years, very closely, on a number of very challenging issues. And I have great respect for their efforts in support of the Agency's mission.

With respect to the regulation of new chemicals, the strength of TSCA lies in its flexibility. Section 5 gives EPA the flexibility to vary its assessments of new chemicals according to the attributes and expected uses of each substance.

The majority of new chemical substances pose little or no risk to health or the environment, and either qualify for an exemption from the pre-manufacture notice requirements or are readily determined to have low toxicity, based on information submitted with



the PMN, use of EPA models, and comparison to previously approved chemicals.

Where appropriate, however, Section 5 does give EPA authority to prohibit or limit the manufacture and use of new chemicals. EPA has used this authority provided under Section 6 to compel testing for many new chemical substances and also to impose restrictions or controls. In fact, EPA has imposed substantial controls on or effectively prohibited the manufacture of more than 3,500 chemical substances since TSCA was enacted.

Thus, in my judgment, the provisions of Section 5 appear well designed to achieve congressional intent. EPA has the necessary flexibility and discretion to give each new chemical substance the level of scrutiny it merits and to impose such restrictions on manufacture and use as are necessary to prevent unreasonable risks to health and the environment.

Section 4 grants EPA the authority to require testing of existing chemicals. EPA has required testing of more than 200 substances under Section 4 and many more substances have been reviewed and determined to be a low priority for testing or not to require testing at all. Also as described in the earlier testimony, a large number of chemicals have been tested under voluntary programs by industry.

There has been some suggestion that the findings required by Section 4 are overly burdensome on EPA, thus rendering Section 4 ineffective. I personally find these arguments unpersuasive. In my judgment, EPA's burden to support a test rule in fact is quite modest. EPA only needs to show that a chemical may present an unreasonable risk or that it may be released to the environment in substantial quantities, or that there is or may be significant or substantial human exposure. And the threshold for making those findings in fact is quite low.

That said, I do believe EPA could improve its performance under Section 4 in a number of ways. Relatively few test rules have been issued in recent years. I realize that is in part because of the substantial effort devoted to the HPV challenge program. It is also the case that a number of testing proposals have languished unfinished for extended periods of time. In my written testimony, I have offered some specific suggestions for how implementation of Section 4 might be improved. But I do not believe the statutory criteria need to be modified. In my judgment, they provide a sound scientific basis for making appropriate testing decisions.

Section 6 gives EPA authority to regulate existing chemicals. The EPA used this authority effectively in the early days of TSCA to in fact regulate several substances under Section 6. But as has been noted, EPA's authority under Section 6 and the effectiveness of that Section has been called into question by the decision in Corrosion Proof Fittings. In that case, the court struck down EPA's ban on certain asbestos-containing products.

The failures in the asbestos rulemaking, however, in my judgment, were failures in implementation and do not reflect deficiencies in the statute. As the court explained in its decision, EPA's product-specific bans in that case were rejected, because EPA specifically in that rulemaking used flawed procedures and flawed methodology. The details are set forth in my written testimony.

I say this not to be critical of the Agency, but because I think it is important that the decision not be misunderstood. In my judgment, the lesson of Corrosion Proof Fittings is not that Section 6 does not work or cannot work. Rather, the lesson is that no matter what the product, when acting under Section 6, EPA of course must use proper procedures, consider relevant factors and provide an adequate explanation for its decision. The Agency does that, in my judgment. Section 6 can and will work, as it did several times during the early days of TSCA, and the Agency's decisions will receive deferential treatment by the courts.

In my judgment, GAO's revisions to Section 6 are not necessary to support effective regulation, nor would they improve, in my judgment, the statutory framework for making regulatory decisions.

Senator INHOFE. You will have to wind up, Mr. Rawson.

Mr. RAWSON. Thank you.

So in conclusion, I would just like to say that the Agency has accomplished a great deal under TSCA since its enactment. While there is always room for improvement, I do not believe that amendments to TSCA are required. I believe TSCA does provide EPA with ample authority to meet the objectives of the Act.

Thank you.

Senator INHOFE. Thank you, Mr. Rawson.

Ms. GOLDMAN.

**STATEMENT OF LYNN R. GOLDMAN, M.D., M.P.H., PROFESSOR,  
ENVIRONMENTAL HEALTH SCIENCES, JOHNS HOPKINS UNI-  
VERSITY, BLOOMBERG SCHOOL OF PUBLIC HEALTH**

Dr. GOLDMAN. Thank you very much. I very much appreciate, Mr. Chairman, the opportunity to testify before your Committee today, and I have submitted my full testimony for the record. I am going to give a very brief summary of it.

As you probably are aware, I am a pediatrician by training. I served for more than 6 years as the Assistant Administrator for Prevention, Pesticides and Toxic Substances at the U.S. EPA. So in that position, I was responsible for the implementation of the Toxic Substances Control Act. I hope I can give you some insights that are more kind of from the inside, how it really works when you are trying to make this law work, which of course as a public health professional I was very committed to doing.

I should say in opening that I have a tremendous amount of respect for the U.S. chemical industry. It is very important to our economy, and it is important to our way of life. And as a former regulator, that is something that one does not take lightly. I also have a tremendous amount of respect and admiration for the people who work at the EPA. I worked with people there who were highly trained professionals, very committed, and did the best that they could do. But unfortunately, they have not been given the tools nor the resources that they need to do their jobs properly.

There is so much in my written testimony that I can barely cover it in the space of 5 minutes. So what I am going to do is very briefly touch on the nine areas that I think are of concern, the first being the area of risk evaluation. We believe as a society we should base our decisions on risk. To understand risk, you need to understand hazards and exposure, and TSCA tells us about neither.

The second area is protection of vulnerable populations. Can we adequately protect children and other vulnerable populations? TSCA has no provisions, unlike most modern environmental statutes, for doing so.

The third area is risk management, can we manage risks under TSCA? And the answer is, no, we cannot. Despite what you may hear from others, the “least burdensome” requirement is too high a hurdle; the professional attorneys, scientists, economists within EPA recognize that this burden is too high. That is why there are no Section 6 rules on the books since Corrosion Fittings.

The fourth area is one of precaution. Does TSCA allow us to take precaution? The answer is no. Because the standard of unreasonable risk does not tilt enough toward protection of health and the environment.

Area No. five is assessment of new chemicals. There are great people in the New Chemicals office, and they make a great effort. The tools are insufficient. Structural information and use of computer modeling misses a lot of chronic risks. Studies have shown this. We know that this is not an adequate way of assessing the risks.

Sixth is right to know and problems with TSCA’s confidential business information provisions. While CBI protection is very important, these provisions allow you to claim as CBI the name of the chemical and where it is made: even the States can’t find that out. As an ex-State official, (I worked in public health for the State of California.) I find this to be unacceptable. When I was at EPA, I could not tell a State environmental official what was in that CBI information.

Seventh is pollution prevention. TSCA does not contain provisions to promote the development of new and safer alternatives.

Eighth in the area of international management of chemicals, EPA has slipped in its leadership in the international arena. We are not a part of the POPs nor the PIC convention. And this is of great concern, not only from the standpoint of protection of health and the environment, but also for our economy. Our position of leadership in the world and the view that others in the world have of our products, the credibility of our process is at risk because we are not full participants in these forays.

Ninth is that TSCA does not establish clear priorities for EPA in regulating toxic chemicals.

In conclusion, I believe that overhaul of TSCA is long overdue. It has been 30 years since Congress enacted it. It has never been reauthorized. I think that the bills that are going through State legislatures to ban individual chemicals are a very bad symptom, along with the fact that EPA is falling behind globally. Further, procedures for new chemicals are not adequate. Even though EPA has the authority to regulate nanotechnology, how do the old QSAR (Quantitative Structure Activity) models apply to nanotech? They don’t at all.

Of fundamental importance as well as the credibility and trust in the Federal process. If States are moving out on their own, I think that that speaks for itself.

I also know, from my experience as a regulator, that one should not undertake such an overhaul without a process that brings all

the parties together. And I want to go back to my first point about the deep respect that I have for the U.S. chemical industry. Industry has a role to play, along with environmental groups, public health people, chemical experts. There needs to be a process, much like the process that the European Union has gone through, to define, what chemical regulation for the 21st century should look like in the United States?

Thank you.

Senator INHOFE. Thank you, Dr. Goldman, for an excellent, well-thought and organized statement.

Mr. WALLS.

**STATEMENT OF MICHAEL P. WALLS, MANAGING DIRECTOR OF REGULATORY AND TECHNICAL AFFAIRS, AMERICAN CHEMISTRY COUNCIL**

Mr. WALLS. Good morning, Mr. Chairman, Senator Jeffords. Thank you very much for the opportunity to be here.

We appreciate this opportunity to reiterate the U.S. chemical industry's belief that the Toxic Substances Control Act provides a strong, robust regulatory framework for health and environmental protection in the United States.

The member companies of the American Chemistry Council are on the cutting edge of technological innovation and progress. Our products provide safe drinking water, life-saving medicines, a safe food supply and jobs throughout the Nation. Our member companies are committed to the safe management and use of their products through compliance with TSCA, other U.S. Federal statutes and their own product stewardship initiatives.

We have three major points to make today. First, innovation starts in the chemical industry. It is critical that the U.S. chemical regulatory framework continue to promote innovation and the technological prowess that has characterized our industry.

Second, our industry invests billions in research and development in health, safety and environmental protection even before our products reach the market. That investment must be protected by a strong regulatory framework.

Third, as science and technology develop, new questions will arise about hazards, exposures and risks to chemicals. It is vital that the U.S. chemical regulatory framework be robust enough to address those future concerns.

In our view, TSCA meets each and every one of these objectives. The statute itself has proven effective and remarkably adaptable to changing needs and priorities. TSCA works, and it works well, and the facts support that conclusion.

TSCA allows the Government to obtain information on unreasonable risks, assess that information and take appropriate action to address them. It empowers EPA with considerable authority, even the authority adopt non-regulatory programs that complement its policy objectives.

TSCA has helped establish EPA as a global leader in developing tools and programs to understand more about chemicals faster than ever before. EPA developed and spread the introduction of predictive tools, like structure activity relationship analysis and other predictive models. EPA has pioneered time, money and ani-

mal saving techniques, such as category approaches. These are also tangible measures of EPA's success under TSCA.

TSCA fuels innovation. More new chemical applications are filed under TSCA than under any other chemical regulatory system. The industry spends more than \$23 billion a year on research and development. Technology is a driving force in our industry, and even as high natural gas prices affect jobs and profitability in our industry, we continue to invest in the future.

My second point is that the industry's significant investment in health, safety and environmental measures should be protected by a strong but flexible regulatory system. TSCA, as you heard, protects appropriate claims of confidential business information and strikes a balance between the industry's interests in competitive information and the public interest in oversight of EPA's TSCA activities.

Moreover, that framework under TSCA has allowed the industry to bring forward a considerable amount of information resident in company files. You heard about the High Production Volume chemical program already from a number of other witnesses. The important point with the HPV program is that the TSCA framework has allowed the chemical industry to be responsive to concerns about chemical hazards, uses and exposures, even without a regulatory mandate.

My final point is that the chemical regulatory framework must be robust enough to deal with future challenges. In this respect again TSCA meets the test. Concerns about children's health, bio-monitoring information and nanotechnology not only can be addressed under TSCA, they are being addressed. EPA has the appropriate authority to require new information about risks, to promote research or to require testing or even to craft new pilot programs on issues like nanotechnology.

Has the chemical industry always agreed with EPA on its implementation decisions under TSCA? Clearly, that has not been the case. Do we agree that there are areas where EPA's implementation of the statute can be improved? We surely do. We welcome the dialog on how to improve understanding about chemicals and ensure that EPA can implement its statutory authority. We have a track record of dialog with the Agency on these issues, as well as with other stakeholders. And that, I submit, is also evidence that TSCA works and it works well.

Thank you for the opportunity to reflect our views on TSCA. I will look forward to your questions.

Senator INHOFE. Thank you, Mr. Walls.

Dr. WILSON.

**STATEMENT OF MICHAEL P. WILSON, PH.D., M.P.H.,  
UNIVERSITY OF CALIFORNIA, BERKELEY**

Mr. WILSON. Mr. Chairman, members of the Committee, thank you very much for inviting me to the hearing today. I am an Assistant Research Scientist at the University of California Berkeley, and I am the lead author of the U.C. report to the California legislature entitled Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation.

The report illustrates that California, like other States, is facing an array of chemical problems. On the other hand, the report finds that a modern chemicals policy that responds to these problems has the potential to deliver an extraordinary set of benefits to the public and to businesses. It could build the foundation for a sustainable chemical industry, it could prevent costly chemical damage, and it could position the United States to become a global leader in green chemistry, the design, production and use of chemicals that are inherently safer for human health and the environment.

Crafting a modern chemicals policy of this type will require that we correct longstanding deficiencies in the Toxic Substances Control Act. The report summarizes the results of several important analyses that have all reached the same conclusions about the deficiencies in TSCA. Our report points out that these deficiencies have produced a flawed chemicals market in the United States that has on the one hand allowed the producers of hazardous chemicals to remain competitive in the market, and on the other, has dampened motivation of the industry and entrepreneurs to vigorously invest in green chemistry technology innovation.

The report describes a data gap, a safety gap and a technology gap that have emerged in the U.S. chemicals market as a result of TSCA. The data gap refers to the lack of information in the market on the safety of chemicals. TSCA does not require producers to generate and distribute adequate information on the safety of their products. Markets cannot function efficiently without information, and the chemicals market is no exception.

The safety gap refers to the well-documented barriers that EPA faces in its efforts to assess the hazards of chemicals and control those of greatest concern. The technology gap refers to the potential for the United States to fall behind globally in the development of green chemistry technologies.

Mr. Chairman, a properly functioning chemicals market would amplify the positive contributions of the chemical industry to our society, while steadily reducing its negative impacts. It is widely recognized that the chemical industry generates extraordinary benefits to our economy and to our modern way of life. Yet over the next 25 years, we will spend up to \$250 billion cleaning up hazardous waste sites, a portion of which are attributable to chemicals. This year alone, some 23,000 Californians will be diagnosed with a deadly chronic disease attributable to chemical exposures on the job.

The effects of exposures that occur during fetal and child development are of course of great concern. It makes sense to prevent these negative impacts and motivate the industry to focus its enormous talent on the design and production of safer chemicals, on green chemistry. This will require that we close the data and safety gaps through a fundamental restructuring of TSCA.

We can close the data gap by requiring chemical producers to generate and distribute information on the safety of their products. We can close the safety gap by providing Government with better tools to efficiently evaluate chemicals and reduce the commercial circulation of the most dangerous ones. These steps alone will cre-

ate a market that favors investment in green chemistry, which will gradually close the technology gap.

We can go further by offering a range of incentives to companies that implement green chemistry solutions, and we can fund green chemistry research and education. This will support our leading companies, it will save us enormous public health expenditures, and it will put us at the forefront of global developments in green chemistry.

Our report recommends the importance of bringing Government, industry, advocates and the scientific community together into a task force to identify and prioritize and frame a chemicals policy in California.

Mr. Chairman, members of the Committee, thank you very much for your attention today. And thank you again for inviting me to this important hearing. I am pleased to answer any questions you might have.

Senator INHOFE. Thank you, Dr. Wilson.

Dr. CHARNLEY.

**STATEMENT OF GAIL CHARNLEY, PH.D., PRESIDENT,  
HEALTHRISK STRATEGIES**

Ms. CHARNLEY. Chairman Inhofe, other Senators, thank you for the opportunity to speak with you this morning. I am basing my statement on 30 years of experience as a toxicologist and risk analyst studying the relationships between chemical exposures and public health outcomes.

In its 1997 final report, the bipartisan Presidential-congressional Commission on Risk Assessment and Risk Management, for which I served as executive director, recommended a sustained stakeholder process should be initiated to review TSCA and its implementation. As Administrator Gulliford has pointed out this morning, a variety of activities has taken place since then that is consistent with the commission's recommendation, such as the establishment of the National Pollution Prevention and Toxics Advisory Committee, the High Production Volume challenge program, and the new extended program in the Voluntary Children's Chemical Evaluation program.

I believe that those programs demonstrate that voluntary, multi-stakeholder initiatives are both possible and succeeding under the umbrella of TSCA.

Basic toxicity data have been generated for most of the chemicals in commerce by volume, and research efforts have provided information about children's exposures and susceptibilities that is incorporated into risk assessment and chemical standard setting. These efforts continue to generate data that will contribute to better and better chemical regulation and to safer, healthier children.

To the extent they are available, environmental and bio-monitoring trend data demonstrate that overall, emissions and body burdens of chemical contaminants in the United States continue to decline. While the public is understandably concerned about the detection of chemicals, bio-monitoring data that provide information solely about trace levels of substances in blood or urine cannot be used to draw conclusions about the likelihood of disease, except in very rare cases.

Exposure does not imply toxicity, and presuming that any chemical exposure is dangerous and that any chemical hazard poses a risk is inappropriate and not supported by science. The dose makes the poison, after all. In addition, focusing solely on the presence of trace levels of chemicals misses the substantial contributions that genetics and economics, social, cultural, behavioral and psychological factors contribute to risk.

Furthermore, current EPA methods for setting standards to limit chemical exposures are precautionary, and account for the possibility that children can be more susceptible than adults to chemical toxicity. If no data are available with which to evaluate risks to children, standard practice is to use extra safety factors that make exposure limits more stringent. If data are available with which to evaluate risks to children, those data are considered as part of the standard setting process.

The HPV chemical testing program convened under TSCA uses a tiered approach to testing. The advantage of the tiered testing approach is that it helps identify early on those chemicals that are more likely to pose a particular risk to children than others, so that those chemicals get higher priority testing at the next year. My point is that although, that through the HPV and Voluntary Children's Chemical Testing programs, both convened under the umbrella of TSCA, there is a big focus on identifying chemicals that might pose a particular risk to children and in any case, when EPA restricts chemical exposures, it errs on the side of precaution to protect children and other potentially vulnerable people.

Finally, our environment is cleaner and our food and water is safer and people are healthier than ever before. Our environmental programs are evidently working overall. Even the New York Times noted on Sunday that people alive today in developed countries are healthier than they used to be, live longer, get heart disease and other chronic illnesses later in life than they used to, experience less disability and have higher IQs Those improvements are attributed to much-improved maternal and childhood health.

While I think that testing chemicals and regulating chemical exposures are certainly very important, I think our obsession with trace contaminants is out of proportion to their likely public health risk. And I think it would be nice if we recognized our environmental accomplishments.

Thank you.

Senator INHOFE. Thank you, Dr. Charnley.

Let me start off, Dr. Goldman, you have suggested that the High Production Volume production is inadequate and that we need more aggressive testing. Would this be testing that would involve lab animals? What type of testing are you referring to?

Dr. GOLDMAN. In terms of the High Production Volume chemical program, when I was at the EPA I was among those who brought the parties together to create the agreement to do the program. I am very much in support of it. I think that we definitely need screening level information on the chemicals in highest production in the Country.

But we need to keep it in perspective. It is only screening data. If I am taking care of you, if you were my patient, and I did this screen on you——



Senator INHOFE. No, let me just ask you to get right to the answer. Would it require more lab animal testing in order to be more aggressive?

Dr. GOLDMAN. You need to have a process first that tells you which findings from the screening indicate that there is a risk. And then, based on that, you gather further information, which may or may not be information derived from examinations in animals. It might lab animals, it might involve other kinds of data gathering, depending on what the results of the screening show.

Senator INHOFE. OK. The reason I am asking the question, we have had several hearings now, I think a lot of people are not aware that the No. 1 and No. 2 domestic violence, according to the, I am not sure who made the evaluation, I guess it was the Department of Homeland Security, is some of the animal rights groups. We have had several Committee hearings on this, where they have come in and talked about actually encouraging people to murder people that are testing, using animals to test.

It has been really a pretty tough thing to deal with. So I just want to keep that in mind, because we do have a real serious problem there that we have been trying to address.

Dr. Charnley, you made a statement, and I think it is worth elaborating on a little bit. You said the dose makes the poison. There are a lot of people who believe just the chemical alone is something that is the problem. There is a chart up here, I was going to use this in my opening statement, I didn't get a chance to do it. This chart is a children's multi-vitamin chart. It shows, for example, copper, which is essential for forming red blood cells and boost the body's ability to mend tissue. Copper is regulated as a secondary drinking water contaminant. Or Vitamin D, an important nutrient added to milk. Too much Vitamin D may lead to kidney stones, high blood pressure, et cetera.

As a toxicologist, does science support the assumption that any chemical exposure is dangerous? I would assume not.

Ms. CHARNLEY. That is correct, no, sir, it does not. As I pointed out in my testimony, the dose does make the poison. At the right doses, vitamins and aspirin might even make you feel better, but they won't harm you. If you take too much of them, then they will make you sick.

Basically the same is true for chemicals. As the CDC States, the presence of a chemical in a blood or urine specimen does not indicate a chemically caused diseases or risk.

Senator INHOFE. I think that is worth bringing out, because so many people are of the opinion that if it exists at all, that that alone is dangerous.

Mr. Rawson, under Section 6, the EPA has to show that it is using the least burdensome requirement, least burdensome requirement. Now, some people have argued here on this panel that we need a lower standard. I would ask you if you consider that to be a very difficult requirement for the EPA to meet, least burdensome requirement.

Mr. RAWSON. I consider it a reasonable standard. I think it is reasonable to expect the Agency to consider alternative approaches and to choose the approach that does protect health and the environment, but while imposing the least burdensome requirements.

And stated differently, if something less than a ban will do the job, then I think EPA should use it. I will just add quickly, that is what happened with acrylamide grout. EPA proposed a ban under Section 6, based on a concern for worker exposure. And the industry came forward and developed a new type of personal protective equipment that eliminated the concern. Therefore, the rule, the proposal was withdrawn. But to me, that is a win-win under Section 6, even though no final action was taken, because a less burdensome approach solved the problem than the proposed ban.

Senator INHOFE. Dr. Goldman, the reason I brought that up, PETA has stated that for each chemical that it would take about 9,000 lab animals per chemical. I don't want you to answer now, but for the record, I would like to get into this thing as to how more aggressive testing could take place without that, or be a little more specific on that. Because this is a problem we are dealing with quite a bit.

Senator JEFFORDS.

Senator JEFFORDS. Dr. Goldman, you were involved in the Johns Hopkins study that evaluated the exposure of babies to certain industrial chemicals. How did the findings of this study support your testimony in favor of TSCA requiring the protection of sensitive populations, especially children?

Dr. GOLDMAN. We are still involved in this work. What we find is many, many industrial chemicals that are in the cord blood of babies when they are born. For most of these, we have no information in the toxicology or the epidemiology literature about what they are doing to children. And as concerned as I am about animals, and by the way, the 9,000 number is a gross exaggeration—

Senator INHOFE. I agree.

Dr. GOLDMAN. I am very concerned about children. And I don't think children should be our test species for chemicals. We should know before we are exposing our children to chemicals what those chemicals may do to them.

Senator JEFFORDS. Dr. Charnley, in your testimony you claim that children are not more susceptible to chemical toxicity than adults. How can you reconcile this conclusion in light of the fact that children, pound for pound, breathe more air, drink more water and eat more food than adults and thus are more exposed to whatever toxins are present in the media?

Ms. CHARNLEY. First of all, I did not say that children are not more sensitive. I think that children of course are probably in most cases more highly exposed. But I think that as to vulnerability, they can be either less than, more than or the same in terms of vulnerability, depending on the chemical and the exposure situation.

When EPA regulates a chemical for which toxicity information about children's sensitivity is available, then they use that information when they set chemical standards. If it is not available, then EPA uses more stringent approaches in order to protect children and other potentially vulnerable populations.

Senator JEFFORDS. Dr. Wilson, in your testimony you noted that TSCA has created data, safety and technology gaps in the U.S.

chemicals market. Can these gaps be adequately addressed by the States or is a Federal overhaul of TSCA necessary?

Mr. WILSON. I think an overhaul of TSCA is necessary. At this point in the State of California, for example, there is no State Agency that knows, has information on the identity of chemicals that are being introduced into commercial circulation in the State, where those chemicals are being used and in what volume, by whom, for what purpose or how people might be exposed. That presents a fundamental barrier to the States in terms of prioritizing and acting on chemical hazards. I think as Dr. Goldman mentioned, what we are seeing in California, last year it was 35 bills introduced into the legislature to address chemical-related problems. It is a symptom in a way of the lack of information that our State agencies have. What is needed, as I said, is an overhaul of TSCA that can get that information out to the States, so that we can act appropriately.

Senator JEFFORDS. Mr. Walls, the Kids Safe Chemical bill that I drafted with Senator Lautenberg would require manufacturers to certify that their products meet the bill's safety standard or that they do not have enough information. Does the chemical industry support this public right to know provision?

Mr. WALLS. Senator, we do not support the Kids Safe Chemicals legislation that you introduced. We believe that under the Toxic Substances Control Act, EPA has sufficient authority to address children's health issues.

I should also note that children's health issues are a priority for our industry. Our industry stepped up, volunteered to participate in the Voluntary Children's Chemical Evaluation program in order to help us and to help EPA understand exactly what are the potential children's exposures to chemicals and how we can properly assess those exposures and take some decisive action. As you heard from Mr. Gulliford, EPA intends to very soon issue a Federal register notice on an evaluation of that program, so that we can start to apply it on a broader basis.

Senator JEFFORDS. Thank you.

Senator INHOFE. Thank you, Senator Jeffords.

Senator THUNE.

Senator THUNE. Thank you, Mr. Chairman. I want to thank the panel for your testimony and for your input and for being here today and responding to questions.

I would like to direct a couple of questions, if I might, to Mr. Rawson. First question would be this: was TSCA designed to eliminate all risks, in your judgment?

Mr. RAWSON. No, Senator. We do not live in a zero-risk world. TSCA is designed to eliminate unreasonable risks.

But I would like to point out that that is a very health protective standard. Because when EPA evaluates risk, it uses a very conservative approach, both in assessing intrinsic hazard and assessing exposure. Typically EPA will assume worst case exposure. So for example, lifetime use of a product or spending 70 years at the fence line of the highest emitter.

On the hazard side, EPA will use uncertainty factors and will assume that humans are more sensitive than animals and that some humans are more sensitive than others. So typically, EPA will not

be satisfied unless maximum theoretical exposures are 100-or 1,000fold below levels at which no effects have been seen in animals.

I do want to emphasize that there is considerable health protective assumptions built into the unreasonable risk standard.

Senator THUNE. You in your testimony indicated that it would be impractical to treat all chemicals alike during the review process. Could you elaborate on that a little bit?

Mr. RAWSON. Yes, Senator. Very simply, not all chemicals are alike. EPA has indicated that a majority of new chemicals that are presented to the Agency through the pre-manufacture notice process are readily set aside based on screening information, comparison to previously approved chemicals, use of EPA models and the like, which I think are quite sophisticated and quite adequate.

There are of course some chemicals that require closer scrutiny. That is where Section 5(e) comes into play and EPA's authority to compel testing or to impose restrictions or controls. So I think that it is appropriate to recognize, as TSCA does, that not all chemicals are alike, and to give EPA the flexibility to devote extensive resources where appropriate and not where not appropriate. It is important to emphasize that if we took a one size fits all approach, EPA would end up spending a lot of time on low priority chemicals and that time would not then be available to address higher priority issues.

Senator THUNE. What safeguards exist to ensure that chemical companies don't cut corners when they bring new chemicals to the market?

Mr. RAWSON. Senator, the bottom line there is that a new chemical can't get to market unless it has EPA's approval, unless it qualifies for an exemption, in other words, it has already been determined to be part of a category that doesn't really warrant pre-manufacture review. But if it doesn't fall into an exemption, then the manufacturer has to submit a pre-manufacture notice and ultimately meet EPA's data requirements. If it is a chemical that EPA feels requires close scrutiny, that falls into one of the many categories of concern that the Agency has identified, the company is going to have to provide the data that EPA wants.

As I said in my testimony and also my written testimony, EPA has effectively restricted or prohibited the manufacture of more than 3,500 chemicals since TSCA has been enacted. And no company, to my knowledge, has ever taken EPA to court on any 5(e) order. In every case, the company has either met EPA's requirements or withdrawn the PMN.

Senator THUNE. Mr. Walls, there has been some discussion today about the precautionary standard. Is there empirical data that exists to support changing from a risk-based approach along the lines of what is used here to more of the approach that is used in the European model?

Mr. WALLS. Senator, we believe that the existing risk-based decisionmaking standard in TSCA is in fact a precautionary approach. But if by precautionary standard you mean a hazard-based standard, we believe there is no empirical data for that suggestion.

Senator THUNE. Mr. Wilson referenced in his testimony this technology gap in the United States. Would you agree that there is a lack of innovation that exists in the United States today?

Mr. WALLS. Senator, I was very interested in Mr. Wilson's testimony about that. In fact, one-quarter of all patents issued in the United States are related to chemistry. That is not evidence of a technology gap. We spend \$23 billion in research and development every year in our industry. That is not evidence of a technology gap. That is evidence of an industry that is committed to technological innovation and progress.

Our companies are also consistently recognized in the Presidential Green Chemistry awards as innovators in chemistry. That is a tradition that our industry has established and one we intend to continue.

Senator THUNE. One final question for Ms. Charnley. There was a recent National Academy of Science report on bio-monitoring that suggested that we cannot assume that the mere presence of a chemical will lead to adverse health effects. As a toxicologist, can you comment on bio-monitoring and its usefulness and any limitations that it might present?

Ms. CHARNLEY. Sure. I think that is correct, that bio-monitoring data that provide information solely about trace levels of chemicals in a blood or urine sample at a single point in time do not allow us to draw conclusions about the likelihood of disease. What that information can let us do is determine that exposure has occurred, to follow trends in exposure over time, to identify unusually exposed individuals, and sometimes to help us clarify the relationship between exposure and dose. But they do not provide information with regard to the risk or likelihood of ill health, except in some rare cases.

Our analytic abilities are now allowing us to detect smaller and smaller amounts of more and more chemicals, but that does not mean that we are at greater and greater risk of chemical-related disease.

Senator THUNE. I see, Mr. Chairman, my time is up. So I thank you all very much for your responses.

Senator INHOFE. Thank you, Senator Thune.

Senator BOXER.

Senator BOXER. Thank you, Mr. Chairman.

Mr. Chairman, I want to start off by asking unanimous consent to place in the record an article that appeared in today's New York Times, if I might.

Senator INHOFE. Without objection, so ordered.

[The referenced material was not submitted in time for print.]

Senator BOXER. Unions say EPA bends to political pressure. In brief, it says, "Unions representing thousands of staff scientists at the EPA say the Agency is bending to political pressure, ignoring sound science and allowing a group of toxic chemicals to be used in pesticides." It goes on, they say the chemicals pose serious risks for fetuses, pregnant women, young children. These are scientists who don't agree with Ms. Charnley, I don't think.

And it goes on to say, "The complaints from Agency employees are the latest to come from within Federal agencies that accuse the Bush administration of allowing politics or industry pressure to

trump science on issues like climate change and stem cell research.” “More and more, the unions are coming together to confront the Agency’s unwillingness to make the appropriate use of science to show risk to public health and the environment,” said a senior scientist, William Herzy.

And it goes on to say, “You go to a meeting, where it comes down, this is an important chemical, this one we have got to save. It is all informal, of course, but it suggest that industry interests are governing the decisions of EPA.” Anyway, I want to put this in the record, because for all the talk about how great the chemical companies are, and I am sure some of them are, they are not all great. I know we are having trouble just getting the chemical companies to admit that they ought to do more to protect the American people in the case of another 9/11. So we have a ways to go.

Ms. Charnley, your testimony kind of shocked me, because I have been, as Senator Jeffords and Senator Lautenberg, working with a lot of doctors and scientists on protecting our kids. And you just painting this real rosy picture. And I guess what I want to ask you is, do you know what the infant mortality rate is in America compared to the rest of the developing world, the developed world, not the developing world, but the developed world, the industrialized world? Do you know those numbers?

Ms. CHARNLEY. I don’t. We do pretty well, but we are not the best.

Senator BOXER. No, we are not the best. We are the second worst. We are the second worst. So for you to come here and say how healthy kids are, read the facts. You come here and present yourself as an expert and you don’t even know what the infant mortality rate is? I mean, that in itself says to me—I don’t really know, you know, who you work for. So maybe you could—I know you do some work for EPA, you sit on some of these panels. But in the course of your work, have you been hired by chemical companies?

Ms. CHARNLEY. I work for—

Senator BOXER. Industry?

Ms. CHARNLEY. I work for industry, for Government, I do some teaching and I have some non-profits. I have a mix of clients.

Senator BOXER. Who are the non-profits?

Ms. CHARNLEY. Environmental Law Institute, one of the mining organizations.

Senator BOXER. Mining—would you get that to me?

Ms. CHARNLEY. Sure.

Senator BOXER. Thank you. That will be very helpful.

Ms. CHARNLEY. And I am not clear about the comment about connecting infant mortality rates to chemical exposures.

Senator BOXER. You are?

Ms. CHARNLEY. Has that been done?

Senator BOXER. Well, you just made a statement about our kids’ health that was incorrect. And I am correcting you on that. You obviously don’t see the connection, and I was going to ask you this. You said it is all about the dose. Would you agree that some chemicals don’t leave the body and they accumulate, so if you look at one dose, that is not reflective if in fact the body keeps on building up, such as mercury?

Ms. CHARNLEY. I think that is exactly what I did say, that looking at one dose is not helpful in terms of evaluating risk, but looking at—

Senator BOXER. Cumulative?

Ms. CHARNLEY.—over time can be very helpful.

Senator BOXER. So would you say that it is, that some chemicals are quite harmful if they accumulate in the body? Would you agree with that?

Ms. CHARNLEY. Only if they accumulate to a dose that is toxic. And it turns out most of the bioaccumulative chemicals like dioxin are now present in our bodies at levels 95 percent less than what they used to be.

Senator BOXER. OK, wait, wait, wait, wait. You would agree with me that at a certain point, if chemicals keep on accumulating and there is no end to the fact that they keep on—at some point they are dangerous, you would agree with that?

Ms. CHARNLEY. If the toxic dose is reached, they would be.

Senator BOXER. OK, very good. I am glad we have that agreement, because that is an important point. Because I think we ought to follow science on what that level is, and not people who are paid by the industry or mining and non-profit companies.

Mr. Wilson, I want to welcome you. You are a breath of fresh air. Is it true you were a fireman before you went into this line of work?

Mr. WILSON. A firefighter/paramedic, yes.

Senator BOXER. Firefighter/paramedic. So I would like to talk to you about that. You know, we heard, and if Senator Clinton were here, I think she would talk about this, when the first responders came down to 9/11, everything was going to be just fine. And now we are seeing all kinds of problems.

So I want to ask you just a larger question about the impact of these chemicals on our workers across the board.

Mr. WILSON. Well, occupational disease, it is an enormous burden in the United States. We have made estimates in the report as to the burden of occupational disease that is directly attributable to chemical exposures in the workplace. And we have provided an analysis of why those numbers actually probably underestimate the true effects. And again, it gets back to the problem that there is a data gap in the market. There is an under-appreciation of the effects of chemical exposures that occur in the workplace among workers, among health care practitioners, physicians. There is a real lack of occupationally trained physicians in the United States

And I worked, during my doctoral dissertation work, I worked with automotive mechanics who were using a brake cleaning solvent to clean engines and brakes and what have you. We identified a number of them that had developed a debilitating neurological disease from their exposure to hexane under uncontrolled conditions. Those individuals went from being productive workers in our society to being disabled individuals with the costs of workers comp and disability and rehabilitation and what have you. We are seeing about 23,000 cases every year in California of deadly chronic disease attributable to chemical exposures in the workplace. And it is a serious problem.

Senator BOXER. Well, I just want to thank you for being here, and I agree with you that TSCA needs an overhaul.

Thank you, Mr. Chairman.

Senator INHOFE. Thank you, Senator Boxer. We have been joined by Senator Warner. Senator Warner, do you have a statement to make or a question for this panel?

Senator WARNER. No, thank you, Mr. Chairman.

Senator INHOFE. All right. Well, first of all, I again apologize to the members for the inconvenience. However, it did seem to work out pretty well. Senator Warner, we had an unfortunate death, there is a funeral that takes place at 11 o'clock that some members of the panel have to attend. Now, the only thing we would be coming back for would be for opening statements at 3 o'clock. I would like to ask if that is the desire of the members, to do that, or do submit those opening statements for the record.

Senator BOXER. Mr. Chairman, I would like to, I have about a 4-minute or 2 minute opening statement, if I could make it. I don't think there is a need to come back. If you could extend until 5 after 11 o'clock, maybe we can get it done.

Senator INHOFE. No, we wouldn't have to extend until 5 after 11 o'clock, if it is a 4-minute statement, we could recognize you right now and that would take us right up to time. If there is no objection on the panel, you are recognized for 4 minutes.

[Laughter.]

Senator BOXER. You know, Mr. Chairman, your subtlety is so incredible.

I want to thank you very much for this opportunity to read my statement. And I will summarize it.

I think what—

Senator WARNER. Mr. Chairman, I will be happy to remain, if that would convenience the Chair, upon your departure, until the colleague from California has completed her remarks. And as you vote to leave, may I compliment you and your staff on this renovated hearing room. This is quite elegant.

[Laughter.]

Senator INHOFE. I think it is, Senator. I also mentioned that this is Cori's last committee hearing, and we recognized her for the fine job that she has done in running this show.

And it was very generous of you, if you would do that, I would appreciate it.

Senator WARNER. I would be happy to. I know that it is an urgent matter and you have to attend to it, and I will be happy to remain until such time as the good colleague from California wishes.

Senator INHOFE. Aren't we nice? Thank you.

[Laughter.]

Senator BOXER. We are very nice. And thank you, Senator Warner. But I would be devastated if Senator Inhofe misses my statement—

[Laughter.]

Senator BOXER [CONTINUING].—because I know how much impact I have on his views on the environment.

Senator INHOFE. I look forward to reading it.

[Laughter.]



Senator BOXER. Thank you.

**OPENING STATEMENT OF HON. BARBARA BOXER,  
U.S. SENATOR FROM THE STATE OF CALIFORNIA**

I also want to thank the staff, Cori, is it, who has given so much to this Committee.

Well, once again we find ourselves conducting the first oversight hearing in many years on an important public health statute. We waited 4 years for the Superfund hearing we held in June, and my understanding is that it has been over a decade since the last comprehensive Toxic Substances Control Act hearing.

So Mr. Chairman, I am very concerned about this pattern, and I believe it has serious consequences for public health.

TSCA was intended to provide a comprehensive framework to address chemical risks when it was passed 30 years ago. Clearly, we know that chemicals widely used and accepted at one time can prove to be terribly hazardous and threaten the most vulnerable among us because of the issues we have talked about, the fact that certain chemicals accumulate in the body. The fact is, after a chemical has been used a long time, we find out more about it.

Unfortunately, we don't understand these threats until we have adequate testing. TSCA does not ensure that proper testing takes place. TSCA was intended to protect the public from hazards associated with the manufacture, import, processing, use and disposal of chemicals throughout society. There are over 82,000 chemicals in the TSCA inventory, including those used in everyday products, like children's toys or household paint.

There have been tens of thousands of chemicals added to the TSCA inventory since TSCA was enacted. Most Americans would probably be surprised to find out that EPA does not routinely assess the human health and environmental impacts of new or existing chemicals. The companies that make these products may not have adequate safety data either, and so we are left in the dark, to our peril.

The GAO has issued several reports on this subject and will testify today, and we missed that, I missed that, but the health and environmental risks of most chemicals in use today are not known. In some cases, we have learned about the potential for serious risks posed by everyday chemicals, and yet they are still on the market, because we don't have a strong program in place and there has been a failure to protect the public.

I have an example right here. A set of children's blocks, sold for use by babies 9 to 24 months old. These are products we see every day on the shelves. Similar blocks were tested in a lab and were found to contain thalates. Animal studies show developmental and reproductive effects of this chemical.

The European Union has regulated thalate exposure in children. EPA has not taken similar steps to protect children and TSCA has proven a weak tool for addressing these concerns. I don't want my grandchildren and anyone else's grandchildren or great-grandchildren or children putting this stuff in their mouth. In Europe, it is regulated. Not here.

I am particularly concerned that TSCA fails to include a provision that specifically protects the most vulnerable among us, in-

cluding children. Other environmental statutes, and for that I thank this Committee, protect vulnerable populations, including the Clean Air Act, the Safe Drinking Water Act, and the Food Quality Protection Act. The Safe Drinking Water Act happened to be my amendment, but I based it on these other protections.

I have serious concerns with other weaknesses in TSCA, including very restrictive confidentiality provisions that interfere with the public's right to know, their right to know the risks that we face. You know, we in California, we trust our people. We tell them what is in a product. You don't like it. But the fact is, they have a right to know, and I will fight with every fiber in my body to make sure the public knows what is in these products.

Let the public vote with their feet. We don't need a law, Mr. Chairman. We told people about the tuna sandwiches they were packing for their kids, and we told them that a lot of the imported tuna, involved in the catching of that tuna was the killing of dolphins. So we said, we will have a dolphin-safe label. It was simple. And guess what? People voted with their feet and they didn't buy that tuna any more, and it had an impact.

And I think in a free society like this one, freedom of information is important. Let the public vote. They ought to know what chemicals are in these products. And it is pretty simple.

I am proud to be a co-sponsor of the Jeffords-utenberg Child, Worker and Consumer Safe Chemicals Act. That would be a positive step in increasing information on chemical risks, expands enforcement authorities. And I hope today's hearing is not the first step to close our eyes and not to listen to the scientists at EPA, but rather to open up our eyes and our ears and reform TSCA, so that it does the kind of good that people expect it to do.

I thank you very much, Mr. Chairman.

Senator WARNER. Thank you very much.

Senator Jeffords, anything further that you know of?

Senator JEFFORDS. I thank the Senator for her statement, and I join her in her statement.

Senator BOXER. Thank you.

Senator JEFFORDS. I look forward to working with you on your statement.

Senator BOXER. Thank you very much.

Senator WARNER. Senator Jeffords, with your concurrence, we shall now stand in recess until the call of the Chair.

Senator JEFFORDS. That is fine with me.

[Whereupon, at 11:03 a.m., the committee was adjourned.]

[Additional statements submitted for the record follow.]

STATEMENT OF HON. JAMES M. JEFFORDS, U.S. SENATOR  
FROM THE STATE OF VERMONT

Chairman Inhofe, thank you for holding this important hearing on what I think is a fundamental gap in the fabric of our public health protections.

Recent scientific and medical advances have triggered renewed concerns about the adequacy of the U.S. chemical management law.

Let me highlight five basic facts that should shape how we reform the antiquated Toxic Substances Control Act.

First, without question, chemicals play a vital role in enhancing our quality of life.

Second, compelling new scientific evidence has uncovered widespread human exposure to industrial chemicals. For example, the U.S. Center for Disease Control conducted a comprehensive study revealing exposure to over 100 industrial chemi-

icals in the bodies of ordinary Americans. Another study found over 200 synthetic chemicals in the umbilical cord blood of newborn babies.

Third, most of these chemicals have never undergone any Federal safety review or testing. The mere presence of industrial chemicals in small quantities in our bodies does not mean that such levels are dangerous. But after 30 years, shouldn't the EPA have data to tell us more about the potential dangers?

Fourth, chemical manufacturers generally are not required to conduct basic health and safety testing before putting their chemicals into consumer products. A study I requested of the General Accountability Office found that the EPA has used its authority to require testing for fewer than 200 of the 62,000 chemicals in commerce in 1979, when the EPA program began.

Finally, the statute fails to give the EPA adequate authority to identify, evaluate and respond to dangerous chemicals in a timely manner.

In 30 years, the EPA has issued regulations to ban or restrict the use of only five chemicals. The Agency hasn't even initiated such a rulemaking since 1989. To make matters worse, the EPA's inaction has occurred in the face of a continuing wave of studies that have found links between chemical exposure and various diseases.

In my opinion, a fundamental overhaul of the Toxic Substances Control Act is long overdue.

A sound chemical policy would promote the use of safe chemicals, and quickly identify and manage those few dangerous chemicals that cause cancer; neurological or development disabilities; or are otherwise devastating to human health.

Doctors from the Mount Sinai School of Medicine estimate that the costs of lead poisoning, asthma, cancer and developmental disabilities caused by exposure to industrial chemicals is roughly \$55 billion annually. For this reason, I was proud to draft the Kids Safe Chemicals bill with Senator Lautenberg.

This bill would protect children by requiring chemical manufacturers to develop basic health and safety data on all chemicals used in consumer products. It would expand public information so consumers can make informed choices, encourage the development of safer alternatives, and give the EPA the tools to take action when needed.

I look forward to today's hearing, and to working in a bipartisan manner to address this critical public health issue.

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STATEMENT OF JAMES B. GULLIFORD ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

#### INTRODUCTION

Mr. Chairman and Members of the Committee, thank you for the invitation to appear before you today. It is my privilege to represent the U.S. Environmental Protection Agency (EPA) during this oversight discussion on the Toxic Substances Control Act (TSCA).

#### KEY ACCOMPLISHMENTS

EPA takes very seriously its commitment to implementing TSCA and to protecting both the American public and our environment from the adverse effects of chemicals. We are also extremely proud of the many accomplishments we have achieved in the past 3 decades and the progress that has been made in protecting human health and the environment.

TSCA provides the Agency with the necessary authority to ensure that new chemicals are adequately reviewed, that EPA can require reporting or development of information needed to assess existing chemicals, and that those chemicals that pose an unreasonable risk can be effectively controlled. Using TSCA as the foundation for our efforts, EPA has, over the decades, developed a wide array of regulatory and voluntary approaches and tools to assist us in our goal to protect both human health and the environment. Using the strengths of both regulatory and partnership approaches we have ensured effective, timely chemical management decisions. We have developed sophisticated modeling programs which assist both the Agency and industry in developing, reviewing, and manufacturing safer chemicals. We have incorporated broad pollution prevention approaches into both our regulatory work and numerous highly successful voluntary programs which have considerably increased the speed at which we have been able to achieve environmental results. We have worked cooperatively with the regulated community, our stakeholders, our counterparts in other Federal agencies, States and Tribes, and the public on a broad range of programs and activities, in order to make informed and transparent chemical

management decisions. We have also worked closely with the international community on chemical management issues because we recognize that global coordination and harmonization is critically important in ensuring a level playing field for all. I would like to take a few moments to share with you some of the highlights of the progress and achievements of our TSCA-related activities.

#### EPA'S REGULATORY ACCOMPLISHMENTS

When TSCA was passed almost 30 years ago, there were 62,000 chemicals on the TSCA Chemical Substance Inventory of existing chemicals. Since that time, under Section 5 of TSCA (which addresses new chemical review and control), EPA has reviewed more than 45,000 new chemical submissions. EPA has regulated more than 1,800 of these new chemicals. An additional 1,700 have been withdrawn by industry. Approximately 20,000 chemicals have gone into production and have been added to the Inventory. The remaining new chemical submissions have either not gone into production or were the subject of applications for review as exemptions from Premanufacture Notification (e.g., Low Volume Exemptions). Voluntary environmental stewardship programs also play a significant role in our efforts to promote the development of safer and greener new chemicals, and innovative programs like Sustainable Futures and the Persistent, Bioaccumulative, and Toxic (PBT) Profiler are key contributors in this regard.

Under Section 4 of TSCA, EPA has issued test rules or used Enforceable Consent Agreements to require the generation of testing on more than 200 chemicals. EPA has also successfully utilized voluntary stewardship approaches to address existing chemicals. In 1998, EPA, working cooperatively with the chemical industry and the environmental community, under the High Production Volume (HPV) Challenge Program, sought commitments from chemical manufacturers to make basic health and safety data publicly available on the chemicals produced in the United States at over a million pounds a year. While annual production volumes vary substantially over the current Inventory of some 80,000 chemicals, these approximately 2,800 HPV chemicals account for more than 93 percent of the production volume from the chemicals we track on the Inventory. This program has also been coordinated with international testing programs which has resulted in greater participation and has ensured that U.S. manufacturers not bear the entire burden of developing this critical data. Under the Bush administration priority implementation of the HPV Challenge Program has continued and, to date, more than 370 chemical manufacturers, either individually or as part of an industry consortia, have stepped forward to sponsor more than 1,400 chemicals under the HPV Challenge, and over 800 chemicals have been sponsored under the complementary international effort. Data have been submitted for over 97 percent of HPV Challenge chemicals and the international effort will continue to contribute information. EPA is reviewing and assessing the data submitted on approximately 1700 HPV chemicals to date, to identify chemicals that may warrant additional follow-up action or assessment.

This past Spring, EPA also made good on its 1998 commitment to make the HPV data publicly available with its release of the internet-accessible HPV Information System. Building on this effort, EPA will co-host a conference this December with NEWMOA, the Northeast Waste Management Officials' Association, which will provide an opportunity for a wide range of stakeholders and interested parties to share experiences in using and accessing the HPV data.

Recognizing the success of the HPV Challenge Program, chemical industry leaders, through the American Chemistry Council, the Soap and Detergent Association, and the Synthetic Organic Chemical Manufacturers Association, came together to extend the HPV program by announcing in late 2005, their intention to develop these health and safety data on an additional 500 HPV chemicals. EPA is very encouraged by this effort and will work closely with the participants as their effort proceeds.

TSCA also provides the Agency with the authority to address unreasonable risks through Section 6. To date, the agency has regulated five existing chemicals or chemical categories and four new chemicals under Section 6.

TSCA, through Section 8 requirements, provides the agency with the ability to require recordkeeping and reporting on a wide range of data, including production volume information, health and safety data, and substantial risk information. For example, more than 50,000 health effects, environmental effects, and environmental fate studies have been submitted to the Agency. This information helps not only EPA, but a number of other Federal Agencies in their efforts to assess chemicals. EPA also receives industry submissions under TSCA section 8(e), of "substantial risk" information which alerts EPA to critical new test data and which, when appropriate, is referred to other Agencies, industry, and stakeholder groups.

Section 12 of TSCA ensures that the United State notifies other countries when certain chemicals are exported. Section 13 prohibits the import of chemicals that would not be in compliance with TSCA. Section 14 puts in place requirements for handling confidential business information submitted by companies, and Section 21 sets forth a process that allows the public to petition the Agency to take action on specific chemical issues.

#### VOLUNTARY EFFORTS

Recently, a number of voluntary phase-out actions by chemical companies have been given regulatory effect through the use of TSCA authority. Several high-profile examples include one company's decision in May, 2000 to voluntarily cease production by 2002 of 88 "PFOS"-related perfluorinated chemicals, which were widely used in many soil and stain resistant products. EPA, under the Bush administration, took prompt regulatory action under Section 5 of TSCA by issuing Significant New Use Rules (SNURs) to ensure that new uses of these chemicals will be reviewed by the Agency prior to manufacture or re-introduction in the marketplace. EPA subsequently proposed a SNUR for an additional 183 PFOS-related chemicals which would subject them to the same requirements. In 2004, following discussions with EPA, another U.S. chemical company announced its decision to withdraw "PentaBDE" and "OctaBDE," polybrominated diphenyl ether (PBDE) flame retardants used in furniture foam and other products, from production by the end of 2004. The Agency also followed up this voluntary action with a SNUR that will ensure that new uses of these chemicals are reviewed by the Agency prior to introduction into the marketplace.

During its work on PFOS, the Agency, through Section 8(e) reporting, became aware of concerns with a related perfluorinated chemical, "PFOA," which is used as a processing aid in the production of a wide range of stick-resistant consumer products. EPA began the development of a risk assessment and, recognizing we do not currently have the data necessary to understand the sources and pathways of human exposure to PFOA, launched a formal process with industry and other interested parties to develop needed information utilizing specific testing agreements, including Memoranda of Understanding and TSCA Section 4 Enforceable Consent Agreements. EPA is thus working to develop the scientific information needed to fully understand how people are being exposed to PFOA and what, if any, concerns those exposures may pose. Industry has responded by initiating new studies, including through enforceable as well as voluntary testing efforts. EPA recognized that the science was still coming in but the concern was there, so EPA Administrator Stephen Johnson asked eight chemical companies to join the Agency in an environmental stewardship program that has resulted in the industry committing to a 95 percent reduction in PFOA emissions and product content by no later than 2010, and to work toward eliminating PFOA exposure from these sources by no later than 2015. The effort to gather exposure data will continue in parallel to the stewardship program. It is clear from the accomplishments I have just outlined that TSCA provides broad authority to the Agency to adequately control new and existing chemicals, and the ability to address emerging chemical issues as they arise. The Agency's recent efforts on PFOS, PFOA, and PBDEs, provide clear examples demonstrating this point.

#### NANOTECHNOLOGY

In addition, we believe TSCA is adequate for addressing issues that may arise with emerging technologies, such as nanotechnology. The use of nanotechnology has enormous potential for a wide array of applications. At this early stage, there are few detailed studies on the effects of nanomaterials in the body or the environment. However, based on early results, it is clear that it is not yet possible to make broad conclusions about which nanomaterials may pose risks. The Agency is moving expeditiously, but thoughtfully, to ensure appropriate oversight of this emerging technology, without impeding its development. TSCA provides the Agency with the regulatory authority needed to help ensure that this emerging technology is used safely. We are using our authorities to regulate new chemical substances under Section 5 of TSCA, which require that all new chemical substances are submitted to the Agency for review prior to manufacture and introduction into commerce. We are also considering developing a stewardship program to increase understanding of both TSCA new and existing chemical nanomaterials to complement our on-going new chemical efforts, assemble existing data and information from manufacturers and processors of these materials, and encourage the development of test data needed to provide a firm scientific foundation for future work and regulatory and policy decisions. We believe that this approach will ensure that the Agency will be positioned to meet

our mandate to protect both the public and the environment from any unreasonable risks.

#### TSCA OVERSIGHT

While I appreciate the opportunity to share with you the highlights of much of our work on TSCA over the past three decades, we recognize that no statute is perfect. For this reason, we are most appreciative of the on-going interest of this Committee in TSCA and the work of the United States Government Accountability Office (GAO) in their recent reports on chemical regulation under TSCA and chemical regulation in the United States, Canada and the European Union. It is clear that there are different statutory approaches to ensure that chemicals are manufactured and used safely and that the public and the environment are adequately protected. As I stated at the beginning of my testimony, I believe that TSCA provides EPA with the statutory tools necessary to achieve these goals. We are committed to using sound science to make risk-based decisions, to complementing these actions with successful collaborative environmental stewardship programs, and to working with Governments around the world on chemical management programs.

#### CONCLUSION

The Agency looks forward to continuing to work closely with members of this committee and your staff, and the GAO on their reviews of TSCA as we work together to protect human health and the environment. There are many dedicated engineers, chemists, biologists, toxicologists, economists, statisticians, attorneys and other civil servants who work directly on TSCA issues at EPA. They are among the most scientifically capable and talented staff at EPA and they work extremely hard to effectively implement the myriad of TSCA related activities that I have just shared with you. As an organization, they have demonstrated with the outcomes of their work the benefits of innovation, collaboration and sound science. I am extremely proud of their achievements and to be newly associated with them. Again, I thank you for the opportunity to be here today and to provide you with this information. I am happy to answer any questions.

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#### RESPONSES BY JAMES B. GULLIFORD TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

*Question 1.* Mr. Gulliford, there has been a lot of criticism of OPPTS' use of models to conduct initial screening of chemicals to determine adverse effects. I find it very interesting that these same critics fiercely defend modeling in the Clean Air program or the Clean Water Program, etc. Can you speak to the nature of your models and the extent to which they are more likely to overestimate risk than underestimate it? Has there been any third party review of your models?

Response. Our experience has shown that EPA's model, is an important and effective tool for screening out potentially hazardous chemicals. My Office (the Office of Prevention, Pesticides and Toxic Substances) has worked over the past 25 years to verify and improve its modeling tools. EPA has guidance and policy, such as the Peer Review Handbook, Information Quality Guidance, as well as draft guidance developed by the EPA Council on Regulatory Environmental Modeling, which addresses the development, validation, and use of models in a planned and systematic process. We have subjected many such tools and models to independent third party peer review (e.g., Science Advisory Board). In addition, EPA has worked, and is continuing to work with the European Union and the Organization for Economic Cooperation and Development (OECD) to verify and validate both qualitative (SAR) and quantitative (QSAR) Structure-Activity Relationship models (designated together as (Q)SARs). EPA uses data that it receives through new chemical notices, test data submissions, and other sources, like the High Production Volume Challenge Program, to support its assessments and to improve the capabilities of its predictive tools, such as (Q)SAR modeling. We also have models that predict human and environmental exposures.

Overall, EPA is confident that the assumptions and inputs used in its models result in risk estimates that are protective of human health and the environment. Verification studies and peer reviews support this statement. In addition, the general lack of substantial risk reports under section 8(e) of the Toxic Substances Control Act (TSCA), which are indicative of errors in our new chemical assessments, further demonstrates the accuracy and quality of our initial assessment tools.

*Question 2.* Mr. Gulliford, we have heard a lot about how companies have not "sponsored" all 11PV chemicals on the list. Didn't you just finalize a Section 4 test

rule covering some of the HPV chemicals that did not have sponsors? Do you plan to issue more of those rules?

Response. EPA issued a test rule for 17 HPV unsponsored chemicals under section 4 of TSCA on March 16, 2006. We are working on a second HPV test rule scheduled to be issued by September 2007 to ensure that this level of test data is available for additional HPV chemicals.

EPA has also used another TSCA reporting mechanism to gather information on unsponsored 1-IPV chemicals. On August 16, 2006, EPA published two final information-gathering rules under section 8(a) of TSCA. The Preliminary Assessment Information Reporting (PAIR) rule, issued under TSCA section 8(a), requires manufacturers of 243 unsponsored HPV chemicals to submit a report on general production or importation volume, end use, and exposure-related information that is readily obtainable. The Health and Safety Data Reporting rule, issued under TSCA section 8(d), requires manufacturers of the same 243 chemicals to submit unpublished health and safety data to EPA. The information required by these rules will be used to support additional section 4 rulemakings, as appropriate.

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RESPONSE BY JAMES B. GULLIFORD TO ADDITIONAL AN QUESTIONS  
FROM SENATOR JEFFORDS

*Question 1.* Mr. Gulliford, nanotechnology has tremendous promise in the fields of health and environmental cleanup. TSCA has been criticized as being too burdensome to provide the safety assurances to promote this technology in a safe manner. What steps are you taking to make sure that EPA can safely and expeditiously evaluate these emerging technologies?

Response. EPA recognizes the promise of nanotechnology and is moving expeditiously, but thoughtfully, to ensure the appropriate review of nanoscale materials, while not impeding the development of this technology. The Agency's current authority to regulate new and existing chemical substances under TSCA extends to nanoscale materials, and we have reviewed, and continue to review, new chemical nanoscale materials.

EPA is working in an open and transparent process to further develop a framework to appropriately address nanoscale materials. We are also considering establishing a stewardship program with stakeholder input to increase our understanding of both TSCA new and existing chemical nanoscale materials to complement our ongoing efforts. We believe this approach will ensure that the Agency will be positioned to meet our mandate to protect both public health and the environment from unreasonable risks. EPA is active in the National Nanotechnology Initiative (NNI) through membership in the Nanoscale Science, Engineering and Technology (NSET) subcommittee of the Committee on Technology (CT) of the President's National Science and Technology Council (NSTC). Through participation in NSET, several of its workgroups, and direct interactions with other Federal Agencies, we have leveraged our research funds as well as increased our ability to assess nanoscale materials.

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RESPONSES BY JAMES B. GULLIFORD TO ADDITIONAL QUESTIONS  
FROM SENATOR BOXER

*Inadequacy of Voluntary Children's Chemical Evaluation Program*

*Question 1.* Assistant Administrator Gulliford, the Voluntary Children's Chemical Evaluation Program is an EPA pilot program to let industry voluntary provide needed safety data on chemicals.

On June 30, 2006, the EPA's Children's Health Protection Advisory Committee wrote a letter to EPA saying that the Committee had "strong concerns with [the program's] structure and implementation."

The primary goal of the program is to ensure publicly available data on the risks to children's health from toxic chemicals. The Children's Committee said that the "program, as implemented, however, is not on track to fulfilling its stated goal." The committee discussed problems with the lack of an adequate peer review process, industry selection of the reviewers and industry production of key documents without EPA oversight.

Is EPA going to implement all of the Children Committee's recommendations?

Please provide me with information on EPA's schedule for implementing these recommendations by August 18, 2006, and regular updates thereafter on EPA's progress.

To the extent that you do not plan to implement any of these recommendations, please explain why you do not plan to implement such recommendations.

Response. Per your request above, the information and response to this question was provided to your staff on August 18, 2006.

#### LEAD EXPOSURE REDUCTION REGULATIONS

*Question 2.* Assistant Administrator Gulliford, Congress amended TSCA in 1992 by adding Title IV, which required EPA to create a series of regulations that protect the public from lead exposures. Lead is a very toxic metal that harms the nervous system, especially of children.

How many of the actions described in Title IV has EPA failed to complete? Please list each action, its corresponding statutory provision, any relevant statutory deadline, the status of EPA's activities responding to Congressional direction, the date that EPA expects to complete the required action, and the health effects caused by the types of exposures to lead that Congress directed EPA to reduce, including the number of children potentially affected by such exposures.

Response. Through EPA's coordinated efforts with other Federal Agencies (HUD, CDC) there has been substantial progress over the years in reducing harmful exposures to lead in children. Over the period of 1976-2002, the percentage of children, ages of 1-5, with elevated blood lead levels has declined steeply from 77 percent to 1.6 percent with 310,000 children having elevated blood lead levels.

EPA's efforts since the inception of the lead program pursuant to the Residential Lead-Based Paint Hazard Reduction Act of 1992 (TSCA Title IV) have contributed to more recent improvements which show that since the period 1991-1994 the percentage of children between the ages of 1-5 with elevated blood lead levels have declined from 4.4 percent to 1.6 percent or 310,000 children as of the latest CDC reporting period, 1999-2002. EPA is committed to continuing to support the Administration's goal of eliminating childhood lead poisoning as a major public health concern by the year 2010.

Health effects associated with exposure to inorganic lead and compounds include, but are not limited to, neurotoxicity, developmental delays, hypertension, impaired hearing acuity, impaired hemoglobin synthesis, and male reproductive impairment. Importantly, many of lead's health effects may occur without overt signs of toxicity. Lead has particularly significant effects in children, well before the usual tenm of chronic exposure can take place. Children under 6 years old have a high risk of exposure because of their more frequent hand-to-mouth behavior (Centers for Disease Control and Prevention (CDC), 1991: <http://www.cdc.gov/ncbddd/leadpublications/books/iplpyciccontents.htm>).

EPA's actions pursuant to Title IV have contributed to mitigating harmful exposure to lead. These include targeted outreach and extensive education activities, as well as regulatory actions.

#### OUTREACH AND EDUCATION

The Agency's outreach and education efforts began in 1992 and continue today. These efforts greatly contribute to the increase in awareness of the hazards of lead generally and the steps the public can take to protect themselves and their families from lead-based paint hazards specifically. Actions include:

- Ensuring that information about known lead-based paint or lead-based paint hazards is disclosed to individuals buying or renting pre-1978 housing. (TSCA Section 1018).
- Operating the National Lead Information Clearinghouse (with additional support from HUD and CDC), which provides the general public and professionals with information about lead hazards and their prevention. (TSCA Section 405).
- Ensuring that information about lead-based paint hazards is provided to owners and occupants of pre-1978 housing before renovation activities take place. (TSCA Section 406).

#### ABATEMENT

EPA has undertaken a range of actions to ensure the abatement of lead hazards are conducted safely, including rulemaking:

- On August 29, 1996, the Agency promulgated regulations for the abatement of lead for target housing and for child-occupied facilities, a subset of commercial and public buildings. (TSCA 402(a) and (h)).
- On August 29, 1996 EPA promulgated a model State program that could be used by a State to administer and enforce a State lead-based paint program at least as protective as the Federal program associated with section 402. Currently 39



states, the District of Columbia, and three Native American Tribes are authorized by EPA to conduct their own programs. (TSCA Section 404).

- On January 2, 2001, the Agency issued regulations that identify lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil. (TSCA Section 403).

#### RENOVATION AND REMODELING

EPA is currently in the midst of a rulemaking to mitigate risks posed by lead dust in renovation and repair and painting activities. Work to support this effort began in 1996; it has been informed by the development of the regulations noted above that identify lead-based paint hazards issued in 2001, and most recently a proposal was published in 2006.

- On March 6, 1996, working with HUD, EPA issued a rule containing lead disclosure requirements for sales and leases of older housing. (TSCA Section 1018).
- In September 1997, the Agency issued renovation guidelines in residential housing. (TSCA Section 402(c)(1)).
- On June 1, 1998, EPA promulgated a regulation that requires each person who performs for compensation a renovation of target housing to provide a lead hazard information pamphlet to the owner and occupant of such housing prior to commencing the renovation. (TSCA Section 406).
- In January 2000, EPA conducted a study of renovation and lead hazards in residential housing. (TSCA Section 402(c)(2)).
- In January 2006, EPA issued a proposal to mitigate the risks posed by renovation, repair and painting activities in housing where children reside. The proposal includes requirements for work place standards and for the training of renovators, for renovations in residential housing with lead-based paint. When finalized, this rule, coupled with outreach and education efforts, will target Agency resources toward a comprehensive program that mitigates risks associated with renovation, repair and painting activities. (TSCA Section 402 (c)).

In carrying out the statutory provisions we have and continue to focus our efforts where opportunities for the most meaningful risk reduction exists.

*Question 3.* Need for Strong State Programs Assistant Administrator Oulliford. States are stepping up to the plate to protect the public from dangerous chemicals. California's proposition 65 requires consumer information when products contain substances known to cause cancer or birth defects. Massachusetts requires facilities to undertake pollution prevention plans were practical. At least eight States, including California, have enacted laws restricting the use or production of brominated flame retardants, which some studies have shown to have similar threats as DDT and PCBs.

Do you agree that States need to and in fact should protect their citizens, especially children and other vulnerable individuals, from dangerous exposures to toxic chemicals?

Response. Yes, all levels of Government—local, State, and Federal—should work together and have the ability to protect their citizens, including children and other vulnerable individuals.

#### EPA RESOURCES DEVOTED TO IMPLEMENTATING TSCA'S PROTECTIONS

*Question 4.* Assistant Administrator Gulliford, provide a spread sheet that describes from fiscal year 2001 to 2006 the amount of money (adjusted to 2005 dollars) on an annual basis that EPA has obligated and the number of employees, in Federal-Time Equivalents, that EPA has designated to work on actions under TSCA:

- 1) Section 5, which authorizes EPA to evaluate submitted information to determine if action is needed to prohibit or limit manufacturing, processing, or the intended use of a chemical;
- 2) Section 4, which authorizes EPA to require manufacturers and processors to conduct tests to determine if a chemical presents an unreasonable risk of injury to health or the environment, or if it is produced in substantial quantities and the potential for release or human exposure is substantial; and
- 3) Section 6, which provides EPA with the authority to prohibit or limit the manufacture, import, processing, distribution in commerce, use or disposal of an existing chemical.

Exclude all money and FTEs used to support voluntary initiatives, such as the High Production Volume initiative, from these figures.

Response. EPA is committed to protecting both the American public and the environment in which we live from the adverse effects of chemicals. The Agency has successfully integrated a wide array of regulatory and voluntary approaches to assist

us in reaching these goals. Using the strengths of both regulatory and partnership approaches, we have ensured a comprehensive program that allows us to make timely and effective chemical management decisions. These approaches focus on generating needed test data, assessing the data, and, when appropriate, taking the necessary steps to reduce the health and environmental risks of new chemicals—principally a regulatory activity—and chemicals already in commerce—where we utilize both regulatory and voluntary activities.

For example, the Agency developed a comprehensive program for addressing High Production Volume (HPV) chemicals that includes:

- a Challenge program to industry, which started in 1998, to voluntarily make basic health and safety data publicly available,
- regulatory backstops, under Section 4 of TSCA, that will ensure that HPV Chemicals are adequately tested; and, under Section 8(a) and (d), that requires reporting that will allow the Agency to make the Section 4 statutory findings on 1-IPV chemicals not sponsored in the Challenge program,
- an information management system, the High Production Volume Information System, or HPVIS, that is making the information accessible and useable for EPA, other Federal and State Agencies, and the public,
- and, finally, required reporting of exposure and use information under the IUR amendments that will allow risk-based assessments of all HPV chemicals.

This type of broad, integrated approach to addressing potential chemical risks is critical to ensuring that the Agency has the information it needs to effectively assess and manage these risks.

The Agency has also successfully incorporated broad pollution prevention approaches into both our regulatory and voluntary programs, which have considerably increased the speed in which we have been able to achieve environmental results. This vital integration of regulatory, voluntary, and prevention approaches have also helped encourage the introduction of safer and greener new chemicals.

The following chart outlines the budgets for FY 2001–2006 for the Agency's Chemical Risk Review and Reduction Program-Project, which includes the HPV and Voluntary Children's Chemical Evaluation Programs (VCCEP):

Fiscal Year	FTF	Extramural \$\$\$ (in thousands)	Extramural \$\$\$ at 2005 Values*
FY 2001 Enacted	237.3	\$17,453.6	\$19,162.0
FY 2002 Enacted	249.8	\$19,655.1	\$21,260.0
FY 2003 Actuals	253.8	\$14,648.7	\$15,481.2
FY 2004 Actuals	256.8	\$16,154.1	\$16,685.0
FY 2005 Actuals	246.7	\$15,530.7	\$15,530.7
FY 2006 Enacted	245.0	\$16,114.2	\$15,495.9

\* Historic inflationary figures adjusted by fiscal year. Dollar amounts do not include payroll.

\*\* The Chemical Risk Review and Reduction Program-Project did not exist prior to FY 2003. Estimates for FY 2001 and FY 2002 are based on activities contained in the previous Agency budget structure.

Question 5. Assistant Administrator Gulliford, provide a spread sheet that describes from fiscal year 2001 to 2006 the amount of money (adjusted to 2005 dollars) on an annual basis that EPA has obligated and the number of employees, in Federal-time Equivalents, that EPA has designated to work on voluntary initiatives concerning chemical testing and exposures, including but not limited to the High Production Volume Initiative and the Voluntary Children's Chemical Evaluation Program.

Response. EPA is committed to protecting both the American public and the environment in which we live from the adverse effects of chemicals. The Agency has successfully integrated a wide array of regulatory and voluntary approaches to assist us in reaching these goals. Using the strengths of both regulatory and partnership approaches, we have ensured a comprehensive program that allows us to make timely and effective chemical management decisions. These approaches focus on generating needed test data, assessing the data, and, when appropriate, taking the necessary steps to reduce the health and environmental risks of new chemicals—principally a regulatory activity—and chemicals already in commerce—where we utilize both regulatory and voluntary activities.

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- an information management system, the High Production Volume Information System, or HPVIS, that is making the information accessible and useable for EPA, other Federal and State Agencies, and the public,
- and, finally, required reporting of exposure and use information under the IUR amendments that will allow risk-based assessments of all HPV chemicals.

This type of broad, integrated approach to addressing potential chemical risks is critical to ensuring that the Agency has the information it needs to effectively assess and manage these risks.

The Agency has also successfully incorporated broad pollution prevention approaches into both our regulatory and voluntary programs, which have considerably increased the speed in which we have been able to achieve environmental results. This vital integration of regulatory, voluntary, and prevention approaches have also helped encourage the introduction of safer and greener new chemicals.

#### CHART

#### *Children's Toys and Dangerous Chemicals*

*Question 6.* Assistant Administrator Gulliford, provide all requests for information that the EPA has sent to the manufacturers of children's toys sold in the United States and chemical manufacturers or processors that produce chemicals used to make children's toys sold in the United States, where the Agency asked for information on the toxicity of chemicals used in the toys, levels of potential exposure to those chemicals, and the potential health effects related to children playing with such toys.

*Response.* EPA takes very seriously its commitment to protect children's health, and TSCA provides authority to protect children from unreasonable risks from chemical substances, mixtures, and articles, including toy products. EPA collects information on chemicals manufactured or imported in the United States and listed on the TSCA Chemical Substances Inventory. These chemicals may be used in a variety of processes and products. EPA recognized the need for additional reporting of processing and use information, including the use of subject substances in consumer products and in products intended for use by children. In 2003, EPA amended the Inventory Update Reporting (IUR) requirements to ensure that the data collected more closely match EPA's information needs. The inclusion of the children's use category in the IUR will provide the Agency and others with specific reporting of the chemicals used in products intended for use by children. The first industry reporting of this information must be completed by December 2006. EPA will use this data to further its understanding of uses potentially affecting children and whether any follow-up actions may be needed.

To further understand and address hazards and exposures associated with chemicals, including children's exposures, EPA works with the U.S. Consumer Product Safety Commission (CPSC) and other Agencies as appropriate on issues regarding consumer products, including those intended for children.

In addition, in response to a recent TSCA section 21 citizen's petition regarding lead in toy jewelry, EPA published a notice in the Federal Register (71 ER 30921 (May 31, 2006)) requesting information on the presence of lead in toy jewelry and on the health effects, particularly to children, from toy jewelry or similar objects containing lead.

#### *Children's Toys and Dangerous Chemicals*

*Question 7.* Assistant Administrator Gulliford, provide a list of the chemicals used in toys sold in the United States, including whether each chemical is known or suspected of causing cancer, developmental effects or birth defects.

*Response.* The Agency takes very seriously its commitment to protect children's health, and TSCA provides authority to protect children from unreasonable risks from chemical substances, mixtures, and articles to which children may be exposed, including toys. To further enhance our understanding of children's exposures to chemical, EPA has several efforts underway to develop information on products and chemicals to which children may be exposed.

EPA collects information on chemicals manufactured or imported in the United States and listed on the TSCA Chemical Substances Inventory. These chemicals may be used in a variety of processes and products. In 2003, EPA amended the Inventory Update Reporting requirements to ensure that the data collected more closely match EPA's information needs. Specifically, EPA recognized the need for additional reporting of processing and use information, including the use of subject

substances in consumer products and in products intended for use by children. The inclusion of the children's use category will provide the Agency and others with specific reporting of the chemicals used in products intended for use by children. The first industry reporting of this information must be completed by December 2006. EPA will use this data to further its understanding of uses potentially affecting children and whether any follow-up actions may be needed.

In addition, under EPA's Voluntary Children's Chemical Evaluation Program (VCCEP), developed after extensive stakeholder dialogue, EPA launched a pilot program to provide data to enable the public to understand the potential health risks to children associated with certain chemicals. Under the pilot, EPA asked companies which manufacture and/or import 23 chemicals that have been found in human tissues and the environment in various monitoring programs to volunteer to sponsor the evaluation under VCCEP. Thirty-five companies and ten consortia responded and volunteered to sponsor 20 chemicals.

To further understand and address hazards and exposures associated with chemicals, including children's exposures, EPA works with the U.S. Consumer Product Safety Commission (CPSC) and other Agencies as appropriate on issues regarding consumer products, including those intended for children.

#### *Cosmetics and Dangerous Chemicals*

*Question 8.* Assistant Administrator Gulliford, provide all requests for information that the EPA has sent to the manufacturers of cosmetics sold in the United States and chemical manufacturers or processors that produce chemicals used to make cosmetics sold in the United States, where the Agency asked for information on the toxicity of chemicals used in the products, levels of potential exposure to those chemicals, and the potential health effects related to applying these cosmetics.

Response. "Cosmetics" as defined under the Federal Food, Drug and Cosmetics Act (12FDCA) are excluded from the TSCA definition of "chemical substance and are regulated by the Food and Drug Administration. (TSCA section 3(2)(B)(vi)). Therefore, EPA has not issued any information requests relating to cosmetics or substances when intended for use as a component of cosmetics covered by the FFDC.

#### *Cosmetics and Dangerous Chemicals*

*Question 9.* Assistant Administrator Wilford, provide a list of the chemicals used in cosmetics sold in the United States, including whether each chemical is known or suspected of causing cancer, developmental effects or birth defects.

Response. Cosmetics are regulated under the Federal Food, Drug and Cosmetics Act by the Food and Drug Administration and are excluded from regulation under TSCA. Therefore, EPA does not maintain a list of chemicals used in cosmetics sold in the United States.

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#### RESPONSES BY JAMES B. GULLIFORD TO ADDITIONAL QUESTIONS FROM SENATOR CLINTON

*Question 1.* We know that the Food and Drug Administration is working to establish information sharing agreements with its regulatory counterparts in Europe, so as to better coordinate information about action taken to protect consumers from unsafe drugs or biologics, and, in this age of globalization, I believe we need to see similar agreements between the EPA and environmental agencies around the world.

The European Union is currently implementing a program through which chemical companies are required to submit basic test data on new chemicals—an authority that does not exist under TSCA. Instead, your agency relies on models that estimate the impact of new chemicals based upon what we know about already-existing chemicals with similar molecular structures.

It would seem to make sense—and this is something that chemical companies, according to the GAO Report, support—to set up mechanisms through which the data collected by the EU is shared with the EPA. That way, regulatory decisions about new chemicals could be based on actual test data, rather than models.

At the time the GAO report was released in 2005, your agency did not have a strategy to obtain such data. Since your testimony noted that the EPA does not require any additional regulatory authority that might be conferred by Congress, do I understand correctly that the EPA is currently able to engage in efforts to increase information sharing with other Governments? What steps have you taken to develop a mechanism through which to share this data? By what date will you establish such a system?

Response. EPA is a leader in international information sharing and is actively engaged in a variety of associated activities. For example, EPA and the European Commission are collaborating with other member countries of the Organization for

Economic Cooperation and Development (OECD) in the development of a Global Data Portal, which is intended to ensure that test data available to the United States, the EU, and other Governments can be shared and accessed. This portal will allow searching, viewing and exchange of test data between EPA's HPV Information System (HPVIS) and the test data collected by the EU, as well as similar data from other countries. As another example EPA will participate in the development of an EU REACH Implementation Project specifically designed to develop guidance on grouping chemicals for assessment. Also, EPA worked closely with the Canadian Government as they implemented the Canadian Environmental Protection Act (CEPA) "categorization" work. That product, when released, will be useful to U.S. chemicals assessment work in that it will provide assessments of thousands of chemicals, many of which are on the TSCA Inventory. We believe this development may provide additional opportunities to collaborate directly on High Production Volume and lower volume chemical issues.

As conveyed in EPA's July 31, 2006 response to GAO's report, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* (GAO-05-458), the Agency has concerns regarding a regulatory approach to collecting the same data that companies are required to submit to the EU. The recommendation referenced in the 2005 GAO report suggests a potentially broad-ranging information collection rule under section 8 of TSCA. While such a reporting rule may result in the provision of some useful information, EPA supports more targeted approaches that are directed at U.S. domestic priorities rather than foreign Government mandates. As appropriate, EPA will evaluate and implement different approaches to collect information to address information needs, taking into account information that will be available through HPVIS, the Global Portal, and other mechanisms.

*Question 2.* More than 50,000 health effects, environmental effects, and environmental fate studies have been submitted to the EPA, and you note that these studies have helped both your agency and other Federal agencies assess chemicals and potential exposure risks.

How has the data collected through FSCA been used to improve or enhance both the CDC's and EPA's biomonitoring efforts? For example, if a chemical is noted as requiring further study, do you utilize the tools and expertise in your biomonitoring programs to develop and carry out tests to assess human exposures?

Response. EPA receives exposure and effects information through a variety of TSCA authorities and programs. Rather than establishing a separate biomonitoring effort under TSCA, EPA works through the established CD ("process (<http://www.cdc.gov/exposurereport/>) to nominate chemicals for inclusion in the National Health and Nutrition Examination Survey (NHANES) biomonitoring efforts where EPA believes data obtained from biomonitoring studies would help us to understand potential population risks.

For example, EPA recently nominated, and CDC accepted, several chemicals, such as certain perfluorinated compounds (PFOS, PFOA, etc.) and certain polybrominated diphenyl ethers (PBDEs), among others, to be added to the National Biomonitoring Program. The first results will be reported in CDC's Fourth National Report on Human Exposure to Environmental Chemicals, which will be released next year (summer 2007).

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STATEMENT OF JOHN B. STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. Chairman and members of the committee, I am pleased to appear today before the Senate Committee on Environment and Public Works, to discuss our work on the Environmental Protection Agency's (EPA) implementation of the Toxic Substances Control Act (TSCA). Tens of thousands of chemicals are currently in commercial use in the United States and, on average, over 700 new chemicals are introduced into commerce each year. Although these chemicals are an integral component in the production of important goods and services, some may be toxic and may adversely affect human health and/or the environment. It was in this context, that the Congress passed TSCA in 1976, authorizing EPA to obtain manufacturer information on the risks of chemicals and to control those that EPA determines will pose an unreasonable risk.

TSCA addresses those chemicals manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States, but excludes certain substances including pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and food additives, drugs, and cosmetics regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA). TSCA authorizes EPA to re-

view those chemicals already in commerce—what are referred to as existing chemicals—and to assess chemicals before they enter commerce so-called new chemicals. EPA lists chemicals currently in commerce in the TSCA inventory. Of the over 82,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when EPA began reviewing chemicals in 1979. Since then, approximately 20,000 new chemicals were added to the inventory and are now in use as existing chemicals.

Prior to the passage of TSCA, chemical substances generally entered the marketplace without review or controls. Without Government intervention, and often with little or no knowledge of their potential adverse health and environmental impacts, some of these chemicals were produced and used in high volumes. Earlier legislation on clean water and air had primarily addressed releases of chemicals into the environment. In contrast, TSCA authorized EPA to control the entire life cycle of chemicals from their production and distribution to their use and disposal—including options for the outright banning of chemical substances to mandating requirements for chemical testing or product labeling. Now, chemical companies are required to submit to EPA, 90 days before beginning to manufacture a new chemical, a premanufacture notice containing information including the chemical's identity, categories of uses, estimated production volumes, and any test data possessed by the chemical company.

My testimony today, which is based on our June 2005 report, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*,<sup>1</sup> describes EPA's efforts to (1) assess existing chemicals used in commerce, (2) control the risks of new chemicals not yet in commerce, and (3) publicly disclose information provided by chemical companies under TSCA.

In summary, EPA does not routinely assess the human health and environmental risks of existing chemicals and faces challenges in obtaining the information necessary to do so. TSCA's authorities for collecting data on existing chemicals do not facilitate EPA's review process because they generally place the costly and time-consuming burden of obtaining data on EPA, rather than requiring chemical companies to develop and submit such data to EPA. Consequently, EPA has used its authorities to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979. Recognizing the need for additional information on existing chemicals, in the late 1990s EPA implemented its High Production Volume (HPV) Challenge Program, under which chemical companies have begun to voluntarily provide test data on about 2,800 chemicals produced or imported in amounts of 1 million pounds or more a year. While the HPV Challenge Program is a laudable effort to develop data on these chemicals, several problems remain, including that the chemical industry has not agreed to provide testing for over 200 chemicals originally identified in the HPV Challenge Program and that even with the test data provided under the program, EPA would need to demonstrate that the chemicals pose unreasonable risks in order to control their production or use under TSCA. While TSCA does not define what risk is unreasonable, according to EPA officials the standard has been difficult to meet. In order to withstand judicial scrutiny, a TSCA rule must be supported by substantial evidence in the rulemaking record. In this regard, EPA officials say the act's legal standards are so high that they have generally discouraged EPA from using its authorities to ban or restrict the manufacture or use of chemicals. Since Congress enacted TSCA in 1976, EPA has issued regulations under the act to ban or limit the production of only five existing chemicals or groups of chemicals.

EPA's reviews of new chemicals can provide only limited assurance that health and environmental risks are identified before the chemicals enter commerce because TSCA does not require chemical companies to test new chemicals before notifying EPA of their intent to manufacture a chemical. Furthermore, chemical companies generally do not voluntarily perform such testing. Because of a general lack of data, EPA has developed sophisticated methods to predict the potential exposure and toxicity levels of new chemicals by using scientific models to compare them with chemicals with similar molecular structures for which toxicity information is available. However, the use of these models can present weaknesses in the assessment because the models are not always accurate in predicting physical chemical properties and the evaluation of general health effects is contingent on the availability of information on chemicals with similar molecular structures. Additionally, chemical company estimates of a chemical's production volume and anticipated uses provided in the premanufacture notices that EPA uses to assess exposure, can change substantially after EPA completes its review and manufacturing begins. However, these es-

<sup>1</sup> IAGAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and*

timates do not have to be amended by companies unless EPA promulgates a rule determining that a use of a chemical constitutes a significant new use, which EPA has done for only a small percentage of new chemicals. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals submitted for review.

EPA's ability to provide the public with information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA. TSCA generally prohibits the disclosure of confidential business information and, according to EPA officials, about 95 percent of the premanufacture notices for new chemicals contain some information that is claimed as confidential. While EPA has the authority to evaluate the appropriateness of confidentiality claims, these efforts are time and resource-intensive, and the agency does not have the resources to challenge a significant number of claims. State environmental agencies and others have expressed interest in obtaining information claimed as confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. Chemical companies recently have expressed interest in working with EPA to identify ways to enable other organizations to use the information given the adoption of appropriate safeguards.

In our June 2005 report, we recommended that the Congress consider providing EPA additional authorities under TSCA to improve its ability to assess chemical risks, such as providing the EPA Administrator the authority to require chemical companies develop test data when production volumes reach certain levels. We also recommended that the EPA Administrator take several actions to improve EPA's management of its chemical program, including revising its regulations to require that companies reassert confidentiality claims under TSCA within a certain time period after the information is initially claimed as confidential. EPA did not disagree with the report's findings and is in the process of implementing several of our recommendations. For example, EPA is currently launching a pilot project to review claims of confidentiality for data on certain older chemicals.

#### EPA HAS LIMITED INFORMATION ON THE HEALTH AND ENVIRONMENTAL RISKS OF EXISTING CHEMICALS AND HAS ISSUED FEW REGULATIONS CONTROLLING SUCH CHEMICALS

Because chemical companies are generally not required to develop and submit toxicity information to EPA, when the agency decides to review existing chemicals, it generally has only limited information on the risks that the chemicals pose to human health and the environment. Furthermore, EPA's authority under TSCA to require industry testing that would provide the information to review the chemicals is difficult to use, according to EPA officials. EPA has used its authority to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979. Furthermore, EPA has rarely banned, limited the production, or restricted the use of existing chemicals. Since 1998, EPA has focused its efforts on obtaining information on existing chemicals through voluntary programs, such as the HPV Challenge Program. This program is intended to provide basic data on the characteristics of about 2,800 chemicals produced in excess of 1 million pounds a year.

#### *EPA Has Limited Toxicity and Exposure Data with Which to Review Existing Chemicals*

EPA's toxicity and exposure data on existing chemicals is often incomplete and TSCA's authority to require testing in support of the agency's review process is difficult to use. While TSCA authorizes the review of existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Chemical companies are not required to develop and submit toxicity information to EPA unless the agency promulgates a testing rule, thus placing the burden for obtaining data on EPA. In addition, if chemical company testing shows that a chemical is not toxic, there is generally no standing requirement that the chemical companies submit this data to EPA. Consequently, when EPA decides to review existing chemicals, it generally has only limited information on the risks of injury the chemicals pose to human health and the environment.

EPA officials told us that in cases where chemical companies do not voluntarily provide test data and health and safety studies in a complete and timely manner, requiring the testing of existing chemicals of concern—those chemicals for which some suspicion of harm exists—is the only practical way to ensure that the agency obtains the needed information. For example, there are currently over 200 high-production-volume chemicals for which chemical companies have not agreed to provide the minimal test data that EPA believes are needed to initially assess their risks. Furthermore, many additional chemicals are likely to be added to become

high production chemicals because the specific chemicals used in commerce are constantly changing, as are their production volumes. Chemical industry representatives told us that TSCA provides EPA with adequate authority to issue rules requiring companies to provide EPA with any test and exposure data possessed by the companies, and that EPA could use such authority to obtain company information on existing chemicals of concern. EPA could then use that information to determine whether additional rules should be issued to require companies to perform additional testing of the chemicals.

However, EPA officials told us that it is time-consuming, costly, and inefficient for the agency to use a two-step process of (1) issuing rules under TSCA (which can take months or years to develop) to obtain exposure data or available test data that the chemical industry does not voluntarily provide to EPA and then (2) issuing additional rules requiring companies to perform specific tests necessary to ensure the safety of the chemicals tested. Officials also said that EPA's authority under TSCA to issue rules requiring chemical companies to conduct tests on existing chemicals has been difficult to use because the agency must first make certain findings before it can require testing. Specifically, TSCA requires EPA to find that current data is insufficient; testing is necessary; and that either (1) the chemical may present an unreasonable risk or (2) that the chemical is or will be produced in substantial quantities and that there is or may be substantial human or environmental exposure to the chemical.

Once EPA has made the required findings, the agency can issue a proposed rule for public comment, consider the comments it receives, and promulgate a final rule ordering chemical testing. EPA officials told us that finalizing rules can take from 2 to 10 years and require the expenditure of substantial resources. Given the time and resources required, the agency has issued rules requiring testing for fewer than 200 chemicals. Because EPA has used authority to issue rules to require testing so sparingly, it has not continued to maintain information on the cost of implementing these rules. However, in our October 1994 report on TSCA,<sup>2</sup> we noted that EPA officials told us that issuing such a rule can cost hundreds of thousands of dollars.

Given the difficulties involved in requiring testing, EPA officials do not believe that TSCA provides an effective means for testing a large number of existing chemicals. They believe that EPA could review substantially more chemicals in less time if they had the authority to require chemical companies to conduct testing and provide test data on chemicals once they reach a substantial production volume, assuming EPA had first determined that these data cannot be obtained without testing. We have long held a similar view based on our reviews involving TSCA, and in our June 2005 report, we recommended that the Congress consider giving EPA the authority to require chemical manufacturers and processors to develop test data based on substantial production volume and the necessity for testing.

*EPA Has Had Difficulty Proving That Chemicals Pose Unreasonable Risks and Has Regulated Few Existing Chemicals under TSCA*

Even when EPA has toxicity and exposure information on existing chemicals, the agency stated that it has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and that they should be banned or have limits placed on their production or use. Indeed, EPA has rarely banned, limited the production, or restricted the use of existing chemicals. Since the Congress enacted TSCA in 1976, EPA has issued regulations under the act to ban or limit the production or restrict the use of only five existing chemicals or chemical classes. For an additional 173 existing chemicals, EPA has required chemical companies to submit notices of any significant new uses of the chemical, providing EPA the opportunity to review the risks posed by the new use.

*EPA Implemented a Voluntary Program to Collect More Industry Data on Existing Chemicals*

Facing difficulties obtaining information on existing chemicals, EPA took steps to address this shortcoming with the implementation of the HPV Challenge Program in 1998. According to EPA, the lack of information on existing chemicals and the relative difficulty of requiring testing under TSCA on the scale that would be necessary for the thousands of chemicals produced at high volumes, has led EPA, in cooperation with chemical companies, environmental groups, and other interested parties, to implement a voluntary program to obtain test data on high-production-volume chemicals from chemical companies. The HPV Challenge Program focuses on obtaining chemical company "sponsors" to voluntarily provide data on the approxi-

<sup>2</sup>NGAO, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective, GAO/RCED-94-103 (Washington, DC: September 26, 1994).



mately 2,800 chemicals that chemical companies reported in 1990, that they produced at a high volume—generally over 1 million pounds.

Through this program, sponsors develop a minimum set of data on the chemicals, either by gathering available information, using models to predict the chemicals' properties, or conducting testing of the chemicals. EPA plans to use the data collected under the program to prioritize high-production chemicals for further assessment, but it has not yet adopted a methodology for prioritizing the chemicals or for determining those that require additional information. In our June 2005 report, we recommended that EPA develop and implement such a methodology for using information collected through the HVP Challenge Program to prioritize chemicals for further review and to identify and obtain additional information needed to assess their risks. At EPA's request, a Federal advisory group has proposed a methodology for prioritizing the HPV Challenge Program chemicals, and EPA anticipates that the agency will implement the proposal during 2006.

Nonetheless, other problems exist in the HPV Challenge Program. Chemical companies have not volunteered to provide data on all the chemicals currently in the HPV Program. In addition, despite the fact that companies may begin raising the production volumes of other chemicals, EPA has no mechanism for placing these chemicals on the HPV Challenge Program list once they are produced in greater volume. We believe that action to implement our previously mentioned recommendation that the Congress consider giving EPA additional authority to require chemical testing could ameliorate such problems.

EPA LACKS SUFFICIENT DATA TO ENSURE THAT THE POTENTIAL HEALTH AND ENVIRONMENTAL RISKS OF NEW CHEMICALS ARE IDENTIFIED

EPA's review of new chemicals provides only limited assurance that health and environmental risks are identified because the agency has limited information with which to review them. In the absence of chemical test data, EPA largely relies on scientific models that do not always accurately determine chemicals' properties or the full extent of their adverse effects. Further, information that companies provide in the premanufacture notices that EPA uses to assess potential exposures to new chemicals are estimates that can change substantially once manufacturing begins. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals submitted for review.

EPA HAS LIMITED INFORMATION ON NEW CHEMICALS AND RELIES ON MODELING TOOLS TO ASSESS THE HEALTH AND ENVIRONMENTAL RISKS OF NEW CHEMICALS

TSCA generally requires chemical companies to notify EPA of their intent to manufacture or import new chemicals and to provide any available test data. Yet EPA estimates that most premanufacture notices do not include test data of any type, and only about 15 percent include health or safety test data. Chemical companies do not have an incentive to conduct these tests because they may take over a year to complete, and some tests may cost hundreds of thousands of dollars. During a review of a new chemical, EPA evaluates risks by conducting a chemical analysis, searching the scientific literature, reviewing agency files (including files of related chemicals that have already been assessed by EPA), analyzing toxicity data on structurally similar chemicals, calculating potential releases of and exposures to the chemical, and identifying the chemical's potential uses. On the basis of this review, EPA makes a decision to (1) take no action; (2) require controls on the use, manufacture, processing, distribution in commerce, or disposal of the chemical pending development of test data; or (3) ban or otherwise regulate the chemical pending the receipt and evaluation of test studies performed by the chemical's manufacturer. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, EPA uses a method known as structure activity relationships analysis to screen and evaluate a chemical's toxicity. This method, also referred to as the nearest analogue approach, involves using models to compare new chemicals with chemicals with similar molecular structures for which test data on health and environmental effects are available.

EPA officials told us that, while the overall accuracy of the models has not been validated for regulatory purposes, they are effective as screening tools that allow EPA to focus its attention on the chemicals of greatest concern—chemicals about which little is known other than that they are structurally related to known harmful chemicals. By applying approaches that make conservative predictions, EPA believes that it is more likely to identify a false positive (where a chemical is determined to be of concern, but on further analysis is found to be of low concern) than a false negative (where a chemical is initially viewed as a low concern though on

further analysis is actually of higher concern). According to EPA, only about 20 percent of the premanufacture notices received annually go through the Agency's more detailed full-review process after they have been initially screened. That is, according to EPA officials, the majority of new chemicals submitted for review can be screened out as not requiring further review because (1) EPA determines on the basis of its screening models that a chemical has low potential to harm human health or the environment or (2) on the basis of other information, such as the anticipated uses, exposures, and releases of the chemicals, only limited potential risks to people and the environment are expected. In addition, using these models, EPA identifies for possible regulatory action, those chemicals belonging to certain chemical categories that based on its prior experience in reviewing new chemicals are likely to pose potential risks such that testing or controls are needed. In our June 2005 report, we recommended that the EPA Administrator develop a strategy for improving and validating, for regulatory purposes, the models that EPA uses to assess and predict the risks of chemicals and to inform regulatory decisions on the production, use, and disposal of the chemicals.

*Estimates of Exposures and Other Information Provided in Premanufacturing Notices Can Change after Manufacturing Begins*

EPA bases its exposure estimates for new chemicals on information contained in premanufacture notices. However, the anticipated production volume, uses, exposure levels, and release estimates outlined in these notices generally do not have to be amended once manufacturing begins. That is, once EPA completes its review and production begins, chemical companies are not required under TSCA to limit the production of a chemical or its uses to those specified in the premanufacture notice or to submit another premanufacture notice if changes occur. However, the potential risk of injury to human health or the environment may increase when chemical companies increase production levels or expand the uses of a chemical. To address this potential, TSCA authorizes EPA to promulgate a rule specifying that a particular use of a chemical would be a significant new use. EPA has infrequently issued such rules, which require manufacturers, importers, and processors of the chemical for the new use to notify EPA at least 90 days before beginning manufacturing or processing the chemical for that use.

*EPA Reviews of New Chemicals Have Resulted in Some Control Actions*

When EPA's assessment of a new chemical identifies health and safety problems, EPA can issue a proposed rule to prevent chemical companies from manufacturing or distributing the chemical in commerce, or to otherwise restrict the chemical's production or use, if the agency believes the new chemical may present an unreasonable risk before EPA can regulate the chemical under the relevant provisions of TSCA. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals that chemical companies have submitted for review. These actions ranged from chemical companies voluntarily withdrawing their notices of intent to manufacture new chemicals, chemical companies entering into consent orders with EPA to produce a chemical under specified conditions, and EPA promulgating significant new use rules requiring chemical companies to notify EPA of their intent to manufacture or process a chemical for new uses.

For over 1,700 chemicals, companies withdrew their premanufacture notices, sometimes after EPA indicated that the agency planned to initiate the process for placing controls on the chemical, such as requiring testing or prohibiting the production or certain uses of the chemical. EPA officials told us that after EPA screens a chemical or performs a more detailed analysis of it, chemical companies often drop their plans to market a new chemical when the chemical's niche in the marketplace is uncertain and EPA requests that the company develop and submit test data.

For over 1,300 chemicals, EPA has issued orders requiring chemical companies to implement workplace controls or practices during manufacturing (pending the development of information), and/or perform toxicity testing when the chemical's production volumes reached certain levels. EPA may issue these proposed orders to control the production, distribution, use, or disposal of a new chemical when there is insufficient information available to reasonably evaluate the human health or environmental effects of a chemical and when the chemical (1) may present an unreasonable risk to human health or the environment or (2) is or will be produced in substantial quantities and (a) it either enters or may reasonably be anticipated to enter the environment in substantial quantities or (b) there is or may be significant or substantial human exposure to the substance. While TSCA does not authorize EPA to require that chemical companies develop this information, the act does allow EPA

to control the manufacturing and processing of the chemical until EPA has sufficient data to determine if the chemical will pose a risk.

For over 570 new chemicals submitted for review, EPA required chemical companies to submit premanufacture notices for any significant new uses of the chemical, providing EPA the opportunity to review the risks of injury to human health or the environment before new uses had begun.

#### EPA'S ABILITY TO SHARE DATA COLLECTED UNDER TSCA IS LIMITED

EPA's ability to make publicly available the information that it collects under TSCA is limited. Chemical companies may claim the information they provide to EPA under TSCA as confidential business information. While EPA believes that some claims of confidentiality shall generally be treated as such if no statute specifically requires disclosure. Exceptions include if the information is required to be released by some other Federal law or court order, if the company voluntarily withdraws its confidential claim, or if the EPA Office of General Counsel makes a final administrative determination that the information does not meet the regulatory criteria substantiating a legal right to the claim. EPA has not performed any recent studies of the appropriateness of confidentiality claims, although a 1992 EPA study indicated that problems with inappropriate claims were extensive. That study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. While EPA may suspect that some chemical companies' confidentiality claims are unwarranted, they have no data on the number of inappropriate claims.

When companies submit information to EPA through premanufacture notices, many claim a large portion of the information as confidential. According to EPA, about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential. Under EPA regulations, information that is claimed as confidential shall generally be treated as such if no statute specifically requires disclosure. Exceptions include if the information is required to be released by some other Federal law or court order, if the company voluntarily withdraws its confidential claim, or if the EPA Office of General Counsel makes a final administrative determination that the information does not meet the regulatory criteria substantiating a legal right to the claim. EPA has not performed any recent studies of the appropriateness of confidentiality claims, although a 1992 EPA study indicated that problems with inappropriate claims were extensive. That study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. While EPA may suspect that some chemical companies' confidentiality claims are unwarranted, they have no data on the number of inappropriate claims.

EPA officials told us that the agency does not have the resources necessary to investigate and, where appropriate, challenge claims that it believes are inappropriate. Consequently, EPA focuses on investigating primarily those claims that it believes may be both inappropriate and among the most potentially important—that is, confidentiality claims relating to health and safety studies performed by the chemical companies involving chemicals currently in commerce. The EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year, and that the chemical companies withdraw nearly all of the claims when challenged.

Officials who have various responsibilities for protecting public health and the environment from the dangers posed by chemicals believe that having access to confidential TSCA information would allow them to examine information on chemical properties and processes that they currently do not possess and could enable them to better control the risks of potentially harmful chemicals. For example, on the basis of a study performed by the State of Illinois with the cooperation of chemical companies and EPA, Illinois regulators found that toxicity information submitted under TSCA was useful in identifying chemical substances that should be included in contingency plans in order to alert emergency response and planning personnel to the presence of highly toxic substances at facilities. Additionally, the availability of this information could assist the states with environmental monitoring and enforcement. For instance, using TSCA data, Illinois regulators identified potential violations of State environmental regulations, such as cases where companies had submitted information to EPA under TSCA but failed to submit such information to the states as required.

Likewise, the general public may also find information provided under TSCA useful. Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example, neighborhood organizations can use such information to engage in dialogue with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

TSCA's provisions are in contrast to those of some foreign Governments' environmental laws, such as Canada, which authorizes its environmental agency to share confidential business information with other Governments under agreements or arrangements where the Government undertakes to keep the information confidential. Chemical industry representatives told us that the industry also sees benefits in allowing EPA to share information with other countries in order to harmonize chemical assessments among developed countries and improve chemical risk assessment

methods by allowing cooperation on improving models used to predict chemical toxicity. The chemical industry is concerned, however, that confidential information be protected from inappropriate disclosure. These chemical industry representatives told us that some countries currently do not have adequate procedures for protecting confidential business information. However, they suggested that the policies and procedures EPA currently uses to protect confidential information are appropriate. Accordingly, they said that the chemical industry would not object to TSCA revisions allowing EPA to share confidential information with foreign countries and organizations, provided that such revisions contain specific reference to safeguards that EPA would establish and enforce to ensure that those receiving the information have stringent policies and procedures to protect it.

Our June 2005 report included two recommendations for addressing the problems we identified related to the confidential business information provisions of TSCA. We recommended that EPA revise its regulations to require companies to reassert claims of confidentiality within a certain period after the information is initially claimed as confidential. We also recommended that the Congress consider amending TSCA to authorize EPA to share with the states and foreign Governments the confidential business information that chemical companies provide to EPA, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties that would set forth the procedures to be followed by all recipients of the information in order to protect the information from unauthorized disclosures. EPA did not disagree with the report's findings and is in the process of implementing several of our recommendations. For example, EPA is currently launching a pilot project to review claims of confidentiality for data on certain older chemicals.

#### CONCLUDING OBSERVATIONS

Mr. Chairman, EPA's efforts to encourage companies to voluntarily provide data on existing chemicals is commendable. However, the fundamental and historical problems the agency has experienced with utilizing its authorities under TSCA continue to limit EPA's ability to manage its chemical review program and assess chemical risks. In this respect, EPA faces considerable difficulties using its authorities to require testing of existing chemicals, which prevents the agency from reviewing substantially more chemicals in less time than it could if it had the authority to require chemical companies to provide test data on chemicals once they have reached a substantial production volume. Moreover, EPA's ability to provide the public with information on chemical production and risks is hampered by the strict confidential business information provisions of TSCA. While protecting such information is a legitimate concern, TSCA currently prohibits EPA from disclosing much data for important purposes such as assisting State agencies in carrying out their environmental management responsibilities and foreign Governments in harmonizing international chemical assessment approaches—a goal generally shared by these Governments and the chemical industry. We believe the actions that we have recommended to both the Congress and EPA would go a long way in addressing the challenges EPA, faces in exercising its authorities under TSCA.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or Members of the Committee may have.

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#### RESPONSES BY JOHN B. STEPHENSON TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

*Question 1.* In the 2005 report, GAO presents statistical data on the number of chemicals for which EPA has required testing or the number of risk reduction actions EPA has taken. Yet you provide no such information for Canada and the European Union. In fact, in the case of the European Union, REACH doesn't even exist yet. Without that data, isn't it impossible for us to make a direct, law-to-law comparison as to the effectiveness of these programs?

Response. Our reports in June 2005 (Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program; GAO-05-458) and in November 2005 (Chemical Regulation: Approaches in the United States, Canada, and the European Union; GAO-06-217R) provided descriptive information on differences in the approaches to chemical regulation in the United States under TSCA; Canada under the Canadian Environmental Protection Act (CEPA); and the European Union (EU) under current legislation and under the EU's proposed legislation known as REACH (Registration, Evaluation and Authorization of Chemicals). Our reports did not compare the relative effectiveness of these programs nor did they provide information on the number of chemical tests required

by or the number of control actions taken under these programs. EPA officials told us that simply counting the number of control actions would not provide an adequate comparison of the effectiveness of various national chemical control programs because counting control actions would not factor in voluntary programs or companies' efforts to reduce chemical risks by switching to safer chemicals. Moreover, because the overall statutory and regulatory approaches to chemical regulation differ among nations, it would be difficult to make direct comparisons of effectiveness. Both Canadian and EU officials told us that concerns over the lack of data on existing chemicals, coupled with difficulties in obtaining data needed to adequately assess the risk of those chemicals, have caused officials in those countries to consider revising their basic chemical regulations.

*Question 2.* You stated in the report summary that you are unsure if the information collected under HPV will help EPA determine the risks of HPV chemicals. What do you suppose the information will be used for, then? Is it really necessary to always have a comprehensive data set to determine risk? Isn't a more targeted, tiered and risk-based approach a standard used worldwide?

*Response.* The screening level information gathered under the HPV Challenge Program will be used to make preliminary judgments about the need for further testing or evaluation of high production volume chemicals. However, any further action beyond the voluntary collection of information by EPA requires the use of TSCA provisions that EPA has found difficult to use, as noted in our prior reports.

We have not recommended that EPA develop a comprehensive data set on all chemicals, and we have encouraged the agency to target its efforts at those chemicals that pose the greatest risks. EPA, under the HPV Challenge Program, collects a data set on program chemicals known as the Screening Information Data Set (SIDS) that was developed by the Organization for Economic Cooperation and Development (OECD). The data set includes information on the identity of the chemical; its uses, sources and extent of exposure; physical and chemical properties; environmental fate; and certain limited toxicity data for humans and the environment. This information allows EPA to make an informed, preliminary judgment about the hazards of HPV chemicals. While the data do not fully measure a chemical's toxicity, it can be used to determine the relative hazards of chemicals and to judge whether additional testing or assessment is necessary. Because of the lack of availability of basic toxicity information on most high volume chemicals prior to 1998, we believe that the HPV Challenge Program is an important first step in obtaining needed basic toxicity information.

However, once the information has been obtained, EPA still faces hurdles in requiring additional testing and/or controlling chemicals that EPA believes will pose an unreasonable risk to human health and the environment. As noted in our June 2005 report, before EPA can issue a rule requiring companies to perform additional testing, the agency must demonstrate that a chemical may present an unreasonable risk to human health or the environment or will be produced in sufficient quantities to present substantial risk to humans or the environment. Consequently, EPA has used its authorities to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979. In addition, if EPA believes banning or restricting the manufacture or use of a chemical is necessary to protect human health or the environment, it must produce substantial evidence in the rulemaking record and must prove that the chemical will present an unreasonable risk to human health and/or the environment. Because the act's legal standards are so high, EPA has issued regulations under the act to ban or limit the production of only five existing chemicals or groups of chemicals.

We have not performed work to determine the approaches or the most appropriate types of approaches used by various nations to regulate commercial chemicals. However, on the basis of the results of our work involving TSCA, we have encouraged EPA to target its limited resources on those chemicals that pose the greatest risks to human health and the environment.

*Question.* You mention in the June 2005 Report that EPA has limited ability to collect data on existing chemicals. EPA has collected information on about 2,000 existing chemicals so far under the HPV Challenge. Considering Canada has primarily used modeling to screen chemicals and REACH isn't even a law yet, has any other country or region in the world collected SIDS base sets anywhere near 2,000 chemicals?

*Response.* We have not performed any work to determine the amount of data collected on existing chemicals in Canada or the EU. Nevertheless, according to EPA officials, the HPV Challenge Program will collect more information in a short amount of time than has been collected to date in Canada and the EU. We have

not verified the information that EPA claims was submitted under the program nor determined the quality of any of the information submitted.

Our June 2005 Report stated that EPA has limited ability to collect data on existing chemicals in the TSCA inventory (not just the high production volume chemicals). It was the lack of basic toxicity information that led EPA to create the High Production Volume (HPV) Challenge Program in order to gather basic toxicity information on those chemicals produced at one million pounds or more. Under the program, EPA collects basic level screening data on HPV chemicals in order to determine the relative hazards and to judge if additional testing is necessary. This allows EPA to make a preliminary judgment about the hazards of HPV chemicals as the data generally do not fully measure a chemical's toxicity. In effect, the HPV Challenge program provides the first in a series of steps needed to adequately assess and manage chemical risks. While it is an important first step in collecting information on existing chemicals, subject matter experts have noted some problems with the HPV Challenge Program. First, information submitted by companies thus far has not been reviewed to determine its quality or completeness. Second, the majority of the data submitted under the program are generated from models, not actual tests. Finally, rather than submitting information on individually designated chemicals, 80 percent of the chemicals are grouped into broad categories for data submission.

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RESPONSES BY JOHN B. STEPHENSON TO ADDITIONAL QUESTIONS  
FROM SENATOR BOXER

*Question 1.* Mr. Stephenson, TSCA's chemical inventory currently has more than 82,000 substances. Could you please describe the extent of EPA's lack of safety data, in particular for children, with respect to the chemicals in TSCA's inventory?

Response. TSCA does not generally require companies to develop any safety information, absent EPA action, for either new or existing chemicals. While TSCA authorizes EPA to promulgate rules requiring testing of chemicals if EPA has made certain findings, TSCA does not require chemical companies to test chemicals prior to their use in commerce for toxicity or to gauge exposure levels before they are submitted for EPA's review, and chemical companies generally do not voluntarily perform such testing. Further, EPA cannot require chemical companies to test existing chemicals and provide the resulting test data to the agency unless EPA first determines on the basis of risk or production and exposure information that the chemicals warrant such testing. EPA has used its authority to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979.

In response to several studies that showed that there were relatively few High-Production Volume (HPV) chemicals for which an internationally agreed upon set of hazard screening data was available to the public, EPA, in cooperation with industry, environmental groups, and other interested parties initiated the HPV Challenge Program in late 1998. The program was created to ensure that a baseline set of data on approximately 2,800 high-production-volume-chemicals would be made available to the public. While the HPV Challenge Program looks promising in that, if successful, it will provide EPA and the public with information not previously available on the properties of chemicals produced at large volumes in the United States, this program may not provide enough information for EPA to use in making risk assessment decisions. While the data in the HPV Challenge Program may help EPA prioritize chemicals of concern for additional review and assessment, the data may not present sufficient evidence for EPA to determine whether a reasonable basis exists to conclude that the chemicals present an unreasonable risk of injury to health or the environment and that regulatory action is necessary. As our earlier reports have indicated, EPA has found it difficult to use the authorities provided under TSCA to require companies to develop such data and to restrict the uses or production of chemicals.

With respect to children's safety, GAO has not performed the work necessary to determine the extent to which EPA lacks data specifically on the adverse effects of chemicals on children. However, the limitations noted above would also apply to data on risks to children.

*Question 2.* Mr. Stephenson, in 1991, the Fifth Circuit Court of Appeals struck down EPA's rule to ban most uses of asbestos. In your view, what is the practical impact of that decision on EPA's ability to use TSCA to enforce mandatory protections on chemicals that present a risk to public health, including to children?

Response. In 1979, EPA began exploring rulemaking under TSCA to reduce the risks posed by exposure to asbestos. Based upon its review of over 100 studies of the health risks of asbestos as well as public comments on the proposed rule, EPA

concluded that asbestos was a potential carcinogen at all levels of exposure. In 1989, EPA promulgated a rule under TSCA section 6 prohibiting the future manufacture, importation, processing, and distribution of asbestos in almost all products. Some manufacturers of asbestos products filed suit against EPA, arguing, in part, that the rule was not promulgated on the basis of substantial evidence regarding unreasonable risk. In October 1991, the U.S. Court of Appeals for the Fifth Circuit agreed with the chemical companies, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban and returning parts of the rule to EPA for reconsideration.

In its ruling, the court concluded that EPA did not present sufficient evidence to justify the ban on asbestos because it did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation required to adequately protect human health or the environment. As articulated by the court, the proper course of action for EPA, after an initial showing of product danger, would have been to consider each regulatory option, beginning with the least burdensome, and then assess the costs and benefits of each option. The court further criticized EPA's ban of products for which no substitutes were currently available stating that, in such cases, EPA "bears a tough burden" to demonstrate, as TSCA requires, that a ban is the least burdensome alternative.

While it is not possible to determine how EPA would have implemented TSCA in the absence of the court's decision, it can be noted that since the decision EPA has exercised its authority to ban or limit the production or use of an existing chemical only once (for equivalent chromium). In this case, EPA officials said that they had started the process for promulgating the rule for equivalent chromium years prior to the asbestos decision. EPA officials have suggested that the court's ruling in the asbestos case created a difficult standard for the agency to meet by requiring that, before EPA takes regulatory action, it demonstrate that its regulations use the least burdensome approach to mitigating unreasonable risks and that its rulemaking is supported by substantial evidence. With respect to children, we note that TSCA contains no provisions specifically directing EPA to address the risks that chemicals pose to children's health.

*Question 3.* Mr. Stephenson, Government Accountability Office reports going back to 1984 have noted that EPA lacks needed toxicity data on chemicals. GAO reports from 1994 and 2005 discuss TSCA's industry-friendly standards as an impediment to EPA's implementing non-voluntary restrictions on the use or production of chemicals. All of these reports also note that EPA lacks adequate resources to fully implement the program. In your opinion, are TSCA's current provisions the best way for Congress to protect individuals, including children, from dangerous exposures to toxic chemicals? Or, should we consider modifying the law?

*Response.* As we reported in 1994 and 2005, and testified on August 2, 2006, there are several actions that the Congress and EPA could take to improve EPA's ability to assess the health and environmental risks of chemicals and to manage its chemical review program. In our reports and testimony, we have recommended that the Congress consider (1) providing explicit authority for EPA to enter into enforceable consent agreements under which chemical companies are required to conduct testing; (2) giving EPA the authority under section 4 of TSCA to require chemical substance manufacturers and processors to develop test data based on substantial production volume and the necessity for testing; and (3) authorizing EPA to share with the states and foreign Governments the confidential business information that chemical companies provide to EPA, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties, that would set forth the procedures to be followed by all recipients of the information in order to protect the information from unauthorized disclosures.

Moreover, we have identified additional options that the Congress could consider to strengthen EPA's ability under TSCA to assess chemicals and control those found to be harmful. In this regard, the Congress could strengthen TSCA by:

- requiring the systematic testing of existing chemicals;
- requiring chemical companies to provide additional information on new chemicals; and
- reducing EPA's evidentiary burden to take action under TSCA.

Detailed descriptions of the above options are contained in our prior reports on TSCA. While such options exist to make TSCA more effective, their likely benefits in protecting human health and the environment would need to be weighed against the potential costs of implementing them.

STATEMENT OF MICHAEL P. WALLS, MANAGING DIRECTOR OF REGULATORY AND  
TECHNICAL AFFAIRS, AMERICAN CHEMICAL COUNCIL

## I. INTRODUCTION

The American Chemistry Council (ACC) appreciates this opportunity to appear before the Committee to discuss the U.S. chemical regulatory control framework, notably the Toxic Substances Control Act (TSCA). In our view, TSCA is a sound statutory and regulatory system. It is a robust vehicle that can effectively address emerging chemical issues, while retaining sufficient flexibility to promote innovation and the active involvement of chemical manufacturers in the safe management and use of chemicals.

ACC is the national trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. ACC member companies are on the cutting-edge of technological innovation and progress, whose products provide significant benefits—benefits that save lives, improve health, protect our food supply, and provide jobs throughout the Nation.

ACC member companies are committed to implementing a set of goals and guidelines that go above and beyond Federal regulation on health, safety, security, and the environment. Since the Council adopted Responsible Care in 1988, our members have reduced emissions by 75 percent and achieved a safety record more than four and a half times better than the average for the manufacturing sector overall. ACC supports the safe management and use of chemical products. The industry's regulatory compliance and proactive product stewardship programs allow ACC's members to manage appropriately the wide range of products made by the business of chemistry.

These comments address the statutory and regulatory safeguards built into the current framework for the management of chemicals; some of the voluntary programs that our industry has committed to that build on those safeguards; and why it is important to ensure that TSCA remains a flexible, science-based statute that can address new scientific challenges and promote technological innovation.

## II. THE OVERALL FRAMEWORK FOR CHEMICALS MANAGEMENT

TSCA is not the only statute that controls risks from chemicals products on the market, although it is an important piece of the overall regulatory framework. Other statutory requirements focus on chemical uses that may create direct human exposures. For example, information and registration requirements for pesticides are covered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The standards for manufacturers of pharmaceuticals, food additives, food packaging, and cosmetics are addressed in the Federal Food, Drug and Cosmetic Act (FFDCA). The Federal Hazardous Substances Act (FHSA) applies to substances used in consumer products. Some 14 different Federal statutes play a role in regulating chemical manufacture, use, distribution and disposal, complemented by State regulatory programs in specific areas.

Unlike the environmental media-driven statutes such as the Clean Air Act, Congress did not set specific metrics or deadlines for actions under TSCA. Instead, Congress has provided the Environmental Protection Agency (EPA) tools to gather information so that risks can be identified and managed, and unreasonable risks eliminated. TSCA was enacted in 1976 in order to prevent "unreasonable risk of injury to health or the environment associated with the manufacture, processing, and distribution in commerce, use, or disposal of chemical substances." Congress properly recognized that while a variety of laws existed to ensure the safety of products, EPA needed tools to identify potential risks to health and the environment, and to take the steps to manage those risks appropriately.

TSCA was intended to be flexible enough to enable a variety of regulatory responses, and address a variety of needs, including support for regulatory action under other statutes. ACC counts this flexibility as one of the key strengths of TSCA, particularly as science, technology, and our ability to understand hazards, mechanisms of action, and exposures to chemicals have evolved.

In TSCA, Congress gave EPA a variety of tools to empower the agency to gather information, assess that information, and initiate action to address any risk which, in the agency's view, is unreasonable. Key provisions of TSCA authorize EPA to:

- Establish an inventory of chemical substances which had been on the market when TSCA was enacted (the "existing" substances), as well as any substance later reviewed and approved by EPA under the "new substance" provisions. (TSCA Sec. 8(b))



- Require the review and approval of any “new” substance prior to manufacturing that substance. Companies submitting a pre-manufacture notice (PMN) are required to submit any available health or environmental test information that they may already have in their possession. In addition to available test information, the manufacturer must provide information on the chemical identity and structure, and anticipated uses, production volume, by-products, human exposures and disposal practices. EPA has established some 35 PMN policies that provide early guidance to submitters on substances that have particular characteristics. EPA has also developed sophisticated and powerful computer modeling—using data gathered over many years—that help predict a chemical’s physical and chemical properties, health hazards, exposure potential, and potential environmental effects. If EPA finds the information provided inadequate, EPA has the authority to ask companies for additional information under this provision. (TSCA Sec. 5)

- Limit “new” uses of existing chemical substances under authority known as a “significant new use rule.” Using this authority, EPA has successfully restricted well over 1,000 substances. These restrictions range from establishing maximum production amounts, dictating allowable uses, instructing on appropriate disposal methods, or other measures designed to manage risk. (TSCA Sec. 5)

- Require companies to test chemicals to assess potential risks to health or the environment. Chemicals that may need test data are brought to EPA’s attention in a variety of ways. For example, the Interagency Test Committee (established under TSCA and comprised of experts from eight designated Federal agencies and institutes, and a number of other liaison members) regularly evaluates and recommends chemicals to test. EPA may also select chemicals on the basis of information provided under any of the information collection sections of the statute. (TSCA Sec. 4)

- Regulate existing chemical substances through a variety of mechanisms, including use restrictions, production limitations, warning labels, record keeping, customer notifications, or in the most extreme cases, outright bans. Although EPA has successfully pursued a number of actions under this part of TSCA, one case is routinely cited (in ACC’s view, incorrectly) for the proposition that “Section 6 demonstrates that TSCA is broken.” Contrary to popular perception, the Corrosion Proof Fittings opinion does not establish a failing in the statute—it simply established that EPA did not follow Congress’ directive. In fact, EPA has successfully regulated other substances under TSCA section 6 including halogenated aromatic compounds, heavy metals, and fibers. (TSCA Sec. 6)

- Require companies to: (a) keep records on allegations of significant adverse reactions; (b) report information on chemical uses and exposures; (c) provide EPA with copies of unpublished health and safety studies; and (d) submit all information in their possession that suggests a chemical presents a substantial risk of injury to health or the environment. (TSCA Sec. 8)

- Require companies to provide notifications of anticipated exports of substances subject to test rules under Section 4, and those subject to orders or rules under Sections 5, 6 and 7. The facts around TSCA implementation comprise an impressive record:

- From 1979 through 2003, EPA reviewed approximately 36,000 new chemicals. More than 3,000 were subject to some form of regulation as a result of EPA’s reviews. More than 1,200 chemicals are subject to consent orders negotiated by the manufacturers with EPA. Such consent orders typically prescribe limitations on use, workplace practices, labeling requirements, and release and disposal restrictions.

- In more than 500 other cases, EPA permitted the new substance to be produced without a consent order, but at the same time promulgated a “significant new use rule” (SNUR) that prohibits certain uses of the substance without further prior review by EPA. In approximately 870 cases, the submitter of the pre-manufacture notice agreed to conduct additional testing in response to EPA requests. In some 1,550 cases, the submitter withdrew the pre-manufacture notice in the face of EPA concerns and likely regulatory requirements.

- Since TSCA was enacted, several hundred existing chemicals have been subject to testing requirements imposed by EPA under TSCA Section 4. In addition to TSCA testing requirements, many companies conduct hazard and environmental fate and effects testing on their products, including sometimes very sophisticated testing that goes well beyond the testing requirements typically imposed by EPA under TSCA. Indeed, the volume of testing that occurs outside of TSCA on a voluntary basis far exceeds testing conducted pursuant to regulatory requirements. When toxicity testing of chemicals is conducted under the auspices of a chemical specific panel of the American Chemistry Council, a copy of the final study report is automatically provided to EPA and several other regulatory Agencies.

- EPA has developed a Preliminary Assessment Information Rule (PAIR) reporting form that it frequently uses to gather information about the manufacture, use,

potential for workplace exposure and environmental release of specific chemicals. To date, EPA has required manufacturers to complete this form for approximately 475 chemicals. EPA also has exercised its authority to require the submission of existing health and safety data for approximately 1,000 chemicals.

- Since TSCA was enacted, well over 10,000 “substantial risk” reports have been filed with EPA under Section 8(e).

### III. VOLUNTARY PROGRAMS UNDER TSCA

As noted earlier, TSCA provides flexibility to EPA in adapting voluntary programs and initiatives that complement the Agency’s regulatory programs. The High Production Volume Challenge (HPV) Program, for example, has provided more hazard information, on more chemicals, faster than any other program EPA has ever established.

#### *HPV Challenge Program*

In 1998, the chemical industry, working with EPA, Environmental Defense and others, developed the HPV Program. This unprecedented voluntary initiative had the goal of making uniform health and environmental screening information on high production volume (HPV) chemicals publicly available by the end of 2005. Through the HPV Challenge Program, more than 300 sponsoring manufacturers volunteered to provide hazard-screening information on 2,222 HPV chemicals.

For each of the chemicals sponsored in the program, industry has provided 17 types of information, including summarized results in four categories: physical-chemical properties, environmental fate, and potential to induce toxicity in aquatic organisms and humans. Data to be summarized for human toxicity include studies assessing acute toxicity, sub chronic toxicity, genotoxicity, and developmental and reproductive toxicity.

All of the information collected under the HPV Program is important and relevant for evaluating a chemical’s potential impact on human health and the environment. Additionally, test categories such as genotoxicity and acute, developmental and reproductive toxicity are specifically relevant to protecting children’s health.

The standard battery of toxicity tests employed by EPA for HPV (and harmonized internationally under OECD) includes tests specifically designed to evaluate endpoints that provide information on a substance’s potential to pose a health hazard:

- to development in the womb;
- to growth and reproduction;
- from acute poisoning;
- to cell components that could possibly trigger transformation into cancer later in life;
- to the nervous system (observation for toxicological effects on the nervous system are included as a component of the protocol in every animal toxicity test);
- to all major organ systems, including the nervous system.

Thus, the standard battery of TSCA HPV tests is both relevant and important to assessing potential health hazards. Results from these tests can and are being used to decide what specific, additional toxicity tests are scientifically warranted and necessary to more completely understand specific organ-system hazards, and to more fully characterize the dose-response relationship.

The HPV program, supported by EPA’s HPV Information System (HPVIS), has made existing health and environmental effects data sets publicly available on approximately 95 percent (by volume) of the chemicals currently in commerce in the United States

More importantly, EPA is using the HPV data to make decisions on priorities for further review. All HPV data—which was always intended for screening purposes and not as a complete data set—are being assessed in EPA’s screening mechanism. The HPVIS screening process was designed by an EPA stakeholder group (the National Pollution Prevention and Toxic Advisory Committee) after detailed review of the needs of a variety of data users. The first step is an automated review, resulting in a prioritization of all chemicals for detailed evaluation. ACC supports that process, and looks forward to its timely completion.

#### *Extended HPV Program*

In March 2005, before the end of the HPV Challenge Program, the chemical industry extended and broadened its current work on HPV chemicals in two ways. First, companies are asked to provide health and environmental information for 574 “new” HPV chemicals—chemicals that did not qualify as HPV chemicals at the start of the original program, but which now meet the volume threshold according to

EPA's 2002 Inventory. Second, the EHPV Program increases the scope of information being collected for all HPV chemicals. In addition to gathering health and environmental information, companies are asked to provide information on use and exposure for both the "Extended" HPV as well as the original "Challenge Program" substances. In this way, the EHPV Program will provide EPA and the public with an extensive source of chemical safety information on HPV chemicals.

Together, these voluntary programs are exemplary illustrations of how industry has taken responsible action, supported through the flexibility inherent in TSCA. All of the important information generated in these voluntary programs will be used by EPA to prioritize HPV chemicals for further evaluation, risk characterizations and risk assessment.

#### *Voluntary Children's Chemical Evaluation Program*

EPA announced its pilot Voluntary Children's Chemical Evaluation Program (VCCEP) in December 2000 to assess certain chemicals for potential risks to children through a series of tiered screens and tests. It was developed as an alternative to a TSCA Section 4 test rule. The VCCEP pilot is evaluating both hazard and exposure information on 20 chemicals voluntarily submitted by thirty five companies and ten consortia. The key question that the VCCEP aims to answer is whether the potential hazards, exposures, and risks to children have been adequately characterized, and if not, what additional data are necessary.

Companies participating in VCCEP present a hazard assessment, exposure assessment and risk assessment on their chemical to an independent peer consultation panel which then makes a recommendation to EPA about additional data needs under the tiered evaluation framework of the program. EPA then makes a data needs assessment about the chemical.

The program is proceeding well and is currently about half completed. Industry has lived up to its commitments under the program. ACC believes this pilot program has been very successful at affirming the viability and improved efficiencies of tiered approaches to chemical evaluation. It has also improved the practice of children's health exposure assessments and has proved the value of an independent peer consultation panel to make data needs recommendations. Although EPA data needs decisions have taken a long time, the pilot VCCEP has successfully evaluated many important chemicals, including brominated flame retardants, vinylidene chloride, benzene, and acetone.

The program has shown that a one-size fits all, single tier test battery approach to children's health questions would be wasteful of laboratory animals, costly, inefficient and not nearly as informative as the approach taken under VCCEP. At the end of the day, VCCEP is providing a strong, scientific basis for deciding whether children's risks from exposure to chemicals have been adequately characterized and additional information is needed to make those characterizations.

Voluntary programs are conducted under the auspices of TSCA and they play an important role in implementing the objectives of TSCA. They permit companies to demonstrate their commitment to product safety, and often result in information developed in ways that are faster or less burdensome than would be the case under a regulatory mandate.

### III. TSCA MEETS NEW SCIENTIFIC AND TECHNOLOGICAL CHALLENGES AND PROMOTES INNOVATION

As science evolves, we learn more and more about the relationship between chemistry and health. TSCA's framework is flexible enough to meet new scientific questions that might be raised about the impact of chemicals on health. Rather than amending TSCA to impose new requirements each time these new questions arise about chemicals, the law and EPA's implementation of it are flexible enough to address these questions under a science and risk based framework. Concerns about endocrine disruption, children's health, biomonitoring information and nanotechnology can and are being addressed today under TSCA's information collection, reporting, testing and risk management provisions, (as well as under other existing statutes such as the Food Quality Protection Act of 1996). These are just today's questions. New scientific questions will continue to arise as science evolves. TSCA provides a dynamic framework for anticipating these issues and developing the scientific information needed to apply its many risk management tools as appropriate.

TSCA's framework also promotes the development of innovative chemistries and technologies. More new chemical notifications are filed under TSCA than in any other major regulatory system, including Europe and Japan. As a result, the business of chemistry in the United States is acknowledged to be a world-leader in solutions that improve science and technology. ACC has no doubt that TSCA has helped foster innovation and a significant competitive position for the industry in the world

economy. Further, TSCA has contributed greatly to the national economy and the relative position of the U.S. chemical industry in the global business of chemistry.

The term “green chemistry” has become a popular term recently, and some have argued that TSCA does not do enough to encourage the production of chemicals that have little or no toxic effects. ACC members believe in green chemistry—in fact they are among the premier practitioners of green chemistry, a fact demonstrated by the regular recognition of ACC member companies in programs such as the Presidential Green Chemistry Awards.

It is important to recognize that green chemistry is a framework that aligns technology and innovation with improvements in the health and environmental “footprint” of materials used in our society. Green chemistry is not just about products, it is also about the improvements and enhancements in production processes.

ACC agrees that Government can and should provide encouragement for such collaborations through the sharing of expertise, financial support for research, information exchange and public education. In fact, a variety of Federal agencies (including EPA and DOE), companies, professional associations such as the American Chemical Society, and universities are working together to encourage green chemistry strategies.

However, it is inappropriate to blame TSCA for the alleged lack of “green chemistry” approaches. The fact that the statute does not explicitly address green chemistry is not surprising, nor is it important. In ACC’s view, TSCA appropriately does not dictate how the process of innovation and collaboration should occur, and in what areas.

#### IV. CONCLUSION

The American Chemistry Council believes that the Toxic Substances Control Act provides a high level of health and environmental protection in the manufacture and use of chemical substances. Through TSCA, EPA has significant regulatory authority to take measures necessary to prevent or mitigate unreasonable risks. Moreover, TSCA complements the industry’s product stewardship programs, as do the legal and marketplace forces that affect the industry.

ACC and its member companies appreciate this opportunity to comment on TSCA.

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#### RESPONSES BY MICHAEL P. WALLS TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

*Question 1.* Mr. Walls, I am acutely aware that TSCA is one of the few laws in the United States that directly impacts a company’s ability to sell goods in the marketplace. Can you comment on the effect on innovation and the ability for small companies to compete if we impose new regulations and made proprietary business information publicly available?

*Response.* TSCA promotes innovation in the United States by making it possible for EPA to quickly review new chemical products for their potential health or environmental risks, and for companies to provide EPA with essential health, safety and environmental information while simultaneously keeping key commercial information confidential. A new regulatory approach that would require proprietary business information to be made routinely available would likely have a severe negative effect on innovation in the business of chemistry.

The issue of proprietary business information and TSCA cannot be taken lightly. Congress clearly understood what types of data would be covered by the statute, and built in strong protections for confidential business information. TSCA’s new chemical notifications and other reporting requirements compel industry to provide a wealth of sensitive data about chemical substances that have commercial value. Examples of such data include:

- A chemical identity of a new substance that may be a trade secret, or which may not yet have received patent protection
- The volume of the chemical that would be produced, which would signal to competitors the potential market size for the chemical
- The preferred molecular weight range for a new commercially valuable polymer
- Impurities, which can signal to those competitors skilled in the art the manufacturing process and or precursor substances
- Proprietary manufacturing processes
- The formulations of commercially valuable products and intermediates
- The commercial uses for which a new or existing substance has value

Since the business of chemistry involves substantial investment in research and development, and results in the development of significant technology, intellectual

property and valuable trade secrets, it is essential that the provisions to protect confidential information not be weakened. The industry's \$23 billion annual investment in research and development relies heavily on the ability to protect that investment. Unfortunately, our desire to protect proprietary business information is often misconstrued as a desire to hide safety information. This is simply not the case. ACC member companies routinely provide all manner of health, safety and environmental information on their chemicals. This includes the submission of data summaries for more than 11,000 human health studies during the course of the High Production Volume Chemical Challenge program.

*Question 2.* Mr. Walls, in a recent congressional staff briefing, GAO stated that the ACC doesn't disagree with the GAO 2005 report. Is that true?

Response. ACC does not agree with GAO's statement. Approximately a year ago GAO asked our reaction to a recommendation that EPA work to share confidential information with other Governments. While we indicated that we would certainly support a discussion of that recommendation, we did not discuss whether that change should be made in a statutory change or some other administrative change. Moreover, we noted that this change was not a sufficient reason to open TSCA to amendment, but we agreed that there were situations in which an ability to share information could be beneficial.

In its July 2005 report, GAO made seven specific recommendations related to TSCA. The GAO recommendations focus on efforts to improve EPA's ability to assess the health and environmental risks of chemicals and to improve EPA's management of its chemical review program. Again, GAO did not recommend wholesale changes to TSCA nor did it suggest that other regulatory systems, such as the European Union's REACH system, should be considered.

Three of the seven recommendations were matters for Congressional consideration. The first recommendation was to provide explicit authority for EPA to enter into enforceable consent agreements. ACC believes that the Agency and companies should have the ability to negotiate consent agreements—and that EPA already has the authority to negotiate those agreements. In its response to GAO, EPA noted that an amendment was not necessary for enforceable consent agreements.

The second recommendation was to provide EPA additional authority to require manufacturers to develop test data based on substantial volume and the necessity for testing. ACC believes that TSCA already provides EPA with sufficient authority to require testing under Section 4 and that additional authority beyond section 4 is not necessary.

The third recommendation for Congressional consideration was to authorize EPA to share with states and foreign Governments the confidential information that chemical companies provide to EPA, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties. ACC recognizes the potential benefit that could be achieved in sharing relevant risk assessment information among the states and foreign Governments. We strongly believe that any Government groups accepting CBI from EPA must provide the same level of protection to the information as EPA does. In addition, we are concerned about whether the U.S. Government would have jurisdiction to police or penalize those Governments that allow confidential information to be released. Sharing CBI among the states and/or other foreign Government is of interest to ACC, but we do not believe it is sufficient to re-open the statute for change.

The remaining four recommendations are focused on EPA implementation. They include the following:

1. Development and implementation of a methodology to use HPV information for further review: This was always the goal of the HPV program. We understand that EPA will be using the screening process developed under the auspices of the National Pollution Prevention and Toxic Advisory Committee. We fully support EPA's efforts to do so.

2. Issue a Section 8 test rule to require companies to submit to EPA copies of all studies and other information submitted to other Governments: Neither ACC nor EPA believe that such a test rule is necessary. In its response to the report, EPA recommended that "other more targeted approaches for collecting information which are directed at EPA's domestic priorities, rather than foreign Government mandates, may be more prudent." EPA has also indicated that such information could be obtained by voluntary actions and that consideration of Paperwork Reduction Act issues would impact Section 8 rulemakings. ACC agrees with these EPA positions.

3. Develop a strategy for improving and validating models that EPA uses: ACC endorses efforts to enhance the usefulness of EPA's models, and we believe that the Agency has already taken action to validate and improve its models.

4. Require companies to re-assert claims of confidentiality: ACC believes that re-assertion of confidentiality claims for all information submitted under TSCA would be extraordinarily costly and ineffective. ACC acknowledges that there may be circumstances in which some information originally claimed as confidential in a new chemical notification may not need such protection after several years on the market. However, requiring industry to reassert confidentiality claims would impose additional, unnecessary costs on industry. It is also unclear whether EPA would be able to accommodate the “declassification” of confidential information in its database.

I note that TSCA requires EPA to disclose information if it is necessary to protect health and the environment against an unreasonable risk of injury, and the statute requires manufacturers to share information with EPA about adverse effects from chemical exposures. There are established processes for EPA to seek the disclosure of CBI, including the possibility that EPA can simply ask the owner of the information for permission to release it. Congress struck an important balance in TSCA between the public right to know and sensitive business information.

This is also a subject that has been discussed with EPA’s toxic advisory committee (National Pollution Prevention and Toxic Advisory Committee), and a pilot project is currently looking at what opportunities might exist to address the issue of legitimate but perhaps “stale” CBI claims.

*Question 3.* Some claim that TSCA actually serves as a barrier to the introduction of newer, safer chemicals. Is this actually the case?

Response. ACC understands that some—notably Dr. Michael Wilson, in his testimony to the Committee—argue that TSCA’s failure to impose substantial data requirements on all existing chemicals discourages innovations in green chemistry. This argument is supported more by speculation than facts. The fact is that more new chemical notifications are filed in the United States than in any other country, and that those new chemicals are the basis for replacing older existing chemicals. As I noted in the response to Question 1, TSCA promotes innovation in chemistry. In fact, the proportion of chemicals reported on the TSCA Inventory Update Rule that have been through EPA’s new chemicals notification process continues to grow every year—reflecting the maturation of markets as new chemicals gain acceptance and are seen as effective replacements for other already established chemicals.

In our view, Government cannot dictate in statute or regulation precisely how the process for innovation and collaboration should occur. The fact that TSCA does not explicitly address “green chemistry” is not surprising, nor is it important. Green chemistry initiatives have existed within EPA and the industry for years, without mention of this concept in TSCA. The chemical industry is highly competitive, and of necessity is responsive to customer, market and legal demands. TSCA helps the industry be responsive by promoting innovation in both the industry’s products and the processes in which chemicals are made and used.

*Question 4.* There seems to be some confusion about the number of chemicals actually in commerce. From some stakeholders we hear there are 50,000, 60,000, even 100,000 chemicals in commerce! We are told the number is really closer to 9,000. Which is it?

Response. We hear these inflated numbers all the time. In fact, the larger numbers reflect the number of chemicals that are on the TSCA Inventory, which is a historical database of all chemicals that were entered into the system in 1979, plus all new chemicals added to the inventory following review by EPA since then. The number of chemicals actually in commerce is closer to 9,000. According to EPA figures, over the past four Inventory Update Rules there have been an average of about 9,000 non-polymeric chemicals in commerce in quantities of more than 10,000 lbs/year. As the chemical industry has demonstrated through the High Production Volume (HPV) and Extended HPV programs, hazard data has been provided to EPA for some 93 percent of the chemicals in commerce by volume—and our industry continues to work with EPA as that data is used to prioritize EPA’s activities.

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RESPONSE BY MICHAEL P. WALLS TO AN ADDITIONAL QUESTION  
FROM SENATOR JEFFORDS

*Question 1.* Mr. Walls, do you believe that the chemical industry would expend fewer resources if the EPA evaluated new chemicals on a premarketing basis as opposed to a premanufacturing basis?

Response. The U.S. system for pre-manufacture review of new chemical substances has spurred innovation, and has helped make the United States a leader in bringing new products to market. According to one study conducted for the

OECD, in the United States an average of 425 non-polymeric substances are notified in the United States each year, compared to 143 in Europe. Over the years EPA's Office of Pollution Prevention and Toxic Substances (OPPT) has developed programs and processes to evaluate new chemical notifications with data and other information, using tools and models that ultimately make the process easier, less expensive, and more efficient in terms of market entry and animal welfare. Conversely, the EU's pre-market system with fixed data requirements has led to markedly fewer new chemical notifications, and at significantly greater expense. We believe that the efficiencies created by the U.S. pre-manufacture system, together with the flexible and tiered approaches to data requirements, actually spur innovation and therefore generally result in the introduction of newer and greener products faster than in other economies.

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RESPONSES BY MICHAEL P. WALLS TO ADDITIONAL QUESTIONS  
FROM SENATOR BOXER

INADEQUACY OF TSCA'S TESTING REQUIREMENTS

*Question 1.* Mr. Walls, just this year, a National Academies of Sciences report concluded, "TSCA authorized EPA to review existing chemicals, but toxicity and exposure information on them is typically so incomplete that it does not support the review process. EPA can require testing if it determines that a chemical meets a specific set of criteria; however in vitro and whole-animal tests are rarely required. Thus, the basis for establishing priorities and requiring testing for industrial chemicals in the United States has not progressed much over the last 20 years."

Yet, you have testified today that, "TSCA's framework is flexible enough to meet new scientific questions that might be raised about the impact of chemicals on health."

Do you think that, in fact, a decades old testing system raises some concerns about TSCA's ability to protect public health?

Response. The National Academy of Sciences report<sup>1</sup> referred to in this question did not fully consider all programmatic aspects of TSCA. TSCA is not just a testing statute. Congress enacted TSCA with an even broader goal of preventing unreasonable risks of injury to health or the environment associated with the manufacture and use of chemical. And yes, we believe that as a statutory framework, Congress got it right. In fact, Congress was remarkably prescient in providing EPA with a strong yet dynamic framework which includes a range of tools that can be adapted as science and our understanding of health and environmental risks evolve. This is evident in EPA's ability to develop and disseminate the guidelines for conducting both animal and non-animal testing as we better understand mechanisms of action and refine our assumptions. And this is evident in TSCA's ability to manage new types of chemistries, including the products of nanotechnologies.

Unlike media or product specific statutes, TSCA is largely a collection of tools. These tools—the authorities to compel action by the regulated community, and the power to act when necessary—are entrusted to the Office of Pollution Prevention and Toxics. ACC and others have from time to time expressed views on whether or not OPPT is appropriately or effectively utilizing those tools. We are therefore impressed that OPPT has formed a Federal Advisory Committee (the National Pollution Prevention and Toxics Advisory Committee) to receive input and advice on its implementation of TSCA. Following a period of extensive input and stakeholder consultation, in February 2005 the NPPTAC made detailed recommendations to EPA on how it should manage and evaluate the wealth of health, safety and environmental information provided to the Agency under the HPV Challenge Program. As you have heard, OPPT is making important strides in this regard, and we believe they are to be congratulated.

Furthermore, as envisioned under the voluntary HPV Challenge program, the collection and public dissemination of hazard data for high production chemicals was never meant to be the final step in either company product stewardship or EPA's regulatory oversight. In the NAS report, the efforts of the NPPTAC were not considered; most likely because the NAS committee deliberations were occurring simultaneous with the discussions of the NPPTAC which led to development of NPPTC's "HPV Chemical Screening Process"<sup>2</sup> The OPPT, using the NPPTAC screening rec-

<sup>1</sup>Toxicity Testing for Assessment of Environmental Agents: Interim Report (2006).

<sup>2</sup> National Pollution Prevention and Toxics Advisory Committee (NPPTAC) recommendations for a High Production Volume (HPV) Chemical Screening Process (2005)

ommendation, will formally evaluate the data submissions on all of the data submitted for HPV sponsored chemicals; each completed submission contains data on 18 internationally agreed “SIDS”(Screening Information Data Set) endpoints that are used as screening-level indicators of potential hazardous effect (toxicity) for humans or the environment, as well as environmental fate. In those cases where an evaluation raises specific questions, or suggests a need for further inquiry, there are a range of follow-up actions available to OPPT that would support voluntary or regulatory hazard communication and risk management activities. These could include gathering additional information on uses and exposures, gathering additional information on potential hazards to support a more in-depth characterization, evaluating adequacy of existing risk management programs and practices including Federal and State regulatory controls, etc.

Indeed, the tiered testing and assessment framework of the HPV Challenge illustrates a critical strength of TSCA—a robust and flexible approach that allows EPA to focus attention and resources on the substances that pose greatest concern from the perspective of potential risk to human health and threats to the environment. The standard battery of TSCA HPV tests is both relevant and important to assessing potential health hazards. Results from these tests can and are being used to decide what specific, additional toxicity tests are scientifically warranted, and necessary to more completely understand specific organ-system hazards, and to more fully characterize the dose response relationship. The HPV Challenge program has shown that a one-size-fits all, single tier test battery would be wasteful of laboratory animals, costly, inefficient and not scientifically justifiable. Indeed, support for the type of tiered testing and evaluation processes embodied in the HPV and VCCEP efforts are endorsed by the National Academy Committee, as stated in their 2006 report:

Existing test strategies include test batteries, tiered-testing strategies, tailored approaches, and strategies that combine various approaches. The committee finds that there are pros and cons of various approaches but leans toward tiered testing with the goal of focusing resources on the evaluation of the more sensitive adverse effects of exposures of greatest concern rather than full characterization of all adverse effects irrespective of relevance for risk-assessment needs.<sup>3</sup>

#### INADEQUACY OF VOLUNTARY CHILDREN’S CHEMICAL EVALUATION PROGRAM

*Question 2.* Mr. Walls, the American Chemistry Council has some member companies, such as Bayer and BP, which participate on both the EPA’s Children’s Health Protection Advisory Committee and the Agency’s Voluntary Children’s Chemical Evaluation Program. Other members participate on the Voluntary Children’s Chemical Evaluation Program, such as Monsanto and Proctor and Gamble.

On June 30, 2006, the EPA’s Children’s Health Protection Advisory Committee wrote a letter to the Agency saying that the Committee had “strong concerns with [the program’s] structure and implementation.”

The primary goal of the program is to ensure publicly available data on the risks to children’s health from toxic chemicals. The Children’s Committee said that the “program, as implemented, however, is not on track to fulfilling its stated goal.” The Committee discussed problems with the lack of adequate peer review process, industry selection of the reviewers and industry production of key documents without EPA oversight.

While the committee is sounding the alarm about the program’s deficiencies, you have testified, “The program is proceeding well. . . .” and that “ACC believes this pilot program has been very successful. . . .”

Do you think that EPA should listen to its Children’s Health Committee and correct the problems highlighted with the program?

Response. ACC was involved in the multi-stakeholder development of the VCCEP pilot program from its inception, as were members of the environmental community (including Environmental Defense (ED)), the animal welfare community and EPA. EPA launched the program, building on the success of the HPV voluntary challenge program. The pilot was designed to test out a tiered, integrated hazard and exposure evaluation of chemicals, as opposed to a hazard only assessment. This approach was chosen since children’s exposures to chemicals are probably more deterministic of their risks than are the inherent hazards of the chemicals, because their exposures can be unique to their behaviors. The goal of the program was to determine whether health risks to children from exposures to chemicals could be adequately characterized—and to answer that question more effectively than a hazard-only,

<sup>3</sup>National Pollution Prevention and Toxics Advisory Committee (NPPTAC) recommendations for a High Production Volume (HPV) Chemical Screening Process (2005)



animal intensive, one-size-fits-all testing program could do. It's important to recognize the innovative nature of this evaluation approach. ACC believes the program has met its objective and has shown that a hazard based "data gap" is not necessarily a "data need." Devoting resources to "data gaps," irrespective of whether the specific information is actually needed (that is, necessary to characterize children's risks with an adequate degree of scientific certainty), would be wasteful of laboratory animals, costly, inefficient and not scientifically justifiable.

The pilot has clearly shown that the tiered evaluation process, in which hazard information is integrated with exposure information, provides a strong scientific basis for deciding whether children's risks have been adequately characterized, and if not, this approach indicates which specific toxicity tests or additional exposure data/information is needed to address this critical question. A recent publication in the scientific literature illustrates the accomplishments to date of the VCCEP<sup>4</sup>. Under the pilot, chemical makers are providing extensive dossiers of both hazard and exposure information on 20 chemicals identified by EPA. This information is rigorously reviewed by an independent panel of scientists (peer consultation) and then EPA makes the ultimate decision—based on the peer consultation panel's report and its own review of all the information—whether additional testing or data is needed to characterize risks to children.

EPA has not yet begun its planned mid-course evaluation of VCCEP, but when it does, ACC will participate openly in that process. ACC will identify both the successes of the pilot as well as the areas where improvements could be made to the pilot.

ACC's suggestions will focus more on how to make the pilot more efficient, not how to build a whole new program with wholly different objectives. It's important to be careful at this midpoint stage to maintain the resolve of the volunteer sponsors to continue in the program. Industry has lived up to its extensive commitments under this program. A two year, multi-stakeholder process created this pilot, and it is now only mid way through to completion. Although the VCCEP program has not moved as quickly as we might have hoped, the pilot has been an excellent test of tiered approaches to chemical evaluation, integrating hazard and exposure information, and of the contributions of independent scientists to EPA's own assessment of data needs.

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STATEMENT OF WILLIAM K. RAWSON, PARTNER AND CHAIR OF THE ENVIRONMENT,  
LAND AND RESOURCES DEPARTMENT, LATHAM AND WATKINS

Mr. Chairman, distinguished members of the Committee and staff—good morning. I would like to begin by thanking the Committee for inviting me to testify today. I consider it a privilege to have this opportunity to contribute to the public discourse on the Toxic Substances Control Act (TSCA). This is an important subject, and I hope that my comments will prove useful to the Committee.

I am a partner in the law firm of Latham & Watkins and chair its environmental practice in Washington, DC. I have been with the firm since 1982, and have practiced in the environmental area, with an emphasis on chemical regulation under TSCA and other environmental statutes, since 1987. I have co-authored a TSCA Deskbook published by the Environmental Law Institute, and have been involved in numerous rulemaking proceedings arising under various sections of TSCA. My testimony is based on my experience representing and counseling companies and trade associations on issues arising under TSCA and other chemical regulation statutes over the last 19 years. However, the views I will express today are solely my own.

TSCA section 2 states that it is the policy of the United States that:

- (1) Adequate data should be developed with respect the effect of chemical substances and mixtures on health and the environment;
- (2) Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment; and
- (3) Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

The question before the Committee today is whether the provisions of TSCA give EPA the authority it needs to achieve these objectives. I believe the answer is "yes."

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<sup>4</sup>P.R.D. Williams, J. Patterson and D.W. Briggs, VCCEP Pilot: Progress on Evaluating Children's Risk and Data Needs. Risk Analysis 26: 781- 799 (2006).

In my judgment, TSCA is a well-crafted statute that has stood the test of time quite well.

#### SCOPE OF TESTIMONY

My testimony will focus on three sections of the statute:

- Section 5 pertaining to review, testing and control of new chemicals;
- Section 4 pertaining to the testing of existing chemicals; and
- Section 6 pertaining to the regulation of existing chemicals.

I will discuss whether the statutory language in each section is appropriate and sufficient to enable EPA to perform its functions under the Act. There are a number of issues concerning how EPA has implemented each of these sections of TSCA; for the most part, I will not discuss those implementation issues, except insofar as they are relevant to assessing the adequacy of the statutory language. I do believe EPA could improve its performance under TSCA by addressing some of the implementation issues.

Also, it is important to understand that TSCA does not stand alone, and actions taken by EPA under TSCA represent only a small part of the total chemical management story in the United States. EPA regulates the use, release and disposal of chemical substances under many other environmental statutes. Other Federal agencies, including OSHA, FDA and CPSC, also have substantial responsibility for ensuring the safe manufacture and use of chemicals under their respective statutory authorities.

Additionally, chemical manufacturers have adopted voluntary initiatives and product stewardship programs to support the safe manufacture and use of their products. Many of the industry's voluntary initiatives have been undertaken in collaboration with EPA and other stakeholders. Again, I will focus primarily on the language of the statute, and defer to others to address the voluntary initiatives and product stewardship efforts that help meet the objectives of TSCA.

This testimony assumes the reader is generally familiar with the provisions of TSCA and EPA's principal accomplishments under each section, as much of that information has been provided elsewhere.

Finally, I would like to express strong appreciation for EPA's mission. I have worked closely with many EPA managers and staff over the years on numerous challenging issues, and have great respect for their efforts in support of EPA's mission.

#### SECTION 5: NEW CHEMICALS

The strength of section 5 of TSCA lies in its flexibility. The provisions of section 5 recognize implicitly that industrial chemicals are not all alike; some are readily determined to have low toxicity and to be relatively innocuous, while others present significant toxicity concerns that require close scrutiny before commercial manufacture is allowed to commence. Section 5 gives EPA flexibility to vary its assessments of new chemicals according to the attributes and expected uses of each substance. In this way, EPA is able to ensure that the introduction of new chemicals into commerce does not pose unreasonable risks, without imposing undue economic burdens or unnecessary barriers to innovation.

Many new chemicals qualify for complete or partial exemptions from the premanufacture notice (PMN) requirements. Section 5 expressly authorizes exemptions for substances manufactured or processed only in small quantities solely for R&D, for substances manufactured or processed for test marketing purposes, and for non-isolated intermediates. Section 5(h)(4) also authorizes EPA to promulgate rules exempting other categories of new chemical substances from all or part of the PMN requirements, if the Agency has determined that the substances "will not present an unreasonable risk of injury to health or the environment."

EPA has used this authority to create additional partial exemptions for polymers, chemicals that will be produced only in low volumes, and chemicals for which the manufacturer is able to demonstrate low release and exposure. EPA also has created exemptions for certain categories of chemicals that are produced but have no separate commercial purpose, such as impurities. Thus, section 5 gives EPA authority to streamline the new chemical review process for categories of chemicals that can be determined upfront not to pose unreasonable risks to health or the environment. In this way, section 5 promotes the efficient use of EPA resources, and also avoids imposing unnecessary burdens on industry.

Some new chemical substances do not qualify for an exemption, but can readily be determined to pose little or no risk to health or the environment based on information provided with the PMN, use of EPA models, and comparison to other previously approved substances (using a methodology known as structure activity rela-

tionship, or SAR). In fact, according to EPA officials, the majority of new chemicals submitted for review can be screened out as not requiring further review based on screening models that show low potential for toxicity, or based on other information (anticipated uses, potential for releases and exposures) demonstrating low potential risks.<sup>1</sup> Again, section 5 allows EPA the flexibility to make these judgments, and to adjust the new chemical review process accordingly.

Many new chemical substances, however, do require close scrutiny before they enter commerce. With regard to these substances, some stakeholders have expressed a concern that there is no minimum base set of tests that must be submitted with the PMN, to facilitate EPA review. However, section 5 effectively gives EPA the authority to require the PMN submitter to conduct the testing that EPA deems necessary in each case to support a determination whether the manufacture or use of the PMN substance will pose unreasonable risks. Thus, additional authority is not necessary.

Specifically, section 5(e) gives EPA authority to prohibit or limit the manufacture and use of any new chemical substance where: (1) existing information is insufficient to permit a "reasoned evaluation" of the substance's health and environmental effects; and (2) either the substance may present an unreasonable risk of injury to health or the environment, or the substance will be produced in substantial quantities and there will or may be substantial human or environmental exposure. EPA has used its authority under section 5(e) to require testing of numerous PMN substances. EPA also has developed a guidance document that identifies numerous chemical categories of concern, and identifies the type of test data that typically will be required for a PMN substance in each category.

In some cases, the PMN submitter has agreed to conduct the testing during the PMN review process (by also agreeing to suspend the statutory PMN review period during the conduct of the testing). In other cases, the testing requirements have been incorporated into a consent order issued under section 5(e). In either event, EPA has received the information that it has deemed necessary to assess the potential risks associated with the new chemical.

Additionally, EPA has authority under section 5(a) of TSCA to promulgate a significant new use rule (SNUR) for a PMN substance, and thereby to require a company to submit a significant new use notice (SNUN) to EPA before engaging in uses identified in the SNUR. SNUNs operate much like PMNs; they enable EPA to evaluate new uses of a chemical substance before they are undertaken and decide whether such uses should be subject to special regulations. EPA has used its SNUR authority to codify the restrictions in section 5(e) orders so they apply to subsequent manufacturers of the chemical, and also to control the uses of existing, TSCA inventory-listed chemicals that raise concern.

EPA's relatively recent use of SNURs in connection with the voluntary phase-out of perfluoroalkyl sulfonate (PFAS) substances is a good example of how EPA can use a SNUR to address hazards associated with an inventory-listed substance. In May 2000, the sole U.S. manufacturer of perfluorooctanyl sulfonate (PFOS) announced it would voluntarily withdraw production. The phase-out was completed in 2002. Following this, the EPA issued a SNUR in March 2002 limiting any new manufacturing or importing of 13 PFAS chemicals that were being produced by 3M.<sup>2</sup> In December 2002, the EPA issued a second SNUR adding 75 additional chemicals, but excluding "low volume, controlled exposure uses in: semiconductor manufacture, aviation hydraulics, and photography."<sup>3</sup> Thus, through close cooperation with industry and use of its authority under section 5(a)(2), the EPA was able to extend the voluntary phase-out by the sole manufacturer to all prospective producers and importers of the subject compounds.

Also, under section 5(f) of TSCA, if EPA determines a new chemical substance "presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 2605 [section 6] of this title can pro-

<sup>1</sup>GAO, Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program, at 12 (June 2005) [hereinafter GAO Report].

<sup>2</sup>67 Fed. Reg. 11,014, 11,020 (Mar. 11, 2002) (Perfluoroalkyl Sulfonates. Proposed Significant New Use Rule) ("EPA determined that the proposed SNUR should be promulgated as final for the 13 chemicals, employed principally in coatings for textiles, carpet, apparel, leather, and paper, on which no comments were received and which 3M, the sole manufacturer, confirmed were discontinued from manufacture before Dec. 31, 2000."). In the original proposed SNUR, these chemicals were referred to collectively as perfluorooctylsulfonates, or PFOS, but commenters noted that this generic usage of the term PFOS was inconsistent with the use by the manufacturer of PFOS to refer only to chemicals with an eight-carbon, or C8, chain length.

<sup>3</sup>Battelle, Overview: Office of Pollution Prevention and Toxics Programs, at 18-19 (Dec. 24, 2003) [hereinafter Battelle Report]; see also 67 Fed. Reg. 72,854, 72,859 (Dec. 9, 2002) (Perfluoroalkyl Sulfonates; Significant New Use Rule).

tect against such risk,” the Agency may issue a proposed rule under TSCA section 6(a) that is effective upon its publication in the Federal Register, or alternatively may issue an order or may apply for an injunction in Federal court to prohibit the manufacture, processing, or distribution in commerce of the substance.

As of September 30, 2002, EPA had taken the following actions:

- Issued 1243 section 5(e) orders (500 with SNURs, and 743 without);
- Promulgated an additional 437 non-section 5(e) SNURs; and
- Taken four actions under section 5(f).

Further, 1552 PMNs had been withdrawn in the face of impending EPA action. Thus, it is clear that EPA has exercised its authority under section 5. to give careful scrutiny to new chemical substances where appropriate. EPA in fact has imposed substantial controls or effectively prohibited the manufacture of more than 3200 chemical substances.<sup>4</sup>

It is noteworthy that under section 5(e)(1)(C), a PMN submitter may file objections with EPA to a proposed 5(e) order, and EPA is then forced to go to court to obtain an injunction to prohibit or limit the manufacture or use of the PMN substance (unless EPA determines that the objections have merit and alters or withdraws the proposed order). To my knowledge, no PMN submitter has ever forced EPA to go to court to obtain such an injunction. In other words, no PMN submitter has ever challenged a 5(e) order judicially; the PMN submitter has either complied or withdrawn the PMN. This means in every case EPA’s data requirements and control requirements have been met, or the PMN has been withdrawn.

PMN submitters have not always been pleased with EPA’s proposed testing requirements or control requirements. Some PMNs have been withdrawn because the PMN submitter did not agree with the proposed testing or control requirements, and the costs associated with those requirements rendered commercialization impractical. But there has never been a legal challenge. Thus, while there may be issues around the edges pertaining to how EPA has implemented section 5 of TSCA, there does not appear to be any basis for arguing that EPA lacks authority to assess or regulate new chemical substances. To the contrary, the provisions of section 5 appear well-designed to give EPA the necessary flexibility and discretion to give each PMN substance the level of scrutiny it merits, and to impose such restrictions on manufacture and use as are necessary to prevent unreasonable risks to health and the environment.

#### SECTION 4: TESTING OF EXISTING CHEMICALS

TSCA section 4 provides EPA with authority to impose health and environmental effects testing requirements on chemical manufacturers and processors. EPA has authority to require testing of existing chemicals under two circumstances: when a chemical “may present an unreasonable risk” (the 4(a)(1)(A) or “A” finding), or when a chemical “is or will be produced in substantial quantities” and either “enters or may reasonably be anticipated to enter the environment in substantial quantities,” or “there is or may be significant or substantial human exposure” (the 4(a)(1)(B) or “B” finding). In each case, EPA also must show that (i) there is insufficient data or experience to determine whether manufacture and use pose unreasonable risks to health or the environment, and (ii) testing is necessary to develop this data. Over the years, EPA has made significant progress in developing testing programs for existing chemicals and has issued detailed regulations governing development of test rules, negotiation of enforceable testing consent agreements, and compliance with testing requirements under test rules and consent orders.

EPA has obtained test data for more than 200 substances under TSCA section 4 test rules or enforceable consent agreements. Many more chemicals have been screened for testing and determined by EPA or the Interagency Testing Committee (ITC) to be low priority for testing or not to require further testing, and testing of many more substances has occurred on a voluntary basis without the need for a test rule. The High Production Volume Challenge Program, which involved more than 2100 substances, is certainly a noteworthy example of a voluntary testing initiative, but many individual substances also have been the subject of voluntary testing that has made action under section 4 of TSCA unnecessary.

There has been some suggestion that the findings required by section 4 of TSCA are overly burdensome on EPA, and render section 4 an ineffective vehicle for obtaining test data.<sup>5</sup> I find these arguments unpersuasive. The burden of proof that

<sup>4</sup>Battelle Report, supra n.3, at 11.

<sup>5</sup>GAO Report, supra n.1, at 26.

EPA must meet to support a test rule in fact is quite modest under both the “A” finding and the “B” finding.

As already described, the statute only requires EPA to show that a substance may present an unreasonable risk, or may reasonably be anticipated to enter the environment in substantial quantities, or that there is or may be significant or substantial human exposure. When evaluating “unreasonable risk” under section 4, the EPA has stated that its determination of whether a chemical “may present” a hazard would not be based on definitive scientific data, but of necessity would involve reasonable scientific assumptions, extrapolations and interpolations.

The EPA has also stated that it is sufficient to show that exposure may arise because of activities associated with the manufacture, use, etc. of the chemical. The DC Circuit Court of Appeals endorsed the Agency’s contention that the mere potential for human exposure is sufficient to support a “may present an unreasonable risk” finding under section 4.<sup>6</sup> The minimum burden that the court required was that the EPA show the risk is “a more-than-theoretical probability,” and the court said that EPA may demonstrate the potential for exposure based on circumstantial evidence.<sup>7</sup> Once the EPA has established this “more-than-theoretical probability,” the burden shifts to industry to rebut this by presenting evidence to the contrary.

In 1990, industry challenged the cumene test rule which was based on a “B” finding. The Fifth Circuit found the EPA’s explanation of the basis for its “B” finding inadequate and remanded.<sup>8</sup> On remand, EPA released the B Policy<sup>9</sup> and applied it to the test rule that had been challenged. No further legal challenge was pursued. (The court had declined to stay testing, so testing had in fact already been completed.) The B Policy establishes standards and criteria for making “B” findings. EPA defined substantial production as one million pounds or more per year. EPA defined “substantial” human exposure differently for three classes of people: workers (1,000 people), consumers (10,000 people), or the general population (100,000 people). EPA defined “significant” human exposure in terms of the nature of the exposure (i.e., if the exposure is more direct than typical exposure. Since then, these criteria have proven relatively easy to apply).

I do not agree with the suggestion that EPA should be permitted to require testing based solely on a production volume trigger and a determination that testing is necessary.<sup>10</sup> Such an approach would effectively negate consideration of potential exposure.<sup>11</sup> EPA’s B Policy expressly recognizes that “level, frequency, and duration of exposure” to a chemical should always be considered when determining the sufficiency of existing data and the necessity of additional testing.<sup>12</sup> Eliminating consideration of the potential for human or environmental exposure would make it marginally easier for EPA to promulgate test rules, but it would not provide a more scientifically sound basis for making testing decisions. Such a change also would not be consistent with EPA’s current policies and practices under TSCA section 4.

I do believe EPA could improve its performance under TSCA section 4 in a number of ways. EPA has issued few test rules in recent years (perhaps because substantial resources have been devoted to the HPV Challenge Program), and some testing proposals have languished unfinished for many years. Some suggestions for improvement include:

*More timely responses to industry alternative testing proposals.* I have worked with numerous chemical industry groups that have submitted alternative testing proposals to EPA in response to testing proposals issued under TSCA section 4. The testing proposals have been intended to meet EPA’s objectives in a more cost-effective manner, sometimes by making greater use of existing studies. EPA has sometimes taken as much as two years to respond to such proposals. More timely responses would help improve EPA’s track record under section 4.

*More flexibility in testing approaches.* Perhaps because of the time and expense associated with the development of proposed test rules, EPA at times has not seemed open to alternative approaches. I have worked with chemical industry groups that have proposed that EPA permit testing to proceed in phases, such that the companies would conduct a portion of the proposed testing initially, and then ask EPA to reconsider, based on the results of the initial testing, whether the bal-

<sup>6</sup>Chem. Mfrs. Ass’n v. EPA, 859 F.2d 977 (DC Cir. 1988).

<sup>7</sup>Id at 984-88.

<sup>8</sup>Chem. Mfrs. Ass’n v. EPA, 899 F.2d 344 (5th Cir. 1990).

<sup>9</sup>EPA, TSCA Section 4(a)(1)(B) Final Statement of Policy: Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure, 58 Fed. Reg. 28,736 (May 14, 1993) [hereinafter, “B Policy”].

<sup>10</sup>GAO Report, supra n.1, at 27.

<sup>11</sup>EPA has recognized on many occasions that production volume is not a surrogate for exposure or even potential exposure.

<sup>12</sup>B Policy, supra n. 9, at 28,742.

ance of the proposed testing was still necessary. These proposals have all been rejected (sometimes after an extended period of delay). In these cases, I believe more flexibility on the part of the Agency would have allowed testing on the subject chemicals to commence in a reasonable and cost-effective manner, without compromising the Agency's ability to obtain the test data that it deemed necessary.

I believe following the foregoing suggestions would lead to better testing decisions, and would improve EPA's track record under section 4. However, I do not believe the statutory criteria need to be modified. I believe the criteria in the statute provide a sound basis for making scientifically appropriate testing decisions.

There have been very few legal challenges to test rules promulgated under section 4. Indeed, there has been relatively little litigation under TSCA generally, especially compared to the steady drumbeat of litigation under other environmental statutes, such as the Clean Air Act. The few legal challenges under TSCA section 4 have generally affirmed EPA's broad authority to require testing.

#### SECTION 6: REGULATION OF EXISTING CHEMICALS

Section 6(a) of TSCA gives EPA authority to regulate the manufacture, processing, distribution, use or disposal of a chemical if the Agency has a "reasonable basis" to believe the chemical "presents or will present an unreasonable risk to health or the environment." Section 6 enumerates various regulatory options—from an outright ban to warning and labeling requirements—and provides that EPA may impose one or more of the enumerated requirements "to the extent necessary to protect adequately against such risk using the least burdensome requirements" (emphasis added).

When promulgating rules under section 6, EPA must take into account the health and environmental effects of the substance, the magnitude of exposure, the benefits of the substance, the availability of substitutes, and the reasonably ascertainable economic consequences of the proposed rule. A rule promulgated under section 6 must be supported by "substantial evidence" in the rulemaking record considered as a whole. Before EPA can regulate under section 6(a), the Agency also must determine whether the problem could be better addressed by EPA or another agency under another statute.

EPA's ability to regulate effectively under TSCA section 6 has been called into question over the years because of the Fifth Circuit's decision in *Corrosion Proof Fittings v. EPA*,<sup>13</sup> which overturned a ban on certain asbestos-containing products. If EPA cannot ban asbestos, the argument goes, then what can it ban? The Government Accountability Office (GAO) has suggested ways that the legal requirements of section 6 might be loosened, ostensibly to make EPA's job easier.<sup>14</sup> However, as will be demonstrated below, the failures in the asbestos rulemaking were failures in implementation, and not caused by deficiencies in the statute.

EPA regulated several substances under section 6(a) during the early years of TSCA. Starting in 1978, EPA used section 6(a) to ban nonessential uses of fully halogenated chlorofluoroalkanes, which were used primarily as propellants for aerosols. In 1980, EPA issued a rule regulating disposal of wastes containing TCDD, a form of dioxin. In 1990, EPA issued a final rule prohibiting the use of hexavalent chromium-based water treatment chemicals in comfort cooling towers. In 1984, EPA issued three immediately effective proposed rules under section 6(a) to address unreasonable risks identified during the review of PMNs. The three chemical substances affected by the rules were intended for use in metalworking fluids, and EPA was concerned that the addition of certain nitrosating agents could lead to the formation of a substance shown to be carcinogenic in animals. Accordingly, EPA banned the use of nitrosating agents in metalworking fluids containing the PMN substances. EPA used its authority under section 5(0)(2) to make the proposed rules under section 6(a) effective immediately.

EPA was not as successful with its attempt to regulate asbestos. EPA's asbestos rule under section 6 was promulgated in 1989 and banned most uses of asbestos still in commerce, including asbestos-containing floor materials, clothing, roofing and other building materials, pipeline wrap, friction products (e.g. brakes), and other automotive products. EPA also banned all new uses of asbestos, and all existing uses that were not currently in production in the United States.

In handing down its decision in *Corrosion Proof Fittings*, the court upheld EPA's determination to proceed under section 6, instead of deferring to other Federal agencies under TSCA section 9. The court also upheld EPA's ban on products not being produced in the United States currently, and the ban on unknown, future uses of

<sup>13</sup>947 F.2d 1201 (5th Cir. 1991).

<sup>14</sup>GAO Report, *supra* n.1, at 34.

asbestos. Concerning the bans on existing asbestos-containing products, the court articulated a “presumption of validity” in favor of EPA’s rule, and rejected a number of arguments advanced by industry petitioners challenging the bans. However, the court found such fundamental errors in EPA’s methodology and rationale for banning asbestos-containing products that all product-specific bans were struck down in their entirety. The asbestos rule and the court’s decision are described more fully in an attachment to this testimony. A few of the Agency’s errors are highlighted in the following paragraphs.

*Inadequate notice of a key element of EPA’s analysis.* EPA used “analogous exposure” data—exposure data obtained under comparable circumstances to the circumstances being addressed—to calculate expected benefits of the asbestos bans. The court found that for some products, use of the analogous exposure estimates constituted the bulk of EPA’s analysis,<sup>15</sup> and in some cases the analogous exposure analysis “completely altered the EPA’s calculus and multiplied four- or five-fold the anticipated benefits.”<sup>16</sup> Yet EPA did not disclose that it was relying on “analogous exposure” data until after the hearings were closed.

*Failure to justify not pursuing less burdensome alternatives.* The Court found EPA gave inadequate consideration of less burdensome alternatives. EPA did give some consideration to labeling asbestos products and stricter workplace rules. However, the court found EPA’s analysis inadequate, because EPA “rejected calculating how many lives a less burdensome regulation would save, and at what cost.”<sup>17</sup> EPA failed to consider adequately the less burdensome options because it believed there was no level of asbestos exposure that would pose zero risk. However, as the court correctly noted, “Reducing risk to zero. . . was not the task that Congress set for the EPA in enacting TSCA.”<sup>18</sup> EPA misconstrued its authority under section 6—aiming for zero risk instead of eliminating “unreasonable risk”—and as a result failed to address adequately the statutory requirement that it employ the least burdensome alternative necessary to protect against unreasonable risks.

The court’s opinion should not be construed to require a quantitative assessment of the costs and benefits of every regulatory option, starting with the least burdensome, in every section 6 rulemaking. In other successful section 6 rulemakings, EPA has considered and rejected less burdensome alternatives without undertaking such a quantitative analysis.

*Inflated Estimates of Benefits.* When calculating the workplace benefits of the bans, the court found that did not consider currently available control technologies that could have provided improved workplace conditions. Additionally, the court criticized EPA’s method of calculating the present value of future health benefits, which the court believed inflated potential health benefits from the product bans.

*Failure to Consider Harm From Use of Substitutes.* In the case of asbestos-containing friction products (primarily replacement drum and disk brakes),<sup>19</sup> which accounted for “the lion’s share of the proposed benefits of the asbestos regulation,” a study commissioned by EPA raised significant concerns about the effectiveness and potential health risks of substitute products. One of the study authors testified that the “replacement/substitution of asbestos-based with non-asbestos brake linings will produce grave risks,” and that “the expected increase of skid-related highway accidents and resultant traffic deaths would certainly be expected to overshadow any potential health-related benefits of fiber substitution.”<sup>20</sup> Further, many of the EPA’s own witnesses conceded on cross-examination that the non-asbestos fibrous substitutes would pose cancer risks upon inhalation. Ultimately, the court concluded that “a death is a death, whether occasioned by asbestos or by a toxic substitute product.”<sup>21</sup> EPA could not ignore the risks and possible toxic effects of the proposed substitutes for asbestos once the potential concerns were brought to the Agency’s attention.

Other equally significant errors are noted in the court’s opinion. It is apparent that the asbestos rule did not fail because of the requirements of section 6. As the court stated in its conclusion, EPA’s product-specific bans were rejected because of “the agency’s reliance upon flawed methodology and its failure to consider factors and alternatives that TSCA explicitly requires it to consider.” One gets the impression, from reading the opinion, that the court was deeply troubled by the number

<sup>15</sup>Corrosion Proof Fittings, 947 F.2d at 1212.

<sup>16</sup>Id. at 1213 n.11.

<sup>17</sup>Id. at 1216.

<sup>18</sup>Id. at 1217.

<sup>19</sup>Notably, the court’s opinion related to after-Market brakes and the difficulty of installing non-asbestos replacement brakes in vehicles designed to use asbestos brakes. At the time, most new cars were engineered for non-asbestos brakes.

<sup>20</sup>Id. at 1224 n.25 (citing written testimony).

<sup>21</sup>Id. at 1221.

of ways the reasoning in the final rule was skewed in favor of its proposed outcome, as reflected by the court's repeated references to "flawed methodology" and "cur-sory," "cavalier" and "meaningless" treatment of data. I say this not to be critical of EPA, but because it is important that the court's decision not be misunderstood.

The lesson that should be learned from Corrosion Proof Fittings is not that section 6 cannot work. The lesson is that no matter what the product, when acting under section 6, EPA must consider all relevant information, conduct proper procedures, and present a reasonable basis for its decision.

#### THE GAO RECOMMENDATIONS

*"Least Burdensome Requirements" test.* GAO has suggested that TSCA section 6 might be amended to eliminate the requirement to demonstrate that the regulatory option chosen is the "least burdensome requirement" necessary to address the identified health or environmental risks. However, before EPA bans the use of a product, it is not unreasonable to require the Agency to show that there is no less burdensome alternative that would be sufficient to protect human health and the environment. Stated differently, if there is a less burdensome alternative that would be adequately protective of human health and the environment, there would seem to be no justification for not using it, and no justification for banning a product that has proven to be valuable in commerce. Further, notwithstanding the result in Corrosion Proof Fittings, if EPA determines that a ban is the least burdensome requirement, the Agency should not be concerned that its judgments will be easily second-guessed by the courts. To the contrary, if regulations imposed under section 6 are based on consideration of the relevant factors, adequately explained and promulgated through proper procedures, they will receive deferential treatment by courts.<sup>22</sup> EPA made the "least burdensome requirement" determination successfully in each of its other section 6(a) final rules.

*"Unreasonable Risk" standard.* GAO also has suggested that section 6 might be amended to replace the requirement to demonstrate an "unreasonable risk" with a requirement to show a "significant risk." GAO indicates that finding "significant risk" would require EPA to show that the "risks are substantial or serious." Moving from "unreasonable" to "significant" risk, however, would be inconsistent with several other provisions of TSCA, which also use the phrase "unreasonable risk" and clearly reflect congressional intent that EPA consider health and environmental impacts and social and economic impacts when regulating under TSCA.<sup>23</sup> This congressional intent is stated explicitly in section 2(c): "[i]t is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter."<sup>24</sup>

The "unreasonable risk" standard requires a balancing of the nature of the potential harm being addressed, the probability of the harm occurring, and the harm that would result from the rule. Thus, full consideration is given to the nature of the potential adverse health or environmental effects being addressed, and the likelihood of that harm occurring. To suggest, however, that EPA might consider imposing a ban on valuable commercial products without any consideration of the potential social or economic impacts of the ban clearly is not consistent with congressional intent for how EPA should implement its authority under TSCA. The asbestos rule, in fact, demonstrates the importance of considering the potential impacts of any product ban, given that there was credible evidence, supported by an EPA-sponsored study and EPA witnesses, that the ban on asbestos brakes for after-market use could cost more lives than it was projected to save.

TSCA is by no means unusual in requiring EPA to consider potential social and economic impacts of its regulatory actions. For example, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires EPA to consider "any unreasonable risk to man or the environment" and take "into account the economic, social, and environmental costs and benefits of the use of any pesticide." Pesticides are subject to very rigorous scrutiny, perhaps more so than any other category of products, and

<sup>22</sup>Corrosion Proof Fittings, 947 F.2d at 1214 (citing *Envtl. Defense Fund v. EPA*, 636 F.2d 1267, 1277 (DC Cir. 1980) ("Under the substantial evidence standard, a reviewing court must give careful scrutiny to agency findings and, at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise.")).

<sup>23</sup>See, e.g., sections 4(a) (testing authority for existing chemicals); 5(e) (allowing regulation of new chemicals pending development of information); and 5(t) (allowing immediate regulation to prevent against unreasonable risk).

<sup>24</sup>15 U.S.C. §2601(c).



to my knowledge the “unreasonable risk” standard has not prevented EPA from exercising its authority in a prudent and health-protective manner.

In short, GAO’s suggestion that the “unreasonable risk” standard in section 6 be replaced with a “significant risk” standard would be inconsistent with other provisions of TSCA and contrary to clear congressional intent, and also is not necessary to protect human health or the environment.

*“Presents or Will Present” Test.* GAO also suggested that section 6 might be amended to require that EPA demonstrate only that a chemical “may present” an unreasonable risk, rather than requiring a demonstration that a chemical “presents or will present” an unreasonable risk. However, experience under section 4 of TSCA does not support this recommendation. Under that section, EPA has authority to require testing of a chemical that “may present an unreasonable risk” to health or the environment. As described earlier in this testimony, the “may present” standard has proven to be a very low threshold, and requires only a “more-than-theoretical basis for suspecting that some amount of exposure takes place,”<sup>25</sup> and hazard information that supports merely a suspicion of toxicity.<sup>26</sup> Such a low standard may be entirely appropriate within the context of section 4, where EPA is deciding whether additional data should be collected. However, such a low standard would be inappropriate under section 6, where the Agency has the ability to ban a chemical. Moreover, if the “may present” standard were incorporated into section 6, it would be possible for the Agency to skip the testing step and proceed directly to a ban merely on the suspicion of a hazard and a “more-than-theoretical basis” for believing that exposure might be occurring, rendering section 4 meaningless.

#### CONCLUSIONS ABOUT SECTION 6

There has been a tendency among critics of TSCA to judge EPA by the number of chemicals that have been banned under section 6. I believe that is an unduly narrow way of looking at EPA’s accomplishments —under section 6 and under TSCA generally.

The EPA took a unique, but instructive approach in a case where they proposed a rule to prohibit the manufacture, distribution, and use of acrylamide grout to protect workers from exposure to acrylamide and another chemical. After eleven years, the proposal was withdrawn because the development of personal protective equipment (PPEs) made the rule unnecessary. A lower cost alternative was available to protect workers from exposure to the acrylamide and other chemicals in these grouts.<sup>27</sup> Since EPA’s concerns were addressed, this action should be considered a success, notwithstanding that no ban was implemented.

Also, as noted earlier in this testimony, EPA has used its authority under section 5(a)(2) to issue SNURs as another way to address concerns related to Inventory-listed substances. The PFAS case described earlier is just one example; there are many others.

Thus, section 6 is not the only mechanism for addressing unreasonable risks. Good product stewardship is a much more efficient approach and is the first line of defense. It is important that EPA have a means to address unreasonable risks when necessary, and section 6 as it is currently designed does provide that authority, but the industry must continue to act responsibly and the EPA, when it takes action, must do so within the statutory guidelines laid out in section 6.

In sum, I believe EPA can regulate effectively under TSCA section 6 as it is currently written, as evidenced by EPA’s successes during the first decade after TSCA was enacted. EPA’s asbestos rule was struck down because in that case, EPA used flawed methodology and failed to consider relevant factors, not because of problems with section 6 itself. GAO’s suggested revisions of section 6 are not necessary, in my judgment, to support effective regulation, and would not improve the statutory framework for making regulatory decisions. I believe the language of section 6 provides a sound basis for EPA decision-making, and does not impose unreasonable burdens on the Agency. To the contrary, it highlights the key factors that should be considered by EPA when contemplating whether to ban or restrict the use of products.

<sup>25</sup>Chem. Manuf. Ass’n v. EPA, 859 F.2d at 984.

<sup>26</sup>45 Fed. Reg. 48,524, 48,528 (July 18, 1980) (Chloromethane and Chlorinated Benzenes Proposed Test Rule; Amendment to Proposed Health Effects Standards) (“EPA’s conclusion that the chemical may present a hazard will not be based on definitive scientific data. This is inevitable; if EPA knew in detail the types of hazards a chemical posed, there would be no need to test. Thus, determinations of hazard potential under Section 4 by their very nature must involve reasonable scientific assumptions, extrapolations, and interpolations.”).

<sup>27</sup>For more details, see Battelle Report, supra n.3, at 21.

## CONCLUSION

Thank you for giving me the opportunity to testify today. In my judgment, TSCA is a well-crafted statute and provides the EPA ample authority to achieve the objectives set forth in the statute. EPA has accomplished a great deal over the years under TSCA (including under section 8, though not discussed in this testimony). I believe EPA could accomplish even more through improved implementation, but I do not believe revisions to the statute are necessary. I hope you find this testimony helpful in your deliberations.

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RESPONSES BY WILLIAM K. RAWSON TO ADDITIONAL QUESTIONS  
FROM SENATOR INHOFE

*Question 1a.* Is it true that EPA must demonstrate an actual risk before it can issue an order, regulate or prevent a new chemical from being introduced? Section 5(e) says that EPA must demonstrate that a chemical “may present” a risk.

Response. EPA does not have to demonstrate an actual risk before regulating a chemical under section 5(e). That section gives EPA authority to prohibit or limit the manufacture and use of any new chemical substance where: (1) existing information is insufficient to permit a “reasoned evaluation” of the substance’s health and environmental effects; and (2) either the substance may present an unreasonable risk of injury to health or the environment, or the substance will be produced in substantial quantities and there will or may be substantial human or environmental exposure. Thus, EPA may act under section 5(e) based on information showing only that a new chemical substance “may present” a risk, or information showing that there will or “may be” substantial human or environmental exposure.

*Question 1b.* Is that too high a bar?

Response. No. In my judgment, the findings that are required are quite reasonable, and this conclusion is supported by the fact that EPA has made those findings and used its authority to regulate chemicals under section 5(e) on numerous occasions. Indeed, as described in my written testimony, EPA has imposed substantial controls or effectively prohibited the manufacture of more than 3200 chemical substances. This number includes more than 1500 premanufacture notices (PMNs) that have been withdrawn in the face of impending EPA action.

It is possible that fewer PMNs may be withdrawn in the future, because EPA has developed a guidance document that identifies numerous chemical categories of concern, and identifies the type of test data that typically will be required for a PMN substance in each category. This means that industry now has a better understanding than it did when TSCA was enacted concerning EPA’s views about which types of chemicals are likely to present the greatest concerns. The result is that fewer PMNs may be submitted for some categories of chemicals. In this way, EPA’s implementation of TSCA is having an impact in many cases without a PMN ever being filed.

Additionally, as is described in my testimony, a PMN submitter may file objections with EPA to a proposed 5(e) order, and EPA is then forced to go to court to obtain an injunction to prohibit or limit the manufacture or use of the PMN substance. To my knowledge, no PMN submitter has ever forced EPA to go to court to obtain such an injunction. In other words, no PMN submitter has ever challenged a 5(e) order judicially; the PMN submitter in every case has either complied or withdrawn the PMN. This means in every case EPA’s data requirements and control requirements have been met, or the PMN has been withdrawn.

*Question 2a.* Why not require a base set of testing for each new chemical for which a PMN is submitted?

Response. Commercial chemicals are not all alike. Any base set of testing that might be chosen would be too much for some new chemicals, and not enough for others. Under the current approach, EPA is able to get the data it needs for each chemical, based on EPA’s scientific judgments in each case. As described in my testimony, the majority of new chemicals in fact either qualify for an exemption from PMN requirements, or are relatively easily screened out based on information provided in the PMN. Requiring the development of additional test data for these substances would serve no useful purpose, and in fact would be counter-productive, because it would clog the new chemical review system and consume substantial EPA resources reviewing the data submissions.

It is important to understand that the PMN submitter has an incentive to provide whatever data EPA requests —whether that consists of a “base set” of testing or something greater. That is the only way to get to market. There may be discussion back and forth with the Agency concerning what data are really needed, but at the

end of the day, the PMN submitter must meet EPA's data requirements to get to market. Stated differently, if a chemical has made it to market, that means the PMN submitter has met EPA's data requirements and demonstrated to EPA's satisfaction that there will be no unreasonable risks to health or the environment.

As stated in my testimony, the strength of section 5 of TSCA lies in its flexibility. EPA is given discretion to vary its assessments and testing requirements for new chemicals according to the attributes and expected uses of each substance. This flexibility promotes the efficient use of EPA resources and avoids imposing unnecessary burdens on industry, while giving EPA the authority it needs to ensure that the introduction of new chemicals into commerce does not pose unreasonable risks. I am not aware of any evidence that EPA has exercised its discretion in a way that has led to inadequate review or inadequate control of new substances. I see no justification for taking that flexibility away by prescribing a base set of testing that must be performed for all new substances, whether needed or not.

There has been some suggestion that commercial chemicals regulated under TSCA should be held to the testing standards applied to pesticides under FIFRA. Dr. Goldman in her written testimony refers to the "reasonable certainty of no harm" standard applied to food use pesticides (but not other pesticide products), and she suggests that such a standard should be applied to commercial chemicals under TSCA. However, pesticides are very different from commercial chemicals regulated under TSCA, because all pesticides are designed to be biologically active—to kill pests or invasive plants. They also are intentionally released into the environment, and many are used on our food supply. It typically takes more than ten years and tens of millions of dollars to conduct required testing and bring a new pesticide active ingredient to market, and the burden on EPA resources who must review all the data submissions are enormous. EPA typically takes more than three years to review a new active ingredient for which a pesticide registration is sought.

It would be completely impractical to take such an approach with all commercial chemicals, and EPA's experience under section 5 shows that it is not necessary. As noted in my testimony, commercial chemicals vary widely in their attributes and potential uses and exposures, and the vast majority of chemicals qualify for an exemption or are readily determined not to pose unreasonable risks. Thus, a FIFRA-like approach to new (or existing) chemicals under TSCA is both unnecessary and would have a severe adverse impact on chemical innovation.

Dr. Goldman also asserts that "TSCA does not require the protection of sensitive populations, including children." That is not a correct statement. TSCA requires EPA to protect against unreasonable risks to human health, and that includes children and other potentially sensitive subpopulations. The suggestion that EPA managers and staff don't consider risks to children absent an explicit mandate from Congress is not fair to EPA managers and staff, nor is it supported in any way by past experience. Test rules promulgated under TSCA section 4 have consistently included testing aimed specifically at chemical risks to children, and EPA chemical assessments always encompass all relevant (i.e., potentially exposed) populations. EPA's IRIS assessments (described further below), for example, explicitly are intended to identify exposure levels that can continue for a lifetime without appreciable risk to the general population, including sensitive subgroups, including children. EPA takes the same approach under TSCA.

*Question 2b.* Do you consider EPA's use of models to review new chemicals adequate?

Response. Yes. We are well beyond the age when every chemical must be tested separately. EPA has gained a lot of experience reviewing chemicals during the first 30 years of TSCA, and its current use of models and SAR (structure activity relationships) is efficient and also health protective. Any research or study that might be done to improve on models is good, but I believe EPA's current use of models is effective and scientifically appropriate. I have seen no evidence to the contrary.

It is important to recognize that models of all kinds are typically applied by EPA in a conservative fashion, meaning that hazards, exposures and/or risks are likely to be overestimated, not under-estimated. This is true under TSCA but also other environmental statutes. Such an approach is inherently health protective, and it also gives industry an incentive to collect chemical-specific data if they believe true risks are likely to be lower than risks estimated through the use of models.

*Question 3a.* Why hasn't EPA tested more than 200 or so chemicals under section 4?

Response. Focusing on the number of chemicals that have been the subject of test rules or consent orders under TSCA section 4 is misleading for several reasons. First, a much larger number of chemicals have been screened for testing by EPA or the Interagency Testing Committee (ITC) and determined to be low priority for

testing or not to require further testing at all. Second, testing of many more substances has occurred on a voluntary basis without the need for a test rule or consent order. The High Production Volume (HPV) Challenge Program, which involved more than 2100 substances, is one obvious example that has been described in written testimony. Third, industry over the years has conducted a large volume of testing on its own, without the need for any action under TSCA section 4 or any structured voluntary program. Thus, focusing on the number of chemicals subject to formal action under section 4 does not give an accurate picture of the number of substances that have been tested over the years, or the amount of test data that is available.

By way of example, EPA maintains a publicly-available Integrated Risk Information System (IRIS) which includes toxicity assessments of various commercially important substances. EPA does not include a substance in the database unless there is sufficient test data to support such an assessment, and each assessment typically includes a determination of a safe daily exposure (oral, inhalation or both) that may be repeated for a lifetime without appreciable risk to the general population, including children. There currently are more than 500 compounds in the IRIS database. The toxicity assessments for some compounds run fifty to a hundred pages, and include citations to hundreds of studies. Moreover, it is well-known that there are many more substances for which similar amounts of data are available but that have not yet been included in the IRIS database, simply because it takes time to do so.

Thus, testing that has been conducted under TSCA represents a small fraction of the toxicity information available to support assessments of commercial substances. This is as it should be, because industry has always conducted a substantial amount of testing on its own initiative, including before TSCA was enacted, and of course a large volume of testing is conducted every year by non-industry researchers as well.

*Question 3b.* Do you think the requirements of section 4 are the reason EPA has not required more testing? In other words, do you think the findings required by the statute are an impediment to testing?

Response. No. The statute requires EPA to show that a substance may present an unreasonable risk (the "A" finding), or that it may reasonably be anticipated to enter the environment in substantial quantities, or that there is or may be significant or substantial human exposure (the "B" finding).

Thus, the burden of proof that EPA must meet to support a test rule in fact is quite modest under both the "A" finding and the "B" finding. Moreover, in practice EPA has set very low thresholds for making these findings, and EPA's approaches have largely been upheld in the few reported court decisions, as described in my testimony.

Dr. Goldman asserts that "the analytic burden required of EPA to write TSCA 4 Test Rules and to defend them from litigation has resulted in a situation such that, repeatedly, over the past two decades, the Government Accountability Office (GAO), the Congress, and others have noted a lack of productivity and the absence of a clear agenda for testing." I would like to make three points in response to this statement. First, these assessments by GAO and others fail to recognize the large body of testing that has been conducted outside TSCA (see discussion above). Second, Dr. Goldman does not point to any particular aspect of the "analytic burden" that is a problem. In reality, as shown above, the statutory findings that are required are quite modest, and if applied correctly, the statutory criteria are well-designed to support sound testing decisions. Third, while legal challenges are not uncommon when an agency implements a new program, in fact there have been very few legal challenges to TSCA test rules, and the decisions of the courts have affirmed EPA's broad discretion to require testing. Thus, the implication that a litigation threat has impaired chemical testing programs is not accurate.

I also do not agree with the GAO's suggestion that EPA should be permitted to require testing based solely on a production volume trigger and a determination that testing is necessary. Such an approach would effectively negate consideration of potential exposure. (EPA has repeatedly recognized that production volume is not a surrogate for exposure information.) EPA's B Policy expressly recognizes that "level, frequency, and duration of exposure" to a chemical should always be considered when determining the sufficiency of existing data and the necessity of additional testing. Eliminating consideration of the potential for human or environmental exposure would make it marginally easier for EPA to promulgate test rules, but it would not provide a more scientifically sound basis for making testing decisions. Such a change also would not be consistent with EPA's current policies and practices under TSCA section 4.

I do believe that EPA could improve its performance under TSCA section 4, and have offered some suggestions in my testimony, but I do not believe the findings

required by section 4 are the problem, and I do not believe amendments to section 4 are necessary to meet the objectives of the statute.

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RESPONSE BY WILLIAM K. RAWSON TO AN ADDITIONAL QUESTIONS  
FROM SENATOR JEFFORDS

*Question 1.* Mr. Rawson, it is my understanding that other countries require chemical companies to provide basic chemical data on new chemicals to regulators. In addition, the European Union is about to require that chemical companies provide similar data on chemicals already in commerce. Shouldn't chemical companies provide similar information to EPA?

Response. Respectfully, I believe EPA is already getting the information it needs for new and existing chemicals, including information well beyond "basic chemical data" in many cases.

Accordingly, I believe the suggestion that a basic data set be required by statute in the United States for all new and existing chemicals is not necessary.

For the reasons expressed above and in my written testimony, I believe EPA currently has ample authority under TSCA sections 4 and 5 to require chemical manufacturers to conduct testing and submit information sufficient to support sound safety assessments of new and existing chemicals. The amount of information that is required will vary from one chemical to the next (whether new or existing), and that is entirely appropriate, because chemicals vary widely in their physical properties, chemical structures, environmental persistence, potential to bioaccumulate, potential toxicities, expected uses, and potential exposures. For many chemicals, EPA has collected data that far exceeds what might be considered "basic chemical data." In other cases, EPA will decide that very little additional information is required, beyond what typically is supplied with a PMN, as happens with many new chemicals under section 5.

No new chemical can get to market without meeting EPA's data requirements, so there is no "data gap" for new chemicals. If something less than a "base set" of data was required to support a PMN, then something less than a base set of data was sufficient to meet EPA's requirements. That obviously will be the case for any chemical that qualifies for an exemption from the PMN filing requirements, and there are many such chemicals.

Under the HPV Challenge Program, EPA now has a base set of screening data for more than 2100 HPV chemicals, so the goal of a base screening set also largely already has been met for the vast majority of existing chemicals that are in commerce in significant volumes. Importantly, this program allowed for exercise of sound scientific judgment, such as the grouping of substances by relevant categories, so that separate testing of each chemical could be avoided where such individual testing was not scientifically necessary. Such chemical groupings obviously avoid the unnecessary use of laboratory animals, but they also save on EPA resources that otherwise would be expended reviewing redundant test data, and they allow testing programs to be completed more efficiently and in less time. The HPV program has been extended in a voluntary industry effort on new HPV chemicals identified in the 2002 TSCA inventory, and also to add exposure information to hazard information that has already been collected. Thus, through this voluntary program and other testing that has occurred over the years, EPA and U.S. industry have largely already out-performed any requirement to generate a base set of test data for existing chemicals.

I do not think it would be wise for Congress to replace the current flexible approach with a statutory "one-size fits all" approach for all new or existing chemicals. Any such prescriptive approach is certain to miss the target more often than it hits the target, because commercial chemicals vary so widely, as already described. Moreover, it would be difficult in such a prescriptive approach to address issues such as the one described in the preceding paragraph, pertaining to when chemicals can be tested by group, rather than individually. Those kinds of decisions cannot be made by statute, but require scientific judgment applied to the facts of each case. EPA must have the flexibility to avoid unnecessary testing and the unnecessary use of laboratory animals.

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STATEMENT OF LYNN R. GOLDMAN, PROFESSOR, ENVIRONMENT HEALTH SCIENCES,  
JOHN HOPKINS UNIVERSITY, BLOOMBERG SCHOOL OF PUBLIC HEALTH

Mr. Chairman and members of the Committee on Environment and Public Works, it is my honor to testify today about the Toxic Substances Control Act.

I am a pediatrician and a professor of environmental health at the Johns Hopkins Bloomberg School of Public Health. I also serve as chair of the Board for the Children's Environmental Health Network and member of the Board of Trustees of Environmental Defense. From 1993-98, I served as Assistant Administrator for Prevention, Pesticides and Toxic Substances at the U.S. Environmental Protection Agency (EPA). While serving in that position I was responsible for the implementation of the Toxic Substances Control Act. Prior to joining the EPA I worked for eight years in public health with the California Department of Health Services. However, my testimony represents my own views and not the views of these other organizations.

When TSCA was passed in 1976, there were great expectations that it would improve our understanding of chemical risks and address these risks in a comprehensive multi-media framework. But, for a variety of reasons, TSCA has not been able to fully live up to these expectations. It is ironic, then, that TSCA has not been the subject of significant legislative action since its passage. In fact, TSCA is probably the EPA statute that has seen the least change in the last 30 years. The people in the Toxics program at the EPA do an excellent job with the tools that they have but they have neither the legislative tools nor the resources that are needed. There are several symptoms that all is not well with TSCA. First is the rising tide of chemicals being regulated on a State-by-State basis. While I support the right of states to take action to protect their citizenry only Federal actions protect all U.S. citizens. Second is the enormous gap that is forming between TSCA and the new chemicals legislation (REACH) in the European Union. And third is the dwindling away of personnel and resources in the EPA devoted to core TSCA efforts.

Today, I will focus on a discussion of a number of areas of concern —and opportunity for change. These include: risk evaluation, protection of vulnerable populations, risk management, precaution, new chemicals, right to know, pollution prevention, international management of chemicals and priority-setting.

#### RISK EVALUATION

To evaluate risk requires the availability of data on hazards and exposures. The Chemical Testing Program was established to carry out the policy expressed in TSCA that adequate data should be developed with respect to the health and environmental effects of chemical substances and that the development of these data should be the responsibility of chemical manufacturers and processors. Unfortunately the analytic burden required of EPA to write TSCA 4 Test Rules and to defend them from litigation has resulted in a situation such that, repeatedly, over the past two decades, the Government Accountability Office (GAO), the Congress, and others have noted a lack of productivity and the absence of a clear agenda for testing. EPA has tried to overcome this problem in a number of ways, including: use of Enforceable Consent Agreements rather than test rules; development of a Master Testing List and voluntary approaches for

screening high volume chemicals in cooperation with the chemicals industry and the OECD (Organization for Economic Cooperation and Development). These voluntary programs are good programs but it is not at all clear how and when EPA will move from screening to more extensive testing of chemicals for adverse endpoints.

Another important information gathering provision is TSCA Section 8(e), a critically important information-gathering tool that serves as an "early warning" mechanism for keeping the Agency apprised of significant new chemical hazards and exposures, and for satisfying the public's right to know about these hazards. EPA's long-standing policy has been, appropriately, that if certain serious health effects are discovered, that information should be considered for immediate reporting to EPA without further evaluation. Over and over again, across the decades, it comes to pass that companies may misinterpret TSCA Section 8(e) and EPA's corresponding policy. EPA has tried to remedy this situation in several ways including by providing guidance documents and via the voluntary Compliance Audit Program (CAP) which, in 1992, allowed participating companies to submit delinquent Section 8(e) information and pay stipulated penalties up to a \$1 million ceiling. Yet, this problem has recurred again and again. Some recent examples of significant information being withheld from EPA include: chromium, diacetyl and PFOA.

EPA collects little to no information about chemical exposures yet such information is essential to the evaluation of risk. TSCA needs to be reformed to give EPA clear expectation for testing of risks of existing chemicals. TSCA also needs to provide for exposure monitoring, by EPA or in collaboration with others such as the CDC. The structure of TSCA should reward companies for the generation of information about chemicals and exposures, through more rapid approvals and/or avoidance of penalties.

## PROTECTION OF VULNERABLE POPULATIONS

TSCA does not require the protection of sensitive populations, including children. Several other statutes, the Clean Air Act, the Safe Drinking Water Act and the Food Quality Protection Act all contain provisions making it clear that such populations should be protected. Children are often more highly exposed to chemicals in the environment, via diet, inhalation, crawling on the floor, mouthing hands and objects in the environment, and route such as transfer from mother to baby in utero or in breast milk. Children are often more susceptible. "Windows of exposure" during development cause susceptibility to irreversible effects like birth defects, neurobehavioral outcomes, and other developmental alterations, and cancer. Parents are not aware that the products in their homes are made with chemicals, many of which have not been assessed at all for risks to children (or even adults). Because the fetus and child are often more exposed and can be more susceptible to adverse effects of chemicals during critical life stages, this is a particularly important vulnerable group. Other groups include people who have genetic differences in response or metabolism of chemicals; the elderly, and people with preexisting conditions. TSCA should explicitly require the protection of vulnerable populations. Exposure and response patterns of vulnerable populations should be

included in risk analyses for chemicals and additional uncertainty factors employed where such information is both missing and relevant.

## RISK MANAGEMENT

In terms of managing the risks of toxic chemicals, the EPA never has recovered from the Fifth Circuit Court of Appeals decision to remand the 1989 Asbestos Ban and Phaseout Rule to EPA. In this case, the court's decision imposed a burden of proof on EPA that significantly increased the level of analysis on potential substitutes and on identifying the least burdensome approach for any future Section 6 action. Second, the court's interpretation of least burdensome alternative under Section 6 appears to define end-of-pipe solutions, where toxic substances are controlled after they are distributed into the environment, as less burdensome than pollution prevention solutions, where toxic substances are reduced or eliminated at their source. End-of-pipe solutions are in conflict with the pollution prevention approach and are more costly over time. EPA needs for Congress to restore its ability to take regulatory action to manage risks of chemicals. Strengthening EPA's ability to manage chemicals risks is this is the single most effective way that Congress could turn the tide on State-by-State regulatory actions on chemicals.

## PRECAUTION

Decisions about chemical risks should be made based on a stronger, more health based safety standard or goal. The current safety standard is to avoid "unreasonable risk to health or the environment", which means that decisions are based on risk benefit balancing. The standard for pesticides in food is one of a "reasonable certainty of no harm". This is a public health standard. Such a standard is needed for chemicals to which we are exposed in our daily lives, just as it is needed to protect us from residues of pesticides in food. Additionally, existing chemicals on the market should be reviewed to assure that they are safe. Certain categories of chemicals, such as persistent chemicals should be given highest priority (as has been done by Canada). Such a precautionary approach would tend to shift the "burden of proof" onto manufacturers, to prove that chemicals are safe rather than on EPA to prove that they are unsafe. Such an approach is in contrast the "least burdensome" provision of current law, which made the banning of asbestos impossible.

## NEW CHEMICALS

Section 5 of TSCA requires that anyone who intends to manufacture or import a new chemical substance in the United States notify EPA 90 days before commencing that activity. The EPA new chemicals program has over the years reviewed thousands of new chemical substances. In many cases EPA has made decisions to prevent risk before a harmful substance enters commerce. The United States' new chemicals program is unique in that it requires review of chemicals prior to manufacture rather than prior to marketing as in most other countries with such systems. I think that there is general agreement among the chemicals regulators worldwide that what would make more sense is a system that gives different types of approvals for R&D and for marketing chemicals. This would help the EPA focus more efficiently on the chemicals which are actually destined for the market. In the case of TSCA, the thousands of chemicals that are submitted and the 90-day review period are challenging. On top of that, the new chemicals program in the United

States does not require any testing prior to PMN submission and therefore over half of all PMNs are submitted without any test data. Ever resourceful, the Agency has developed tools to use Structure Activity Relationships (SAR) to predict and assess the fate and effects of new chemicals. Other systems, most notably the "pre-REACH" Pre-marketing Notification scheme used in the European Union (EU), require a "base set" of testing on new chemicals. In the 1990s the United States and EU evaluated the utility of SAR and found that it worked for some endpoints but not others, particularly a number of chronic health effects.

When EPA determines that there is a risk associated with a PMN it has tools that can be used to manage those risks. TSCA Section 5 gives EPA the ability to require additional tests or other measures such as disposal controls and worker protection. Over the years, the new chemicals program has made wonderful efforts to inform the chemical industry about the criteria used to assess chemicals. These efforts have encouraged development of safer chemicals, and I believe have caused the industry to screen out "bad actors" before presenting them to the EPA in the first instance.

TSCA's new chemical provisions would be improved if EPA's effort were focused premarket rather than premanufacture approvals and would benefit greatly from the addition of risk related data to the agency's determinations.

#### RIGHT TO KNOW

Empowering the public with information is a powerful tool for environmental progress. The creation of the Toxics Release Inventory (TRI), established in Section 313 of the Emergency Planning and Community Right-to-Know (EPCRA), led the way to a new era of public disclosure and a more constructive dialogue between citizens and industry on emissions reduction and pollution prevention. For a toxic chemicals program, it is almost inevitable that the "right to know" ethic will expand to other chemical information. The public release of environmental data gives everyone the ability to participate in the broader national effort to set a toxics agenda and address chemical issues based on the extent of risk posed. The states, local Governments, industry, labor unions, public interest groups and grass-roots community groups are increasingly finding ways to work together on environmental improvements. All problems of chemical management cannot be solved through direct EPA action. As one example of this, the EPA has unsuccessfully attempted to foster and enhance the participation of individual states in chemical management by providing them with TSCA derived chemical data. As a former State regulator, I know the value of site specific information in risk assessment and priority setting. Yet, the language of the law has been interpreted to say that such information cannot be shared with State officials if it has been declared as "confidential business information". In relation to this problem, there is a large amount of information reported to the EPA under TSCA information claimed as confidential business information; studies have found that much of which does not deserve such protection.

EPA has attempted to reform the CBI process but such efforts have foundered on resource limitations and the language of the law, which gives manufacturers too much leeway. Some examples from a survey of the data conducted by EPA in 1998:

- In 1998, more than 65 percent of the information filings directed to the Agency through TSCA were claimed as confidential.
- Submissions under the former Inventory Update Rule show that about 20 percent of facility identities were claimed as confidential.
- In 1998, 40 percent of Section 8(e) substantial risk notices had chemical identity claimed as confidential.

There is a need to reform the CBI provisions in TSCA. Also Congress needs to rethink the role of the states, which has expanded greatly since 1976, and identify ways to provide them not only with more information but also with more opportunities to participate in chemicals management efforts

#### POLLUTION PREVENTION

Preventing pollution offers significant opportunities for protecting the environment and public health in a cost effective manner. The adoption of a pollution prevention ethic is a logical development in a toxic chemicals program, given the focus on improving environmental protection through changes in the manufacture, processing and use of chemicals in our society. Fundamentally, we need to encourage use of safer chemicals and processes in our industrial sector. In order to achieve this TSCA would need to be altered in a number of fundamental ways. First, EPA needs stronger coordination among its "media" offices when it comes to chemicals to prevent the movement of harmful substances from air to water to waste. Second, TSCA does not reward the development of newer safer alternatives. Newer chemicals are



reviewed more carefully than existing ones and the lack of regulation of hazardous existing chemicals does not create an incentive to remove them from the market. Congress needs to examine ways to create incentives for greener chemicals and chemical use patterns. TSCA should support and reward companies for research and development and for creating safer substitutes through tools such as exemptions and more rapid approvals for market. TSCA should be a tool to break down the “silos” at EPA to assure that chemicals are managed properly from cradle to grave and not inappropriately shifted from one medium to another (for example, from water to air).

#### INTERNATIONAL MANAGEMENT OF CHEMICALS

Increasingly it is recognized that a number of very persistent and/or very hazardous chemicals need to be managed globally. In 1992 the Rio Conference adopted Agenda 21, which contained a number of goals for international management of toxic substances. Since that time we have seen the development of many new institutions including: the InterGovernmental Forum on Chemical Safety, a global treaty on prior informed consent for the import of highly toxic chemicals (the Rotterdam convention or PIC) and the global treaty on Persistent Organic Pollutants (POPs). Yet the United States has been slow to join these issues and in fact has not ratified the POPs and PIC conventions. A “clean” approach to ratification is needed so that the United States can fully participate in these important efforts to protect the health of the global community.

#### PRIORITY SETTING

Because there are so many chemicals on the market that have yet to be evaluated, what is needed is for Congress to set a clear agenda for priorities in evaluation and management of chemicals, as well as clear expectations for action. Some factors that might be considered include:

- Children’s exposure pathways and uses that are likely to expose children
- Biomonitoring and environmental data; which chemicals are in peoples bodies
- Cancer, developmental, reproductive and ecological effects and chemicals classes associated with such effects
- Higher production volumes
- Bioaccumulative or environmental persistence properties
- Use patterns; chemicals uses more likely to result in exposures to humans and the environment

#### CONCLUSION

In summary, overhaul of TSCA is long overdue. The Kids Safe Chemicals Act of 2005 is an effort that takes the debate in the right direction. EPA needs clear requirements and regulatory authority that requires placing a high priority on protecting health (especially for vulnerable populations) and the environment. Minus congressional action on TSCA we will continue to see the erosion of Federal management of chemicals on many levels. We will see more states taking action to manage chemicals, thereby creating confusion in the markets and unequal levels of protection State by State. We also will continue to see the dwindling down of activities on the Federal level with a commensurate increase in the risk that “bad actors” will get through the net. And we will increasingly see the European Union and others move into the lead in this area, thus putting us at a competitive disadvantage. This is a complicated area but at the end of the day there is one simple principle that should be kept foremost, which is assuring the American public that the products on the market, the air they breathe, the food and the water, are safe.

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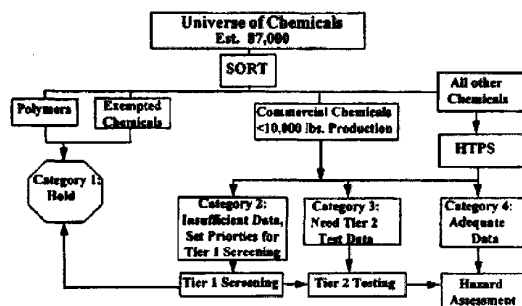
#### RESPONSES BY LYNN R. GOLDMAN TO ADDITIONAL QUESTIONS FROM SENATOR INHOFE

*Question 1.* Doctor Goldman, during the hearing we had an exchange about animal testing in which you suggested that there were other methods besides animal testing that might be utilized to determine health effects of chemicals. Can you provide specific examples of types of testing that does [sic] not involve animals or humans? How do these tests differ from modeling?

Response. Senator Inhofe, there are a variety of ways to generate data that provide information about toxicity of chemicals. Given the vast numbers of chemicals that need to be assessed, it makes sense to employ a tiered testing framework. The framework which was developed by the EPA along with stakeholders in the Endocrine Disruptor Screening and Testing (EDST) Advisory Committee (which I chaired

1996-98) provides an illustration of how such an approach can work to utilize methods besides animal testing in a logical fashion-(Figure 1). Although this framework was developed for the detection of health effects related to endocrine disruption, I believe that the general concept of a tiered approach that we developed for the EDST framework can very logically be extended to other types of toxicity to human health and the environment. Moreover, this framework was supported by scientists from various disciplines as well as by all of the involved stakeholder groups.

FIGURE 1-SCREENING PROGRAM OVERVIEW



The way that such a tiered approach can work is that initially chemicals can be sorted and some chemicals can be removed from further consideration on the basis of unlikelihood of exposure (the boxes labeled “polymers” and “exempted” chemicals), very low to no production volume, or having already been assessed. Such chemicals can initially be prioritized using information such as chemical structure, physical properties, structure activity relationships (SAR), production volume, conditions of use, permitted uses, and existing toxicology studies; no new animal studies would be required at this stage. Of these tests, only one (SAR) involves the use of modeling. For endocrine disruption it was determined that a cutoff for “high” production volume would be >10,000 lbs/year, far lower than the one million lb cutoff for the HPV program. Under the EDST program such chemicals would be subjected to high throughput prescreening (HTPS) tests; these are *in vitro* tests that use cell-culture based assays (but not animals or SAR models) to provide a further indicator of whether a chemical is a priority for further assessment. For the EDST program at this point chemicals can be judged low priority, can go directly to hazard assessment, or can be prioritized for Tier 1 screening or Tier 2 testing. Tier 1 screening involves 13 tests, six of which are *in vitro* (and therefore do not use animals), two of which use nonmammalian species (tadpoles and fish), and two of which use smaller numbers of animals than conventional tests. Again, after Tier 1 screening chemicals are prioritized for whether or not any further action is needed, and, if so, if that would involve hazard assessment or proceeding to Tier 2 testing. All five of the tests in Tier 2 involve the use of animals, however only one uses mammals (rats) and the others use, respectively, Japanese quail, frogs, fish and an invertebrate called mysid shrimp. Using nonmammalian species is not only more humane but also assures that the chemicals with the greatest potential for hazard are tested in species that are of economic and ecological importance to humankind, such as fish, birds and shrimp and/or most sensitive to ecological damage, such as frogs. In any case, by using a tiered approach the chemicals that wind up in Tier 2 are those for which the value of information is highest, thus (in my view) more clearly justifying the use of animals.

This example illustrates how much information potentially can be made available prior to requiring testing and that it is possible to focus the use of animal tests only on the chemicals that are most likely to be “bad actors”. This example was for endocrine disruptors because the 1996 Food Quality Protection and Safe Drinking Water Acts required that EPA develop such a screening and testing program. However, the basic approach could be applied much more generally and with appropriate legal authority the Federal Government could inform us about risks to a much greater extent than we are today.

*Question 2.* Assuming that some types of biological effects information can only be gleaned by testing on biological specimens, i.e. animals. Do you have any concerns about [sic].

Response. At this time there are indeed biological responses that can be assessed only via testing on whole biological systems, animals. At the same time, knowledge

is rapidly advancing and new scientific approaches under development in the areas of genomics, proteomics, and metabolomics perhaps some day will lead to the development of testing technologies that can replace animal testing, in whole or in part. Even today, *in vitro* testing can be used to rapidly screen and assess chemicals and to determine which chemicals are a higher priority for further testing, and which are not.

Given how slowly we have made progress to assess risks of chemicals I am concerned that some might invoke concerns about testing on animals to justify our failure to assess the toxicity of most chemicals to which we, and our children, are exposed. At the same time that we take steps to develop new strategies to minimize use of animals and to find ways to assess hazards of novel substances like products of nanotechnology, we also need to increase our knowledge about the hazards of chemicals in our environment. These efforts can go hand in hand. Any new alternative methods must be consistent with sound scientific practices necessary to obtain valid results, while addressing the “3 R’s”, reduction, refinement, and replacement, of alternatives to animals testing. Reduction involves development of methods that reduce the number of animals required for a test method. Refinement involves development of methods that lessen or eliminate pain or distress in animals or enhance animal well-being. Replacement involves development of methods that replace animals with non-animal systems or replace an animal species with a phylogenetically lower species (for example, replacing mammals with fish or invertebrates). The process of assessing and validating new test protocols is complicated and requires the input of scientists from many disciplines including toxicology, statistics, exposure sciences and basic sciences such as molecular biology.

RESPONSES BY LYNN R. GOLDMAN TO ADDITIONAL QUESTIONS  
FROM SENATOR JEFFORDS

*Question 1.* TSCA’s Lack of Protections for Children Ms. Goldman, please describe some of the concerns that you have regarding EPA’s ability to use TSCA to protect the health of vulnerable individuals, including children?

Response. In brief, the Toxic substances Control Act (TSCA) contains no provision for special consideration of risks to children and other vulnerable populations. We know that, at various life stages, children are more exposed to chemicals that occur in drinking water, in certain foods, in air, in dust and dirt and in certain products such as toys. They may have slower—or faster metabolism or elimination of substances during various developmental stages. We also know that during fetal and early childhood development there is the potential for irreversible harm to occur, via mechanisms birth defects, adverse impacts on the developing brain or growth, immune system effects and increased cancer risk. The law should require that the EPA consider the juncture between exposure and vulnerability during the development of a child. In addition, there are many other vulnerable individuals in the population: people with increased risk on a genetic basis; the elderly; and those who are severely ill and/or immunocompromised. Some suggestions are:

- Clear requirements that EPA place a high priority on protecting children’s health and on protecting other vulnerable subpopulations.
- A strong safety standard, such as a “reasonable certainty of no harm”
- Health protection of children is the basis for chemical regulatory decisions.
- An additional safety margin for children, pregnant women, the fetus, nursing women, and women of child-bearing age
- Recognition of and protection for children most at risk, including children of lower socioeconomic status, children of racial and ethnic minority status, children with special health care needs, and children whose parents have occupational exposure to chemicals.
- Establishment of protocols for data collection, hazard and exposure assessments that explicitly consider children and their most sensitive and vulnerable health effects.
- Consideration of multiple and synergistic effects of different chemicals, of chemicals with multiple pathways of exposure, and of chemical mixtures.

*Question 2.* Potential reforms to TSCA Ms. Goldman, please describe the aspects of TSCA that you would change in order to ensure that EPA has the legal authority to quickly stop exposure to dangerous chemical substances and to prevent such exposures, while conserving limited public resources.

Response. First, to assure that children are adequately protected, I think that TSCA needs to be reformed in order to include:

- Clear requirements that EPA place a high priority on protecting children’s health and on protecting other vulnerable subpopulations.

- A strong safety standard, such as a “reasonable certainty of no harm”
- Health protection of children is the basis for chemical regulatory decisions and these decisions are based on active processes of review of information..
  - An additional safety margin for children, pregnant women, the fetus, nursing women, and women of child-bearing age
  - Recognition of and protection for children most at risk, including children of lower socioeconomic status, children of racial and ethnic minority status, children with special health care needs, and children whose parents have occupational exposure to chemicals.
  - Establishment of protocols for data collection, hazard and exposure assessments that explicitly consider children and their most sensitive and vulnerable health effects.
  - Consideration of multiple and synergistic effects of different chemicals, of chemicals with multiple pathways of exposure, and of chemical mixtures.

Second, to strengthen the EPA’s ability to protect the public from harmful chemicals, TSCA should be reformed to..

- Not allow exposure to chemicals that do not meet core information requirements.
- Assure commitment to timeliness, and that protective measures are adopted by default if action is not taken on a timely basis.
- Reward the generation of information about chemicals and exposures.
- Support and reward for research, development and innovation that produces safer substitutes.
- Assure collection of; biomonitoring data under appropriate scientific guidelines.
- Require periodic review of chemicals, with more frequent review of more hazardous materials.
- Include strong enforcement provisions including routine inspections and random audits of testing facilities and laboratories.
- Give citizens the ability to file suit and to petition EPA for action on toxics.
- Increase the public’s “right to know” by reform of TSCA’s overly broad confidential business information provisions

Third, to conserve limited public resources, TSCA should be reformed to:

- Shift the burden of proof such that the onus is on industry is to demonstrate safety of a chemical by supplying required data.
- Provide a tiered approach to the assessment of chemicals in commerce.
- Strengthen participation by State (and sometimes local) Government which often can act more efficiently and in a more targeted fashion than the Federal Government.
- Strengthen role of other Federal agencies including NIEHS, NTP, and CDC, in biomonitoring and in assessment of hazards of chemicals.
- Promote the “three R’s” (reduction, refinement and replacement) to reduce the burden of animal testing.
- Promote international cooperation in the management of chemicals in commerce internationally
- Assure a transition that includes a process for establishing priorities for review and approval of existing chemicals. Priority is to be given to “the worst first”—after consideration of children’s exposures, biomonitoring data, developmental neurotoxicity, disparate impacts on certain populations, intrinsic properties (such as bioaccumulative or environmental persistence), use patterns, and production volume.
- Assure a fair and predictable process that provides clear expectations for industry and predictable outcomes of assessment and review, so that private resources are not wasted as well.

#### IMPACT OF APPLYING PROTECTIONS FOR CHILDREN IN TSCA

*Question 3.* Ms. Goldman, Congress has included protections for children and other vulnerable populations in numerous public health and environmental laws, including the Safe Drinking Water Act, Clean Air Act and the Federal Food, Drug and Cosmetic Act.

Please describe the range of benefits that you believe would occur if Congress included similar provisions in TSCA.

Response. The benefits are likely to be quite large. According to a study done by Mt. Sinai university, for the United States alone: “Total annual costs are estimated to be \$54.9 billion (range \$48.8-64.8 billion): \$43.4 billion for lead poisoning, \$2.0 billion for asthma, \$0.3 billion for childhood cancer, and \$9.2 billion for

neurobehavioral disorders. This sum amounts to 2.8 percent of total U.S. health care costs.”

Of these, I would expect that \$9.5 billion each year (the costs attributed to childhood cancer and neurobehavioral disorders) could potentially be saved. This amount would increase substantially were one to add in costs attributed to exposures to susceptible adult populations as well as a number of costs that they were not able to assess, including costs of pain and suffering and late complications that are not yet well understood. [1]

#### LIMITATIONS OF CURRENT PROTECTIONS FOR CHILDREN’S TOYS

*Question 4.* Ms. Goldman, please describe the limitations of other Federal agencies’ regulations to protect children’s health from toxic substances in children’s toys. In particular, please describe the critical role that EPA regulation could play in filling gaps in the regulatory scheme of other Federal agencies, such as the Consumer Product Safety Commission.

Toys are regulated by the Consumer Products Safety Commission (CPSC) under the Federal Hazardous Substances Act. If you go to their webpage and you will find pages and pages of toy product recalls. However, almost all are for the (very important) goal of protecting children from injuries, such as aspiration, choking, and strangulation by toys. Except in the case of lead, there is little to no action related to chemicals in toys, even though Congress has given CPSC the authority to recall toys for reason of chemical risk. CPSC does not even regulate chemicals in pacifiers, children’s products with great likelihood of exposure. Instead, CPSC relies on voluntary efforts to achieve such protection (such as addressing hazards from nitrosamine or phthalates in pacifiers). In its defense, CPSC does not have adequate staffing and resources to address the thousands of chemicals that are in children’s products. Although the drafters of TSCA envisioned a coordinated process between EPA and the other regulatory agencies in reality the process by which EPA is to “refer” chemicals to other agencies does not function well. The EPA needs to be able to directly take action when it has evidence that chemicals in children’s products are a health risk.

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#### STATEMENT OF MICHAEL P. WILSON, PH.D, M.P.H, UNIVERSITY OF CALIFORNIA, BERKELEY

Mr. Chairman and members of the committee, thank you very much for inviting me to the hearing today on chemicals policy and the Toxic Substances Control Act. I am Michael Wilson, an assistant research scientist with the Center for Occupational and Environmental Health at the University of California, Berkeley and the lead author of a report regarding chemical problems in California and the steps the California Legislature can take to respond to those problems. I will speak briefly about the report, entitled Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation, which was published by the University of California in March of this year. I would like to acknowledge co-authors Daniel Chia and Bryan Ehlers and the Advisory Committee of experts that provided technical guidance and rigorous review of the document over a two-year period.

The report responds to three questions posed to the University by the California Legislature:

- What are the key chemical challenges facing California?
- What are the causes of those challenges?
- How might the Legislature respond to those challenges?

In answering these questions, we found that California, like other States, is facing an array of problems with chemicals. These problems are experienced in different ways by the businesses in our State that purchase and use chemicals, by our Government agencies, and by consumers and workers. But three themes emerged out of our investigation. First, there is insufficient information in the marketplace to make informed decisions about chemicals. Second, Government is overly constrained in its capacity to protect public and environmental health from chemicals.

And third, more needs to be done to motivate investment in safer chemical technologies, known as “green chemistry.”

While the focus of the report is on the challenges that exist in California, the report finds that the root cause of these challenges can be traced to longstanding deficiencies in Federal regulation, particularly with the Toxic Substances Control Act, or TSCA. The report illustrates that the weaknesses of TSCA have produced a Data Gap, a Safety Gap, and a Technology Gap in the U.S. chemicals market. I would

like to briefly explain these three Gaps and their relevance to chemicals policy in the United States

The first of these, the Data Gap, is perhaps the most fundamental. As you have heard from other witnesses, TSCA does not require chemical producers (United States or foreign) to generate and disclose robust information on the toxicity of the vast majority of chemicals in commercial circulation. Markets cannot function without good information, and the chemicals market is no different. We found that California businesses that use chemicals are unable to identify and choose the safest chemicals for their needs. This leaves them with uncertainties and liabilities arising from the potential effects of these chemicals on their workers, on their customers, and in the environment. Even large firms, such as those in California's electronics industry, are finding it very difficult and expensive to identify and replace hazardous chemicals in their supply chains. These firms simply do not have the right kind of information to identify safer chemical alternatives. Of course, small business owners, workers, and consumers are affected even more acutely by the lack of appropriate information in the chemicals market.

This pervasive lack of information also poses a barrier to the competitive advantage of innovative companies that are investing in green chemistry. In the current chemicals market, customers, investors and others are unable to efficiently differentiate between conventional chemicals and safer alternatives. The report finds that green chemistry will become commercially viable only when the market allows these entities to make informed purchasing decisions. It is one of the proper roles of Government to ensure that the market has sufficient information to function properly, and in this regard, TSCA has come up short.

The second challenge recognized in the report is the Safety Gap. It is also a proper function of Government to ensure that the production and use of goods does not come at the expense of public and environmental health. Here again, TSCA has fallen short. It is well recognized that U.S. EPA has been greatly constrained in its ability to assess the hazards of chemicals in commercial circulation and to control those of greatest concern. This has allowed hazardous chemicals to remain competitive in the market, and it has unnecessarily put the public at risk. It is also costly. For example, the EPA expects that if production and regulatory practices remain the same, 600 new hazardous waste sites will appear in the United States each month of every year over the next 25 years; clean-up costs are estimated at over \$250 billion. The CDC reports that about half of the top 50 chemicals at existing waste sites can cause birth defects; others are toxic to the human nervous system.

Other social costs of chemical exposures are more subtle. There is evidence that hundreds of chemicals are accumulating in the human body. Some of these—including flame retardants, wood preservatives, and stain repellants—have been identified in the umbilical cord blood of newborn babies. Of course, the effects of chemical exposures during the uniquely sensitive period of human development are of great concern. Furthermore, chemical exposures in the workplace continue to produce a substantial burden of occupational disease in the United States. In California, about 23,000 workers each year are diagnosed with chronic diseases that are attributable to chemical exposures on the job. The Safety Gap created by TSCA is allowing real problems to continue unchecked, problems that will likely expand as global chemical production doubles over the next 25 years.

Together, the Data Gap and Safety Gap are contributing to stagnant conditions in the U.S. chemicals market. This is producing what we characterize in the report as a U.S. chemical Technology Gap. Only 248 new chemicals introduced since 1979 have reached High Production Volume status in the United States, about 8 percent of the High Production Volume chemicals in commercial circulation today. In its 1996 Vision 2020 report, the U.S.-based Council for Chemical Research, together with the American Chemical Society, the American Institute of Chemical Engineers, the American Chemistry Council, and the Synthetic Organic Chemical Manufacturers Association, wrote that the vast majority of chemical products are manufactured in the United States using technologies developed 40 to 50 years ago and that new technologies are needed that incorporate economical and environmentally safer processes, use less energy, and produce fewer harmful byproducts. Ten years after the Vision 2020 report, the websites of the 50 largest U.S. chemical companies all contain a statement of commitment to achieving sustainability goals, but their spending on research and development has decreased or remained flat since 2000, according to the National Science Foundation.

It is not surprising, therefore, that the Committee on Grand Challenges for Sustainability in the Chemical Industry, convened by the National Academy of Sciences, concluded in its December 2005 report that in "going forward, the chemical industry is faced with a major conundrum—the need to be sustainable (balanced economically, environmentally, and socially in order to not undermine the natural systems

on which it depends)—and a lack of a more coordinated effort to generate the science and technology to make it all possible.” The committee included academic scientists as well as representatives of Dow, PPG Industries, ConocoPhillips, and Agraquest.

The U.S. private sector is simply not investing vigorously enough in cleaner technologies, such as green chemistry, that are likely to mark the next era of innovation and growth in the global chemicals market. It is a reflection of the current State of the chemicals market (and the Technology Gap in particular) that with very few exceptions one can still earn a Ph.D. in chemistry at U.S. universities without demonstrating even a rudimentary understanding of how chemicals affect human health and the environment. U.S. chemistry graduate students are not required to gain an understanding of the principles of toxicology. This is a serious problem not only for public and environmental health but for the long-term competitiveness of the U.S. chemical industry itself, as noted last year by the NAS Grand Challenges committee.

So what is to be done? First, our report acknowledges that the U.S. chemical industry generates important benefits for society in the form of an extraordinary array of substances serving all sectors of the economy. At the same time, our report finds increasing evidence that many of these substances can adversely affect human health and disrupt the biological systems on which life itself depends. This is precisely what makes chemicals policy so difficult. Some of the properties that make chemicals useful to society also make them hazardous to people. Once we acknowledge this paradox, however, we can begin to think about how to re-design the production and regulatory systems so that they amplify the positive contributions of chemicals to society while steadily reducing their negative impacts. This represents a system that is founded on the principles of green chemistry. It essentially introduces the toxicity of chemicals into the market on an equal footing with price and function, and in doing so it moves the market steadily toward the design, production, and use of chemicals that are inherently safer for people and ecological systems.

In short, a fundamental overhaul of the Federal Toxic Substances Control Act is needed. A modern U.S. chemicals policy will need to put in place the market conditions that advance the technical and commercial viability of green chemistry. These new market conditions will begin to motivate the chemical industry to focus its enormous talent and technical capacity on innovating green chemistry at a level commensurate with the scale and pace of chemical production. It will open new market opportunities for green chemistry entrepreneurs. It will not, however, be achieved through voluntary initiatives by the industry, nor will it be achieved by piecemeal approaches to chemicals policy, or by providing occasional funding to universities to conduct green chemistry research. While these can help identify best practices, for example, they are not sufficient—even collectively—to correct the uneven playing field in the chemicals market that has been engendered by TSCA. The UC report recommends that correcting these market flaws will require a comprehensive approach to chemicals policy that closes the Data Gap, the Safety Gap and the Technology Gap.

This is the key challenge of chemicals policy for California and the nation, and I think it is reasonable to conclude that it is a fairly formidable challenge. Meeting this challenge, however, will deliver real value to the American people. It will build the foundation for an economically and environmentally sustainable chemical industry in the United States; it will solve a host of costly chemical problems that are affecting public health, businesses, and Government; and it will support our industry leaders in becoming globally competitive in green chemistry and other cleaner technologies.

Mr. Chairman and members of the Committee, thank you very much for your attention today, and thank you again for inviting me to this important hearing. I would be pleased to answer any question you might have.

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RESPONSE BY MICHAEL P. WILSON TO AN ADDITIONAL QUESTION  
FROM SENATOR INHOFE

*Question 1.* Does the UC report advocate the adoption of a reach-like approach?

THE UC REPORT DOES NOT CALL FOR THE ADOPTION OF A REACH-LIKE APPROACH  
IN THE U.S.

Response. The UC report proposes three overarching goals for chemicals policy in California: Close the Data Gap, the Safety Gap, and the Technology Gap. It then describes a number of issues that are important for policymakers to consider with

respect to each of these goals (Chapter 7). The Data Gap refers to the lack of information in the market on the safety of chemicals. The Safety Gap refers to the barriers that Government faces in its efforts to assess the hazards of chemicals and control those of greatest concern. The Technology Gap refers to the potential for the United States to fall behind globally in the science, technology, and commercial applicability of green chemistry.

We developed these three policy goals (Chapter 3) based on discussions with chemicals policy stakeholders in the United States, on our participation in 35 chemicals policy meetings and conferences in the United States (Appendix A), and in studying reports published by the National Academy of Sciences (1984),<sup>1</sup> the U.S. General Accounting Office (1994),<sup>2</sup> the Congressional Office of Technology Assessment (1995),<sup>3</sup> Environmental Defense (1997),<sup>4</sup> the U.S. EPA (1998), the U.S. Government Accountability Office (2005), former EPA officials, and academic researchers. These reports all point to deficiencies in the U.S. Toxic Substances Control Act (TSCA) that have prevented the statute from serving as an effective vehicle for Government, industry, consumers, and workers in the United States to assess chemicals in commercial circulation and control those of greatest concern. The UC report uses the terms Data Gap, Safety Gap, and Technology Gap to describe the set of conditions in the United States that have emerged as a consequence of these deficiencies.

THE UC REPORT DESCRIBES REACH AS THE E.U.'S STRATEGY TO ADDRESS A SET OF CHEMICALS POLICY PROBLEMS THAT ARE ESSENTIALLY IDENTICAL TO THOSE OF THE U.S. EXPERIENCE UNDER TSCA.

The chemicals policy deficiencies identified in the E.U. by the European Commission in its justification for REACH are essentially identical to those of the United States:

- There is a lack of health, environmental, and other information on the great majority of chemicals in commerce; 99 percent of chemicals in commercial circulation in the E.U., by volume, lack adequate information on health and environmental effects.
- There is an implicit presumption that chemicals are safe unless proven otherwise by a public entity.
- The ability of public agencies to assess and demonstrate chemical risks has not kept pace with the rate of chemical production; only about 140 of 100,000 existing chemicals in the E.U. have been subject to risk assessments.

The UC report indicates that an array of strategies could be employed to address this same set of problems in the U.S. The report devotes a chapter to a discussion of the experience in Massachusetts under the Toxics Use Reduction Act of 1989 (Chapter 6), and it lists 13 different policy mechanisms that could be used to directly or indirectly limit chemical hazards. It proposes a set of attributes of the most effective policy mechanisms, as follows (Chapter 7):

- meet the proposed objective in a measurable way,
- place the least demands on Government,
- leverage market forces,
- leverage existing statutes and programs,
- be cost-effective and fair,
- consider impacts across the chemical life cycle (including the workplace),
- ensure public access and participation,

<sup>1</sup>Sensitive physiological processes can be disrupted during the rapid growth and development characteristic of embryonic and fetal life and the first year following birth. Development of the brain, for example, requires the formation and interconnection of billions of neurological cells; development of the endocrine system and reproductive organs is guided by a precisely timed sequence of hormones that exert their effects in the parts-per-trillion range.

<sup>2</sup>Children's metabolic pathways, especially in fetal life and in the first month after birth, are immature. Among other factors, growth of the blood-brain barrier, which can provide protection against some chemicals, is incomplete during fetal and early child development, such that chemicals are able to move directly from the maternal blood stream into the developing fetal brain.

<sup>3</sup>Relative to their size, children's intake of air, water, and food is far greater than that of adults. The amount of air a resting infant breathes, for example, is twice that of an adult, normalized by body weight. Children therefore experience disproportionately higher doses of environmental agents, including chemicals.

<sup>4</sup>Children have more years of future life than adults and thus have more time to develop diseases initiated by exposures early in life. Many chronic diseases, including cancer and neurodegenerative diseases, appear to arise as a result of cellular changes that take place many years before the actual manifestation of the disease. Critical windows of exposure to hazardous chemicals in utero, during early child development, and during puberty are more likely to produce chronic disease than similar exposures encountered later.



- integrate environmental and occupational health justice factors,
- emphasize prevention (including green chemistry) over mitigation,
- encourage continual learning by the regulated entity,
- motivate technology innovation and diffusion, and
- be adaptable to change.

The report finds that to close the Data Gap, Safety Gap, and Technology Gap, California will need to: (1) require the disclosure by chemical producers of more complete information on chemical toxicity, ecotoxicity, exposure and other information; (2) improve the capacity of Government to act in an efficient and timely manner in controlling the most dangerous chemicals; and (3) implement additional incentives that motivate industry investment in green chemistry science and technology, and devote public resources to green chemistry education, research, and technical assistance programs. The first two of these parallel the intent of the REACH proposal, whereas the third is implied but not made explicit in REACH.

The similarities between the policy goals recommended in the UC report and those of REACH reflect the fact that both are responding to essentially the same problems; the similarities also reflect a general concern among the industry representatives we spoke with that harmonization of standards across jurisdictions is becoming increasingly important as these jurisdictions begin to contemplate chemicals policy strategies. To prevent a scenario in which U.S. producers are forced to contend with an increasingly diverse global regulatory environment, the UC report suggests that some aspects of REACH (such as data requirements) might be harmonized with chemicals policy initiatives in California and the United States

THE UC REPORT DRAWS FOUR BASIC CONCLUSIONS ABOUT THE IMPLICATIONS OF REACH FOR CALIFORNIA.

First, the report presents evidence suggesting that REACH will improve the technical and commercial viability of green chemistry by improving accountability and oversight in the chemicals market. Second, the report notes that REACH could present a unique challenge to California's small and medium-sized chemical producers, and that California could take steps now to assist these businesses in meeting REACH requirements. Third, the report proposes that REACH could present an opportunity for California to gather toxicity and other information on many chemicals in commercial circulation, and that for this information to be most useful, California will need to gather sales data on the distribution of chemicals sold in the State. Fourth, the report concludes that while REACH is expected to drive innovation in safer chemicals, it is also conceivable that some producers will seek to market "non- E.U.-compliant" hazardous chemicals in countries where regulatory oversight is weak, such as in the United States, particularly during transitional "sell-through" periods.

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RESPONSES BY MICHAEL P. WILSON TO ADDITIONAL QUESTIONS  
FROM SENATOR JEFFORDS

*Question 1.* Dr. Wilson, in the ever-expanding global market, will the European Union's REACH initiative alter chemical industry behavior in the United States? If so, to what extent?

Response. It is clear that REACH will affect all U.S. producers of chemicals and chemical products that manufacture in, or import into, the E.U. It will also indirectly affect all U.S. companies whose supply chains include chemicals or chemical products that are manufactured in the E.U., or that are manufactured in the United States and exported into the E.U. It is not possible to predict how REACH will affect "behavior" among U.S. producers of chemicals and chemical products; however, some chemical industry observers expect that important changes could occur in the chemicals market as REACH is implemented, and others suggest that the political climate surrounding chemicals policy in the United States could be affected. These potential developments are summarized below.

*Question 2.* Dr. Wilson, if hazardous chemicals are banned in the European Union but not at home, will the U.S. market for such chemicals expand?

Response. Thank you for these questions. It is appropriate to open a discussion of TSCA and chemicals management in the United States with a question pertaining to the European Union's proposed Registration, Evaluation, and Authorization of Chemicals initiative, known as REACH. As you know, we were asked by the California Legislature in January 2004 to evaluate chemical challenges facing California, and we, too, recognized the importance of REACH for the U.S. chemical industry and for United States and California chemical management programs. Our

report, *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*, which the UC Office of the President released to the Legislature on March 14, 2006, discusses REACH at some length. I will refer you in some questions to responses I prepared for Senator Inhofe, above, which describe issues related REACH.

A. REACH WILL INTRODUCE A NEW LEVEL OF ACCOUNTABILITY FOR CHEMICAL PRODUCERS WITH OPERATIONS IN THE E.U.

Over a period of 11 years, REACH will introduce new responsibilities and a greater degree of Government oversight for U.S. producers of chemicals and chemical products (that manufacture in, or import into, the E.U.). Generally speaking, producers will be responsible for disclosing more information about the health and safety of the chemicals they produce (particularly for chemicals sold in larger volumes); they will be required to distribute this information into supply chains to end users; and they will be required to gather information from end users to determine how chemicals are being used. REACH will gradually remove the distinction between chemicals already on the market (so-called "existing" chemicals) and "new" chemicals. Producers will need to seek Government approval for certain chemicals on a use-by-use basis. These so-called "chemicals of very high concern" will be presumptively removed from commercial circulation unless the producer can demonstrate that the production and use of these chemicals can take place under adequately controlled conditions, or if this is not the case, that their "socio-economic benefits outweigh the risk to human health or the environment. . . and if there are no suitable alternatives." These measures represent a degree of responsibility and oversight that is new in the global chemical production system, including that of the U.S. This will engender a new level of accountability in some sectors of the global chemicals market, including that of the U.S.

STATEMENT OF GAIL CHARNLEY, PH.D., PRESIDENT, HEALTHRISK STRATEGIES

Since the early 1990s, our awareness and understanding of the special susceptibilities of children to chemical exposures has improved substantially. Our precautionary methods for setting limits on chemical exposures take children's unique exposure characteristics into account and provide margins of safety that protect children when greater susceptibility to toxicity is known or suspected. A variety of voluntary programs have been initiated under the umbrella of TSCA that have generated basic toxicity data for most of the chemicals in commerce by volume, including information about children's exposures and susceptibilities. These efforts will continue to produce data and chemical-specific exposure limits will continue to be generated and fine-tuned as new data on developmental toxicity become available. Meanwhile, to the extent they are available, environmental and biomonitoring data demonstrate that chemical emissions and body burdens continue to decline.

TSCA PROGRESS

In its 1997 final report, the Presidential/Congressional Commission on Risk Assessment and Risk Management<sup>1</sup> (for which I served as executive director) evaluated and made recommendations regarding the risk assessment and risk management policies and practices across the Federal Government. With regard to TSCA, the Risk Commission concluded:

Given the divergent views about the situation, the history of litigation, the advances in the world of testing and toxicologic interpretation, and the willingness of all parties to engage in dialogue, the Commission recommends that EPA, industry, academia, and worker, consumer, and environmental organizations be convened in a sustained stakeholder process to review TSCA and its implementation, to propose criteria for developing test batteries, to seek consensus on making weight-of-evidence judgments about such data. [and] to define criteria for making data more accessible to the public.<sup>2</sup>

Since the time of the Commission's report, a variety of activities has taken place that is consistent with that recommendation. Among the prominent ones are:

<sup>1</sup>The Commission was mandated by the 1990 amendments to the Clean Air Act, comprised ten commissioners appointed in a bipartisan manner, and operated between 1994 and 1997.

<sup>2</sup>U.S. Commission on Risk Assessment and Risk Management (1997). Final Report, Volume 2. Risk Assessment and Risk Management in Regulatory Decision-A faking. GPO #055-000-00567-1. page 128. Available at <http://www.riskworld.com/nreports/1996/risk-rpt:RR6ME001.HTNM>

- U.S. EPA convened the National Pollution Prevention and Toxics Advisory Committee, a national advisory body that provides advice, information, and recommendations on the overall policy and operation of programs managed by the Office of Pollution Prevention and Toxics in performing its duties and responsibilities under TSCA. The Committee provides a forum for public discussion and the development of independent advice to the EPA Administrator by taking advantage of the experience, strengths and responsibilities of a broad range of Agency constituents and stakeholders.

- The High Production Volume (HPV) Challenge Program was launched in 1998 as a cooperative effort among EPA, the American Chemistry Council, and Environmental Defense. More than 300 companies and consortia volunteered for the program, providing safety information on nearly 95 percent of U.S. chemical production by volume. The HPV program is a tiered testing program that generates a basic set of toxicity data first on key end points, including reproductive, developmental, systemic, and genetic toxicity. The results of the basic testing allow scientists to evaluate potential hazards and decide whether additional toxicity tests are needed and, if so, which specific tests would be appropriate. This tiered testing and evaluation framework promotes an efficient use of resources, including laboratory animals, by targeting substances posing the greatest potential hazards. The HPV Challenge Program is nearly complete and has greatly accelerated the public availability of hazard screening data and critical information used to evaluate the potential health and environmental effects of HPV chemicals. The HPV program is now supplemented by the Extended High Production Volume Program, a voluntary, industry-led initiative that continues to generate toxicity screening data for newer HPV chemicals and to make those data publicly available.

- The Voluntary Children's Chemical Evaluation Program is a voluntary pilot program that is part of EPA's Chemical Right-to-Know Initiative. The goal of the pilot is to better understand potential health risks to children associated with certain chemical exposures. The key question of the program is whether the potential hazards, exposures, and risks to children have been adequately characterized and, if not, what additional data are necessary. EPA has asked companies that manufacture or import 23 chemicals found in human tissues and the environment to volunteer to sponsor chemical evaluations. Sponsorship requires the companies to collect or develop health effects and exposure information on their chemicals and then to integrate that information in a risk assessment and a data needs assessment. Like the HPV program, VCCEP uses a tiered testing scheme to generate a basic set of toxicity and exposure data and then uses the results to determine what types of further testing is needed. The results of the pilot program thus far illustrate how various parties can work together under a voluntary program and how toxicity and exposure data can be integrated to make decisions regarding the adequacy of risk information for children. The program has been in operation since 2002 and is currently being reviewed and fine-tuned.<sup>3</sup>

These programs demonstrate that voluntary, multi-stakeholder initiatives have been initiated and are succeeding under the umbrella of TSCA. Since the mid-1990s, basic toxicity data have been generated for most of the chemicals in commerce by volume and research efforts have provided information about children's exposures and susceptibilities that has been incorporated into risk assessment and chemical standard-setting. These efforts will continue to generate data that will contribute to better and better chemical regulation and to safer, healthier children.

#### BIOMONITORING AND THE ROLE OF THE ENVIRONMENT IN CHILDREN'S HEALTH

Establishing a role for chemicals in public health in general or children's health in particular is complicated by the fact that "environment" includes many more complexities than just chemical contaminants, such as physical safety, nutrition, socioeconomic factors, infectious agents, naturally occurring substances, ultraviolet radiation, tobacco smoke, and natural disasters. The National Children's Study defines a child's environment broadly, including natural and man-made environment factors, biological and chemical factors, physical surroundings, social factors, behavioral influences and outcomes, genetics, cultural and family influences and differences, and geographic locations.<sup>4</sup> Notable among the varying definitions of environment and the various attempts to quantify environmentally attributable proportions of disease is the comparatively small role that chemical exposures evidently

<sup>3</sup>For a status report, see Williams PRD, Patterson J, Briggs DW (2006). VCCEP: Progress on evaluating children's risks and data needs. *Risk Analysis* 26:781-801

<sup>4</sup>U.S. EPA/Environmental Protection Agency (2001). The National Children's Study. Conducted in partnership with the U.S. Department of Health and Human Services. Available at <http://www.nationalchildrensstudy.gov/>

play against the backdrop of socioeconomic conditions, behavioral factors, psychological factors, infectious agents, nutrition, and other considerations.

Several studies have attempted to evaluate the role of environment in ill health. For example, one evaluation estimated the extent to which global ill health is attributable to environmental risk factors, excluding genetics, diet, smoking, and some component of injuries but including food additives, infectious agents, pesticides, passive smoking, behavioral factors related to personal and household hygiene, some malnutrition, and the natural environment (e.g., dust and natural disasters).<sup>5</sup> That study concluded that 12 percent of disease in established market economies is potentially attributable to environmental factors. Compared to all ages, the proportions of children's environmentally attributable disease burden is about 0.8 percent.

This is not to say that chemical exposures do not play a role or that their contribution should be ignored; even if their contribution is small, it could constitute a public health problem by virtue of the numbers of people affected. However, given their relatively small contribution, chemical contaminants should not be treated in isolation from other factors if an effective environmental strategy for protecting, and improving public health—and especially children's health—is desired.

Attributing specific health outcomes to specific chemicals at environmentally relevant levels of exposure is, except in the rarest of cases, unlikely to be either possible or defensible. For example, while the cause of childhood asthma may be traced to genetic influences, its occurrence may be triggered by environmental tobacco smoke or urban air pollution. An environmental health strategy that targets specific exposures without considering the contributions of other risk factors and the multifactorial etiology of disease will not be effective. In any case, dissecting out the contributions of genetics and economic, social, cultural, behavioral, and psychological factors for the purpose of identifying and reducing environmental risks in general, or chemical risks in particular, is unlikely to be straightforward. As EPA put it recently:<sup>6</sup>

One of the greatest challenges to elucidating the connection between environmental exposure and disease is the fact that exposure to an environmental pollutant or stressor is rarely the sole cause of an adverse health outcome . . . Other factors include, for example, diet, exercise, alcohol consumption, heredity, medications, and whether other diseases are present. . . Also, different people have different vulnerabilities. . . All these factors make it difficult to establish a causal relationship between exposure to environmental pollutants and disease outcome. . .

For the reasons discussed above, biomonitoring data that provide information solely about trace levels of chemicals in blood or urine at a single point in time cannot be used to draw conclusions about the likelihood of disease except in very rare cases. Biomonitoring data can be used to demonstrate trends in exposure over time, to establish that exposure has occurred, to identify individuals with unusual exposures, or to help clarify the relationship between exposure and dose in some cases, but generally do not provide an indication with regard to the likelihood of ill health. As the recent National Academy of Sciences report *Human Biomonitoring for Environmental Chemicals* put it:

The ability to generate new biomonitoring data often exceeds the ability to evaluate whether and how a chemical measured in an individual or population may cause a health risk or to evaluate its sources and pathways of exposure. . . For some chemicals (such as mercury and lead), the health risks and effects are well known; but for most of the chemicals currently measured, the risks cannot be interpreted.<sup>7</sup>

As the Centers for Disease Control and Prevention puts it in its *National Report on Human Exposure to Environmental Chemicals*:

The presence of a chemical in a blood or urine specimen does not mean that the chemical causes a health risk or disease.<sup>8</sup>

Our analytic abilities increasingly permit the detection of substances in biological samples in smaller and smaller trace quantities. That does not mean we are increasingly at risk of chemical-related disease. Trace levels of chemicals in the body are unlikely to overwhelm the body's natural ability to detoxify and eliminate them.

<sup>5</sup>Smith KR, Corvalan CF, Kjellstrom T (1999). How much global ill health is attributable to environmental factors? *Epidemiology* 10:573-84.

<sup>6</sup>EPA Environmental Protection Agency (2003). Draft Report on the Environment 2003. Technical Document. EPA-600-R-03-050. Office of Research and Development and Office of Environmental Information. Washington, DC. Available at <http://www.epa.gov/indicators/roe/index.htm>

<sup>7</sup>National Academy of Sciences/National Research Council (2006). *Human Biomonitoring for Environmental Chemicals*. National Academy Press. Washington, DC. Page 2.

<sup>8</sup>Centers for Disease Control and Prevention (2005). *National Report on Human Exposure to Environmental Chemicals. Third Report*. Atlanta, GA. Available at <http://www.cdc.gov/exposurereport/>

Given our incomplete knowledge of the inter-relationships among multiple chemical and non-chemical, environmental and non-environmental stressors, interpretation of the potential impact of exposure to trace levels of chemicals, if any, will probably be dependent on eventual decoding of the human genome map. Meanwhile, using laboratory animals to provide information on chemical toxicity can help us identify target organ systems and target risk management strategies, but is unlikely to provide insight with regard to the potential impact of trace levels of chemicals.

The good news is that, to the extent that they exist, environmental and biomonitoring trend data demonstrate that emissions and body burdens of contaminants continue to decline. EPA emissions data show that pollutant levels have generally declined while our economy has grown.<sup>9</sup> For example, dioxin and furan concentrations in the environment and human tissues have been declining since the 1970s. Samples taken of sediments from remote lakes impacted purely by atmospheric deposition and transport and of archived soils and herbage show low background levels of naturally occurring dioxins and furans prior to 1900 followed by a sharp rise after 1930, coinciding with the onset of industrialization and the large-scale production and use of organochlorine compounds, peaking in the 1970s, with a slow decline until the present day. Evidence for this decline has also been found in studies on archived sewage sludge, air measurements, and biological samples.<sup>10</sup> Human tissue concentrations of 2,3,7,8-TCDD taken from residents of Germany, France, the United States, and Canada show that exposure has declined by more than 95 percent since 1972.<sup>11</sup> Other data show that if exposure to dioxin-like compounds stays at present levels (which is unlikely), current body burdens will fall by more than 50 percent by 2020.<sup>12</sup>

Studies show that the levels of contaminants in breast milk are also declining. For example, data from Germany, Norway, and the Netherlands indicate that concentrations of dioxins and furans in breast milk have decreased by at least 50 percent since 1980.<sup>13</sup> Other substances for which trend data are available show continued declines as well. The extent to which chemicals present in breast milk present a health risk to the breast feeding infant is not known. Virtually all national and international expert committees have concluded that, on the basis of available information, the benefits of breast feeding outweigh the possible risks from chemical contaminants present in human milk at normal levels.<sup>14</sup> In fact, epidemiologic research shows that human milk and breastfeeding of infants provide advantages with regard to general health, growth, and development, while significantly decreasing risk for a large number of acute and chronic diseases.<sup>15</sup>

An expert committee was convened by the European Centre for Ecotoxicology and Toxicology of Chemicals to review trends over time in chemical exposures and in children's health.<sup>16</sup> That committee drew a number of conclusions that are germane to evaluating the role of chemical exposures and children's health:

- In comparing time trends of disease improved reporting systems, changes in diagnostic criteria/procedures, a more active approach to early detection of cases to improve prognosis and a better health care system in general must be taken into account. There is clear evidence of increasing rates of asthma in children, although rates in some countries may now have stabilized. There is no convincing evidence of widespread trends in other acute or chronic childhood respiratory diseases. Indoor air quality appears to be related to both asthma and, in some cases, to other respiratory-related diseases (such as otitis media). Interpretation of the available information on asthma and allergies is made difficult by inconsistent application of diagnostic criteria over place and time. Contemporaneous with the increasing frequency

<sup>9</sup>See for example, EPA (2000). National Pollutant Emission Trends, 1900-1998. EPA-454/R-00-002. Office of Air Quality Planning and Standards. Research Triangle Park, NC. Available at <http://www.epa.gov/ttn/chieftrends/trends98/trends98.pdf>

<sup>10</sup>Euro Chlor (2003). Dioxins and Furans in the Environment. Science Dossier. Brussels, Belgium. Available at [www.eurochlor.org](http://www.eurochlor.org)

<sup>11</sup>Aylward LL, Hayes SM (2002). Temporal trends in human TCDD body burden: Decreases over three decades and implications for exposure levels. *Journal of Exposure Analysis and Environmental Epidemiology* 12:319-328

<sup>12</sup>Lorber M (2002). A pharmacokinetic model for estimating exposure of Americans to dioxin-like compounds in the past, present, and future. *The Science of the Total Environment* 288:81-95

<sup>13</sup>LaKind JS, Berlin C, Naiman DQ (2001). Infant exposure to chemicals in breast milk in the United States: What we need to learn from a breast milk monitoring program. *Environmental Health Perspectives* 109:75-88

<sup>14</sup>La Leche International (1994). Pesticides and breast feeding. *LEAVEN* 30:37-40

<sup>15</sup>American Academy of Pediatrics (1997). Policy statement on breast feeding and the use of human milk. *Pediatrics* 100:1035-1039

<sup>16</sup>European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) 2005. Trends in Children's Health and the Role of Chemicals: A State of the Science Review. Brussels.

of asthma, data also suggest that other atopic disorders such as upper respiratory and food allergy may be increasing. Atopic dermatitis remains the leading skin disorder in young children.

- Although the frequency of neurodevelopmental disorders such as autism and attention deficit disorder is commonly believed by the public to be increasing, the limited data available do not support this perception.

- Data on reproductive effects are also limited and often suffer from serious data quality issues. Whilst geographic heterogeneity is apparent, broad population trends for these outcomes (sperm quality, hypospadias, cryptorchidism) are difficult to identify except for decreasing age at puberty in females.

- There is no evidence for major trends in the frequency of childhood cancer. Data indicate that developed countries tend to have a gradually increasing incidence of leukaemia with a corresponding drop in the incidence of lymphoma. Increases in brain tumour frequency are possibly related to the development of new diagnostic capabilities rather than to a true change in the incidence in the rate of malignant disease. With the increasing number of childhood cancer survivors, secondary cancers following chemotherapy appear to be on the increase.

- A wide range of environmental factors is thought to have an impact on children's health, extending well beyond industrial chemicals. These factors include nutrition (protein, vitamins, anti-oxidants), lifestyle and behavior choices such as tobacco and alcohol use, parental health, socio-economic status, choice of living environment (urban vs. rural, etc.), and parent-sibling behavior. From the available data, no general conclusions on the contribution of specific chemicals can be drawn across the multiple health outcomes addressed in [the committee's] report.

It is illogical to presume that any chemical exposure is dangerous and that any potential chemical hazard poses a risk. And, even if they were occurring, increases in childhood health problems would be unlikely to be associated with environmental contaminant concentrations that are decreasing. Even the New York Times notes that people alive today in developed countries are healthier than they used to be, live longer, get heart disease and other chronic illnesses later in life than they used to, experience less disability, and have higher IQs.<sup>17</sup> Much of those improvements is due not just to better medical care but also to better nutrition, higher birth weights, and fewer hazardous occupational and environmental exposures.

#### LIMITING CHEMICAL EXPOSURES

Current EPA methods for setting standards to limit chemical exposures are precautionary and account for the possibility that children can be more susceptible than adults to chemical toxicity. When information on developmental toxicity is available, it is considered. When developmental toxicity is the most sensitive endpoint of toxicity, it serves as the basis for standard-setting. When no information on developmental toxicity is available, a database uncertainty factor is used to make the standard more stringent than it would be otherwise, in order to be precautionary and account for the possibility that children might be more susceptible than adults.

Traditionally, chemical risk assessment has been performed by comparing a measured or estimated human dose to a dose associated with a toxicity endpoint, such as a no-observed adverse-effect level (NOAEL) or a benchmark dose, after adjustment by adequate uncertainty and/or safety factors. Adjusting for uncertainty generally involves dividing a NOAEL or benchmark dose derived from human data by 10 to yield a level of exposure that would be protective of individuals who might be more sensitive than those tested or observed. If no human data are available, a NOAEL or benchmark dose identified using laboratory animals is divided by 100-10 to protect sensitive individuals (intraspecies factor) and 10 to account for the possibility that humans could be more sensitive than the species tested (interspecies factor). The resulting lifetime exposure level is considered likely to be without adverse effects in humans, including sensitive subgroups or life stages, because the intraspecies uncertainty factor is meant to protect sensitive groups such as children or the elderly.

A number of scientists have attempted to investigate quantitatively whether the intraspecies uncertainty factor is adequate to account for the variability to chemical toxicity between the overall human population and its potentially more sensitive groups, including children. Dourson et al (2002) reviewed 17 studies that performed quantitative analysis of the extent of toxicodynamic and pharmacokinetic variability using different data and different starting points, some specifically evaluating age

<sup>17</sup>New York Times, Sunday July 30, 2006

effects in both humans and animals.<sup>18</sup> That analysis suggests that a high percentage of the population, including children, is protected by using a 10-fold uncertainty factor for human variability. Studies indicating that in some cases the young would not be protected by the standard uncertainty factor were those that evaluated acute lethality in laboratory animals (LD50s) and are therefore less relevant to evaluating risks from environmental exposures. Based on specific comparisons for newborns, infants, children, and adults, the range of the population protected is between 67 and 100 percent. Studies using larger populations that include sensitive individuals suggest that the value is closer to 100 percent.<sup>19</sup>

Other evaluations concur with those of Dourson et al (2002). For example, the German Research and Advisory Institute for Toxic Chemicals concluded that, based on toxicokinetic differences, the most susceptible group of neonates is protected by a 10-fold intraspecies uncertainty factor in most cases.<sup>20</sup> The authors also conclude, however, that the protection of neonates and infants may require consideration of their lower xenobiotic clearance rates and recommend using a log-normal density function, based on the differences in adult and neo-natal clearance rates, in the framework of probabilistic risk assessments.

Conclusions about the adequacy of the 10-fold intraspecies uncertainty factor do not mean that interindividual sensitivity varies 10-fold, as is often thought. Its application to a value in the low end of the distribution of human sensitivities, such as a NOAEL, and its use in conjunction with other uncertainty factors and conservative assumptions, actually cover total human sensitivity variations of 100 to 1,000 times (see Exhibit 4).

In the absence of important data on a substance's toxicity, such as reproductive or developmental toxicity, standard EPA practice has been to use a "database uncertainty factor" in addition to the other factors. The database uncertainty factor is generally a factor of 10 that is added to the calculation of an exposure limit, making it ten times more stringent than it would be otherwise. In other words, EPA uses an extra uncertainty factor when there is inadequate information about developmental effects, reproductive effects, or developmental neurotoxicity in order to be precautionary and health-protective.

#### AGE AND CHEMICAL EXPOSURES

Children's exposures to chemicals from their environment are qualitatively and quantitatively different from those of adults. For example, children are likely to be exposed to different levels of chemical contaminants in foods than adults because they consume more calories of food per unit of body weight, fewer types of foods, and more processed foods.<sup>21</sup> The National Academy of Sciences report *Pesticides in the Diets of Infants and Children*<sup>22</sup> concluded that differences in diet and thus in dietary exposure to pesticide residues account for most of the potential differences in pesticide-related health risks that may exist between children and adults.

Normal childhood behaviors such as hand-to-mouth activity and crawling on the floor or ground can increase children's exposures to potential toxicants through ingestion and contact with dusts and residues. Greater risk of lead poisoning from lead-based paint is a well-known example of that problem. Children breathe more than adults on a body-weight basis, so may be exposed to higher doses of air pollutants. Children consume more water than adults on a body-weight basis, so may be exposed to higher doses of water pollutants. Infants consume breast milk, an important source of nutrition and immunologic protection, but sometimes a source of fat-soluble contaminants such as PCBs. Children may not perceive hazards as quickly

<sup>18</sup>Dourson M, Charnley G, Scheuplein R. 2002. Differential Sensitivity of Children and Adults to Chemical Toxicity. II. Risk and Regulation. *Regulatory Toxicology and Pharmacology*, 35:448-467

<sup>19</sup>Hattis D, Banati P, Goble R. 1999a. Distributions of Individual Susceptibility Among Humans for Toxic Effects. How Much Protection Does the Traditional Tenfold Factor Provide for What Fraction of Which Kinds of Chemicals and Effects? *Annals of the New York Academy of Sciences* 895:286-316; Hattis D, Banati P, Goble R, and Burmaster D. 1999b. Human Interindividual Variability in Parameters Related to Health Risks. *Risk Analysis* 19:705-720; Renwick AG and Lazarus NR. 1998. Human variability and noncancer risk assessment an analysis of the default uncertainty factor. *Reg Toxicol Pharmacol* 27:3-20

<sup>20</sup>Schneider KI, Gerdes H, Hassauer M, Oltmanns J, Schulze J. 2002. *BerUcksichtigung der Risikogruppe Kind bei der Ableitung gesundheitsbezogener Umweltstandards*. UFOPLAN-Nr. 201 61 215. Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG), Freiburg

<sup>21</sup>U.S. Department of Agriculture (1985). *Nationwide Food Consumption Survey: Continuing Survey of Food Intakes by Individuals, Women 19-50 Years and Their Children 1-5 Years*. Human Nutrition Information Service. Washington, DC

<sup>22</sup>National Academy of Sciences/National Research Council (1993). *Pesticides in the Diets of Infants and Children*. National Academy Press. Washington, DC

or effectively as adults, so may experience some greater exposures by not avoiding them as readily. In contrast, adults have higher exposures than children to chemicals associated with activities such as home car repair, cleaning, home painting, and other recreational or maintenance activities. Occupational exposures also would be greater for adults than children, although there are situations, such as pesticide application, where parents' exposures result in children's exposures when applicators return home after working.

Exposure is not the only determinant of toxicity, however. Once exposure has occurred, age-related differences in the body's ability to absorb, distribute, metabolize, and eliminate chemicals can produce different doses from the same exposures. Risks to health are determined by exposure, dose, and susceptibility. Even if children's exposures or doses of substances exceed those of adults on a body-weight basis, they will still not be at risk unless the doses are high enough to produce toxicity. The dose or level of exposure that is capable of producing toxicity is determined by children's inherent susceptibility, which may be greater than adults in some cases and less in others.

#### AGE AND SUSCEPTIBILITY

There are many physiologic and pharmacologic reasons why the susceptibility of children and adults to the impacts of chemical exposures may differ. The developing organism experiences many complex, integrated events involving the regulation of cell growth, differentiation, and morphogenesis. Interfering with those events through mutation or through altered cell division, enzyme function, or energy sources can have significant adverse impacts on development.<sup>23</sup> Many environmental factors can have an impact on normal development, including nutrition and folic acid availability, maternal smoking and alcohol consumption, prescription drugs, and chemical contaminants such as lead and organic mercury.

Children are more sensitive than adults to the toxic effects of many chemicals, such as lead. At the same time, children are often less sensitive to many chemicals than are adults. For example, unlike the situation in adults, liver toxicity and death from acetaminophen poisoning is extremely rare in children<sup>24</sup>. The metabolism and elimination rates of many drugs and other substances are known to be higher in children than adults. As a result, children will often have lower body burdens of drugs or chemicals than adults for the same exposures, when expressed on a body-weight basis. For example, as Exhibit 1 shows, morphine is cleared about 2-3 times faster by children than by adults. The chemotherapy drug methotrexate is cleared six times faster by children than by adults. The antipsychotic drug Thorazine is cleared five times faster by children than by adults. As a result, kids require higher pharmacologic doses than adults of those drugs to achieve efficacy.

Thus, while some chemicals may be metabolized to toxic metabolites more quickly by children, those metabolites are likely also to be deactivated and eliminated more rapidly, presumably becoming less toxic by decreasing their effective doses. Children's generally more rapid elimination rates may compensate in part for any increased sensitivity during development.<sup>25</sup> A number of environmental exposures, including pesticides, parental occupational exposures, and infectious organisms have been suggested as possible precursors to cancer or other health effects in children; however, the considerable research conducted to date has yielded inconsistent or limited evidence identifying those factors as disproportionate threats to children's health.<sup>26</sup>

Rodent bioassays show that younger animals are less susceptible to chemical carcinogens in some cases and more susceptible in others. Pesticides in the Diets of Infants and Children included a table summarizing the results of studies that had been performed through 1983 in which the effects of age on chemically induced car-

<sup>23</sup>Wilson J (1977) Current Status of Teratology; General Principles and Mechanisms Derived from Animal Studies. In: Handbook of Teratology; General Principles and Etiology, ed. J Wilson and F Fraser. New York: Plenum Press; Faustman EM, Silbernagel SM, Fenske RA, Burbacher TM, Ponce RA (2000). Mechanisms underlying children's susceptibility to environmental toxicants. *Environmental Health Perspectives* 108:13-21

<sup>24</sup>Penna A, Buchanan N (1991). Paracetamol poisoning in children and hepatotoxicity. *British Journal of Clinical Pharmacology* 32:143-149

<sup>25</sup>Renwick AG (1998). Toxicokinetics in infants and children in relation to the ADI and TDI. *Food Additives and Contaminants* 15S:17-35

<sup>26</sup>Public Health Policy Advisory Board (1999). Health and the American Child. Part I: A Focus on Mortality Among Children. Risks, Trends, and Priorities for the Twenty-First Century. Washington, DC



cinogenesis in rodents had been evaluated. That list was updated in 2001.<sup>27</sup> As can be seen in Exhibit 2, the data indicate that there are a similar number of studies showing that younger animals are less susceptible than adults to chemically induced carcinogenesis as there are showing that they are more susceptible under the conditions of the bioassays. A number of studies showed that age played no role at all in susceptibility.

The National Academy of Sciences report concluded that those results clearly demonstrate that age may be an important factor in susceptibility to chemically induced carcinogenesis, but they do not support the conclusion that younger animals are always more susceptible than older animals. The database also illustrates the difficulty associated with assessing quantitatively the extent of the differences in susceptibility due to age. Virtually all of the studies evaluated used only one dose level, so the underlying dose-response relationships are unknown and comparison of sensitivities is possible only at the relatively high, single dose levels used. Generalizations about the effect of age on susceptibility to chemical carcinogens are thus difficult to make.

Data on acute chemical toxicity show similar results. Exhibit 3 shows how the lethal dose of DDT varies with age, indicating that in this case, infant rats are much less susceptible to toxicity than adult rats. A review by Ed Calabrese of the data available on LD50s showed only small differences due to age. In some cases, young animals were more susceptible and, in some cases, adult animals were more susceptible.<sup>28</sup> In only a few cases did the differences exceed an order of magnitude, however, and in many cases, there were no differences. Data on the maximum tolerated doses of chemotherapeutic agents in humans show that they were frequently higher for children than adults, indicating greater susceptibility of adults, although the differences between age groups were usually less than or equal to two.<sup>29</sup> Studies of pesticide acute toxicity also show variability. In one study, no more than 2- to 3-fold differences in sensitivity were observed, with the younger animals more sensitive to toxicity than older animals in only four out of 36 cases.<sup>30</sup> In another study, however, 14 of 15 organophosphate pesticides showed greater acute toxicity to young rats than to adult rats.<sup>31</sup>

Chemical exposures can affect normal prenatal or childhood development by interfering—either directly or indirectly—with the large network of regulatory genes that control growth and development. In contrast to physiological responses, which can vary in response to exposures or other stimuli and then return to normal, developmental systems move inexorably forward.

Perturbation of critical components of the regulatory gene network can have two possible outcomes. The consequences of interference may not be repaired as development moves forward or the complexity of the system may confer the ability to compensate for perturbations, should they occur, illustrating again the difficulty of making generalizations about age and susceptibility.<sup>32</sup>

What the scientific evidence on age-related susceptibility to the effects of chemical contaminants does show is that children may be more than, less than, or just as sensitive as adults, depending on the chemical and the exposure situation. Children may be less sensitive to the effects of a chemical than adults if they do not absorb it as readily, if they clear it more rapidly, if they lack the enzymes required to activate it, if they detoxify it more quickly, or if they compensate more readily for any damage. Most of the available information on age-related differences in sensitivity comes from experiments using single, high doses of chemicals that produced short-term, acute toxicity, however. Those observations may be poor predictors of what occurs when low doses of chemicals are received over long periods of time or of developmental toxicity. Long-term exposure to low doses of chemicals can produce dif-

<sup>27</sup>Charnley G, Putzrath RM (2001). Children's health, susceptibility, and regulatory approaches to reducing risks from chemical carcinogens. *Environmental Health Perspectives* 109:187-192

<sup>28</sup>Calabrese EJ (1986). *Age and Susceptibility to Toxic Substances*. New York: John Wiley & Sons

<sup>29</sup>Bruckner JV (2000). Differences in sensitivity of children and adults to chemical toxicity: the NAS panel report. *Regulatory Toxicology and Pharmacology* 31:280-285

<sup>30</sup>Gaines TB, Linder RE (1986). Acute toxicity of pesticides in adult and weanling rats. *Fundamental and Applied Toxicology* 7:299-308

<sup>31</sup>Brodeur J, DuBois KP (1963). Comparison of acute toxicity of anticholinesterase insecticides to weanling and adult male rats. *Proceedings of the Society for Experimental Biology and Medicine* 114:509-511

<sup>32</sup>Davidson EH, Rast JP, Oliveri P, Ransick A, Calestani C, Yuh CH, Minokawa T, Amore G, Hinman V, Arenas-Mena C, Otim O, Brown CT, Livi CB, Lee PY, Revilla R, Rust AG, Pan Z, Schilstra MJ, Clarke PJ, Arnone MI, Rowen L, Cameron RA, McClay DR, Hood L, Bolouri H (2002). A genomic regulatory network for development. *Science* 295:1669-1678

ferent types of toxicity than short-term exposure to high doses. On the other hand, low environmental exposures to chemicals are less likely to overwhelm developing detoxification and other defense mechanisms, so age-related differences at low doses may be quantitatively less pronounced than at high doses.<sup>33</sup> For example, data for the insecticide chlorpyrifos show that young animals are more sensitive than adults to its nervous system toxicity at high doses, but are less or similarly sensitive than adults at low doses.<sup>34</sup> The reason for the difference in this case is that young animals can compensate for toxicity faster than adult animals can at lower doses by synthesizing replacement cholinesterase faster, but cannot compensate for it fast enough at higher doses.

The effect of age on susceptibility to chemical toxicity appears to depend on the chemical of concern, the toxic effect that is observed, the dose that is received, and the period of development during which exposure occurred, with infants, children, or the developing fetus more sensitive than adults in many cases but less sensitive in others. Susceptibility to chemical toxicity is the result of extremely complex biological interactions and there is no systematic method or model to predict age-related susceptibility.<sup>35</sup> There is no scientific support for any statement implying that children are always more sensitive than adults to environmental chemical exposures.

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RESPONSES BY GAIL CHARNLEY TO ADDITIONAL QUESTIONS  
FROM SENATOR INHOFE

*Question 1.* Dr. Charnley, it has been suggested that children are more highly exposed to industrial chemicals and thus they are a more vulnerable subpopulation that TSCA needs to categorically protect. Scientifically, can it be assumed that children have higher exposure in all cases and can it be assumed that the children are always more vulnerable than adults to chemicals to which they are exposed?

Response. Children are more highly exposed to chemicals than adults in many cases, although not always. For example, children are likely to be exposed to different levels of chemical contaminants in foods than adults because they consume more calories of food per unit of body-weight, fewer types of foods, and more processed foods. Children's chemical exposures and metabolic profiles can be qualitatively and quantitatively different from those of adults, so they may experience higher or lower doses on a body-weight basis for the same exposure levels. When possible, chemical risk assessments should include consideration of different exposure characteristics for children and any other groups of people or particular life stages that might be more or less exposed than average. Children can be more sensitive to a certain chemical toxicity than adults because they may be more vulnerable to external challenges during critical stages of the developmental process. In other cases, they can be less sensitive to chemical toxicity than adults due to more efficient elimination processes, less mature activating enzymes, and enhanced ability to repair damage. The intrinsic relative susceptibility of children depends on the specific physical, toxicological, and metabolic characteristics of the particular chemical at issue and on the exposure situation of concern. Broadly based statements indicating that children are generally more sensitive to chemical insults are not supported by existing scientific data. And, even if they were occurring, increases in childhood health problems would be unlikely to be associated with environmental contaminant concentrations that are decreasing. In developed countries, people are healthier than they used to be, live longer, get heart disease and other chronic illnesses later in life than they used to, experience less disability, and have higher IQs. Those improvements are due not just to better medical care but also to better nutrition, higher birth weights, and fewer hazardous occupational and environmental exposures. There is no evidence for a relationship between the U.S. infant mortality rate and exposure to chemicals from the environment.

*Question 2.* Dr. Charnley, many allege that TSCA does nothing to protect children's health. How do TSCA and the various programs in OPPTS address children's health issues?

Response. Several voluntary, multistakeholder programs evaluating children's health as related to chemical exposures have been successfully initiated and con-

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<sup>33</sup>Scheuplein R, Chamley G, Dourson M (2002). Differential sensitivity of children and adults to chemical toxicity. I. Biological basis. *Regulatory Toxicology and Pharmacology* 35:429-447

<sup>34</sup>Mattson JL, Maurissen PJ, Nolan RJ, Baal( KA (2000). Lack of differential sensitivity to cholinesterase inhibition in fetuses and neonate compared to dams treated perinatally with chlorpyrifos. *Toxicological Sciences* 53:438-446

<sup>35</sup>Wargo J (1996). *Our Children's Toxic Legacy*. New Haven: Yale University Press

ducted under the umbrella of TSCA. For example, the High Production Volume testing program has generated a basic set of toxicity data on key end points, including reproductive, developmental, systemic, and genetic toxicity. The results of the basic testing allow scientists to evaluate potential hazards and decide whether additional toxicity tests are needed and, if so, which specific tests would be appropriate. In other words, if initial chemical testing indicates that a threat to children is possible, further testing focuses on that possibility. Another program, the Voluntary Children's Chemical Evaluation Program is a voluntary pilot program that is part of EPA's Chemical Right-to-Know Initiative. The goal of the pilot is to better understand potential health risks to children associated with certain chemical exposures. The key question of the program is whether the potential hazards, exposures, and risks to children have been adequately characterized and, if not, what additional data are necessary. The results of the pilot program thus far illustrate how various parties can work together under a voluntary program and how toxicity and exposure data can be integrated to make decisions regarding the adequacy of risk information for children. Finally, EPA's pesticides program includes explicit consideration of children's potentially greater exposures and sensitivities. Pesticide sponsors must provide data indicating that children are not at increased risk compared to adults if they do not wish to have their product regulated more stringently than it would be if children are at greater risk or if no data on children's potential risks are available.

*Question 3.* Dr. Charnley, you mentioned some groups for whom you do work. Can you elaborate on your work for industry, non-profits and trade organizations?

Response. I work only part-time. I spend more than half of the time that I work working pro bono for organizations such as the National Academy of Sciences, the Environmental Literacy Council, the National Toxicology Program, the Society for Risk Analysis, and the Environmental Law Institute. When I get paid for work, my clients have been generally a mix of nonprofits (e.g., American Council on Science and Health, Ranchers-Cattlemen Action Legal Fund, Public Health Policy Advisory Board), Government (e.g., U.S. Environmental Protection Agency, U.S. Agency for International Development, Agency for Toxic Substances and Disease Registry, State of California), industry associations (e.g., American Chemistry Council, CropLife America), companies (e.g., Bayer CropScience, 3M, United States Borax), and law firms (e.g., Crowell & Moring, Schiff Hardin, Kirkland & Ellis). I have also done some teaching at Yale, Harvard, Georgetown, and George Mason. An elaboration of the kinds of work I have conducted can be found on my website, [www.healthriskstrategies.com](http://www.healthriskstrategies.com).

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RESPONSES BY GAIL CHARNLEY TO ADDITIONAL QUESTIONS  
FROM SENATOR JEFFORDS

*Question 1.* Dr. Charnley, you mention in your testimony that there are several voluntary initiatives, including the HPV Challenge Program that are succeeding under the umbrella of TSCA. However, I understand that problems exist in this program such as companies not volunteering to provide data on all HPV program chemicals and EPA has no mechanism for placing these chemicals on the HPV list once they are produced in greater volume. How would you remedy these problems?

Response. It is true that some companies did not volunteer to sponsor chemicals in the HPV Challenge Program. Those chemicals not sponsored in the program are called "orphans."

However, TSCA does provide a mechanism through which EPA can obtain health and environmental information from those companies. Sections 8(a) and 8(d) of TSCA enable EPA to order companies that make or import those orphan chemicals to provide production information and unpublished health and safety studies. In fact, EPA issued section 8(a) and 8(d) rules on August 16, 2006, covering 243 HPV Challenge orphan chemicals. These rules are among EPA's Office of Pollution Prevention and Toxics largest rulemakings in terms of the number of chemicals covered. Companies affected by these rules must submit this health and environmental information to EPA no later than November 14, 2006.

Additionally, under TSCA's Inventory Update Rule (IUR), as amended in 2003, companies that manufacture or import chemicals are required to report information periodically (e.g., the types of chemicals, the amounts manufactured or imported, certain details about their manufacture, and other data) to EPA. Any chemical substances produced or imported in quantities of one million pounds or more annually are automatically considered HPV. In 2005, at the conclusion of the HPV Challenge Program, the chemical industry extended its HPV commitment by launching the Extended HPV (EHPV) Program. Through the EHPV Program, industry has com-

mitted to sponsor chemicals that were not HPV in the original HPV Challenge Program, but were reported as HPV in the 1998 and 2002 IUR. Chemicals that are not voluntarily sponsored in the EHPV will become “orphans” and may be subject to another 8(a) and 8(d) final rule by EPA in the future, demonstrating that TSCA can be both effective and flexible.

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RESPONSES BY GAIL CHARNLEY TO ADDITIONAL QUESTIONS  
FROM SENATOR BOXER

*Question 1.* Provide a list of all of your clients, including their corporate or individual names, and whether they are a not-for-profit organization.

Response. Please refer to my response to Senator Inhofe’s question No. 3.

*Question 2.* Provide a description of the general nature of your work for your clients, including whether you have promoted initiatives to limit the application of Government regulation. Please do not limit your answers merely to work on advisory committees or boards of directors.

Response. Please refer to my response to Senator Inhofe’s question No. 3.

*Question 3.* Please confirm that the Environmental Law Institute is not a paying client of yours.

Response. Please refer to my response to Senator Inhofe’s question No. 3.



**Testimony  
of  
the  
Synthetic Organic Chemical Manufacturers Association**

*Submitted to the*

Senate Committee on  
Environment & Public Works

*On*

"The Toxic Substances Control Act"

*Prepared by*  
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**August 2, 2006**

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**I. Introductory Comments**

SOCMA appreciates the opportunity to submit this testimony regarding the Toxic Substances Control Act (TSCA). Our goal is to describe the unique nature of the batch and specialty chemical manufacturing sector of the U.S. chemical industry and share with you how TSCA allows small companies to thrive in an increasingly competitive marketplace, while protecting public health and the environment.

SOCMA is the leading trade association representing specialty and batch chemical producers. Approximately 90 percent of SOCMA's members are small businesses, according to the definitions established by the Small Business Administration. While commodity chemicals make up most of the production volume in the global marketplace, specialty chemicals make up most of the diversity (the number of different chemicals) in commerce. As a condition of membership to SOCMA, chemical companies must subscribe to our environmental and security management system, called ChemStewards®. This self-imposed program requires companies to develop systematic approaches to environmental and chemical risk management.

SOCMA will focus its remarks today on six specific areas. First, this testimony will highlight the unique nature of specialty chemicals and batch manufacturing. Second, the testimony will cover certain risk assessment and risk management authorities granted to the Environmental Protection Agency (EPA) by Congress and the intent of Congress when crafting the TSCA statute. Third, the testimony will address the evolution of chemical risk management in the United States. Fourth, the testimony will speak to some of the challenges faced by EPA when taking actions under TSCA. Fifth, SOCMA's testimony will briefly address the findings of certain Government Accountability Office (GAO) reports on the effectiveness of the statute. And sixth, this testimony will discuss how regulations can impact small chemical business decisions.

## **II. The Unique Nature and Role of the Batch and Specialty Chemical Manufacturing Sector**

**Specialty chemicals** are used in the development of most every other type of product made in the United States, whether as a building block, raw material, performance additive, ingredient or processing material. Specialty chemicals perform very specific functions, based largely on their molecular structures, which give them unique physical and chemical properties.

Specialty chemicals differ from commodity chemicals in that each one may have only one or two uses, while commodities may have dozens of different applications for each chemical. While commodity chemicals make up most of the production volume (by weight) in the global marketplace, specialty chemicals make up most of the diversity (number of different chemicals) in commerce at any given time.

The specialty chemical economic sector is critical to other manufacturing industries and, therefore, all regional economies. Without these substances, nylon would not be strong enough to use for seatbelts, medicine would revert back to what it was in the 1800s, and our armed forces would not have the equipment and supplies necessary to defend our country.

Although they make up the diversity of chemicals in commerce, the majority of specialty chemicals never come into contact with the public. Many of the substances, called intermediates, are used as building blocks to make other chemicals. The manufacture of chemicals from intermediates takes place at industrial sites in closed processes. The intermediates are totally consumed in the process and no longer exist in the resulting product.

Specialty chemicals are also used as additives to enhance the performance of certain materials, such as the case with nylon. The molecules are often bound in a matrix that

inhibits their release; therefore, the probability that someone could be exposed to the specialty chemical is greatly diminished.

Another term associated with SOCMA is **batch manufacturing**. Commodity chemicals are typically produced in continuous processes, 24 hours a day, 7 days a week. Specialty chemicals, because of their complex chemistries and narrowly focused applications, are frequently produced batch-by-batch in a reaction vessel. Since continuous processes employ continuous feeds and yields, the production volume is usually far greater, per chemical, than for batch processes. The main difference, however, is that a batch process is not necessarily automated, and the chemical reaction (which yields the desired product) has a distinct beginning and ending for each batch.

Batch producers are necessarily flexible and they can make many different products during any given production year. Their business is driven by customer demand, and many chemicals are made on short notice. As a result, the types and quantities of chemicals onsite at a batch manufacturing facility often change from week to week or even day to day.

### **III. Certain Risk Management Authorities Granted to EPA by Congress and the Intent of TSCA**

In 1976, Congress granted EPA broad authority to regulate chemicals in commerce; however, it was the intent of Congress to provide a series of checks-and-balances so that decisions were scientifically and economically sound, and not politically motivated. TSCA allows EPA to collect existing information, require the generation of new information, receive accounts of previously undetected hazards and risks, and manage known risks posed by certain chemicals. The statute also provides the Agency with an opportunity to review new chemicals prior to their introduction into commerce.

While this authority gives EPA the ability to protect human health and the environment, there are provisions in the statute that reduce the likelihood of arbitrary or



politically-motivated decisions. For example, before EPA can require a company to conduct a costly and animal-intensive toxicity test, it must first have a reason for collecting that information. The Agency must find that the substance may pose a risk or is used in such a way that there may be a potential for substantial exposures to the chemical. Requiring these findings ensures that there is a need for EPA to know the information, versus collecting information that is nice-to-know. It also sets the framework for a scientifically and economically sound approach to chemicals management that is tiered and risk-based.

When EPA does find that a chemical presents, or will present, an unreasonable risk, TSCA provides the Agency with very broad authority to take action to reduce the risk. (Note that the word “reduce” is used in this regard. Congress did not intend TSCA to be a zero-risk statute.) EPA can require a company to communicate the risk in a specific fashion, place restrictions on how a chemical is used, ban certain uses and even ban the chemical from the marketplace altogether. Because Congress gave the Agency such broad authority, it also felt the need to ensure that the Executive Branch fully understand the potential consequences of its actions. TSCA requires that EPA fully explore various options to manage the risk, from scientific, economic and social perspectives, because restrictions and bans directly affect a company’s ability to do business in the marketplace and can threaten the survival of a small enterprise.

Upon careful reading of the statute and its history, it is obvious that Congress took great care in trying to strike the balance between protecting human health and the environment and fostering innovation and the vast benefits that come with economic prosperity.

#### **IV. The Evolution of Regulatory Chemical Risk Management in the United States**

To fully appreciate the evolution of regulatory chemical risk management in the United States, it is important to look at TSCA in its entirety and not just individual sections. The first question that could be asked is why a distinction was made between

existing and new chemicals. (This distinction was not only made in the U.S.; in fact, it was made by all regions that established chemical control laws in the 1970s.)

When TSCA was enacted, EPA was required by Section 8 to establish an inventory of chemicals that already existed in commerce and promulgate regulations that required companies to update the information periodically. This was to provide a baseline of information that enabled the Agency to know what was out in the marketplace. Requiring EPA to conduct risk assessments on the existing chemicals all at once was simply not feasible, nor did it make sense. Instead, Congress added provisions to Section 8 that required companies to keep records of alleged significant adverse reactions to any chemical and to report any known substantial risk immediately to the Agency. Congress provided EPA with additional authority under Section 8 to collect existing information related to hazards and exposures, even if the risks were not fully characterized.

If EPA determined that the existing hazard and exposure information was insufficient to adequately determine a chemical's risk, then Congress intended for that information to be used by the Agency to justify requiring companies to conduct additional testing and submit the studies to EPA under TSCA Section 4. Once EPA had sufficient information, if it determined that the chemical posed an unreasonable risk, the Agency could take action under Section 6. The caveat, however, is that EPA would have to fully consider the consequences of its proposed actions.

This approach to chemical risk management is straight-forward and makes sense. However, the implementation phase was not always so easy. Over the years, EPA has faced an enormous amount of pressure from the regulated community, which has been worried about the costs of regulatory compliance, and environmental activists, which have wanted EPA to quickly determine the risks of all chemicals in commerce and take immediate action on those that are found to present risks. To find a balance between the two interests and maintain a workable and scientifically sound regulatory scheme, EPA decided to pursue a tiered, targeted and risk-based approach to chemicals management. Resources would be focused on those chemicals with the greatest potential to cause harm

to the most people. The Agency first tested this novel regulatory concept in the area of new chemicals, which EPA is required to review before they are entered into commerce.

TSCA does not require companies to generate new hazard data for chemicals that they wish to sell into commerce. The intent of Congress was to preserve the high degree of innovation in this country and not place barriers of entry into the marketplace, especially for small business. It can be readily observed that regions requiring testing before a chemical can be sold into commerce do not have as many new chemicals introduced into their regional markets, including new and often safer chemicals. In the absence of measured data, EPA had to devise a way to quickly review a chemical and decide whether or not the chemical could pose an unreasonable risk, or if the Agency needed more information to get a clearer picture.

The Agency proposed that companies would submit processing and use-related information on a form, the pre-manufacture notification (PMN), which would allow EPA technical staff to estimate the concentrations to which people could be exposed. If the estimates indicated a potential for significant exposures, EPA could then restrict certain processes and uses until more hazard information was developed to allow for a more adequate risk characterization. Over time and with the advent of computers, the Agency was able to develop software models to assist in estimating concentrations of chemicals to which people could be exposed.

In addition to novel ways of getting potential exposure information, EPA devised a way to enter into enforceable consent agreements with companies, where the submitter and the Agency would agree to an appropriate battery of tests to further characterize a chemical's hazards. This hazard information would provide greater clarity on the chemical's risk to human health and the environment. EPA was successful in getting companies to submit hazard information because it was not cost effective for a company, under a threat of processing or use restrictions, to fight the Agency in court. In addition, companies that wanted to submit more new chemicals did not want to create any bad will with the Agency that would be reviewing them. Also, EPA chose the reasonable and

workable approach to ask for testing in a tiered manner that used the exposure information to help determine which tests would be appropriate.

EPA has been successful in obtaining hazard and exposure information for new chemicals. During the nearly three decades of chemical reviews, Agency technical staff noticed that the hazard information revealed patterns that could be associated with certain chemicals' molecular structures. Scientists in the field of chemistry already knew that certain physical and chemical properties could be ascertained according to a chemical's molecular structure. (This is really what chemistry is all about: predicting the way that molecules behave.) It was reasonable for Agency scientists to assume that structure-activity relationships (SAR) would hold true for chemical reactions taking place inside the body. However, even to this day, the chemical reactions taking place inside the body are not nearly as well-understood as reactions taking place in a test tube, where most variables can be recognized and controlled.

EPA technical reviewers understood that predicting chemical reactions inside the body, the basis upon which the field of toxicology is based, was in its infancy (and still is, when compared to other natural sciences). The question then became: To achieve protection of human health and the environment, how accurate does EPA have to be when characterizing the hazards of chemicals? If the Agency took a conservative enough approach, then the need for scientific certainty would be diminished accordingly. This is why EPA began estimating ranges of toxicity, versus trying to characterize certain endpoints with exactitude.

A GAO report to Congress in June 2005 on TSCA repeatedly questioned the accuracy of the models used by EPA to review new chemicals. The point that the report misses is that the conservativeness of the models is sufficient to protect human health and the environment. That is not to say that the models cannot be improved. With an ever-increasing amount of data from testing programs, such as the HPV Challenge, and consent agreements under the new chemicals program, EPA will have plenty of data to

begin refining its models. Patience is needed, however, because this should not be an overnight process.

The field of toxicology is still evolving and the discipline should be afforded the same time that it took other natural sciences to develop. The constant demand by some that EPA do everything at an unreasonably rapid pace, like what has been proposed in Europe, is premature and may inhibit the natural evolution of the science. It may also lead to some bad decision-making.

#### **V. EPA's Implementation of TSCA**

While proponents of TSCA reform have pointed out that the statute itself prevents EPA from carrying out its duties, a thorough and careful review of the Federal Register and associated dockets reveals that at least some EPA actions were not as well thought out as they could have been. A review of opinions from related court cases over the years readily demonstrates this fact.

That is not to say SOCMA thinks that EPA has not been doing its job well; on the contrary, when TSCA was passed, chemical risk management was in its infancy, as were certain aspects of the fields of toxicology, exposure assessment and chemical risk assessment. SOCMA believes that EPA has been able to successfully develop ways to achieve the objectives and goals of TSCA, while allowing innovation to foster in the marketplace. In SOCMA's opinion, the main factors contributing to EPA's difficulties in implementing TSCA are more due to its choices in the timing and sequence of Section 4 test rules, and over-reaching bans of uses in Section 6 risk management actions, versus challenges posed by the statute.

For example, if EPA had approached the risk management of asbestos in a step-wise fashion, first concentrating resources on those uses that could result in the highest concentrations of airborne particles, then their chances of success when challenged in court would have dramatically increased. SOCMA believes that trying to ban most uses

of a substance with readily demonstrable, life-saving benefits is, and should be, a challenge for the Agency. Many proponents of TSCA reform point to this one specific case as proof that TSCA does not provide EPA sufficient authority to manage risks. Just reading the opinion of the Court of Appeals for the Fifth Circuit, which is clearly written even for lay audiences, shows where EPA could have maximized their chances for success in regulating the uses of asbestos. The Agency tried to ban a critical use of the substance where there were no readily available substitutes. Further, EPA did not evaluate other risk management approaches short of a ban. SOCMA thinks this is a major factor in why the rule was successfully challenged in court.

It is also the opinion of SOCMA that the Agency's difficulties in promulgating test rules has been less due to statutory requirements placed on EPA, than to decisions in timing and sequence. In most cases, if the Agency had chosen to conduct data call-ins under Section 8 first, then reviewed the available information, especially pertaining to uses and potential exposures, SOCMA believes that the Agency would not have faced the challenges that it has faced when attempting to promulgate the test rules. Since EPA will now be collecting use and exposure information as part of the Inventory updates from industry, issues surrounding the promulgation of Section 4 test rules should diminish.

All things considered, SOCMA believes that EPA is doing a reasonable job in its implementation of TSCA, especially when looking at where the Agency started, where it is now, and its plans for the future. SOCMA also believes that the Agency's moves in the areas of pollution prevention and cooperative partnerships will diminish the necessity of using TSCA regulatory tools to manage chemical risks in the future.

#### **VI. The Findings of the GAO Report and Letter on the Effectiveness of TSCA**

The Government Accountability Office (GAO) produced a report in June 2005, with recommendations to Congress and EPA and, a letter comparing TSCA with the Canadian Environmental Protection Act (CEPA) and the European Union's proposed system for the Registration, Evaluation and Authorization of Chemicals (REACH).

The June 2005 GAO report, *Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, primarily focuses on EPA's history with actions under Sections 4, 5 and 6 of TSCA. SOCMA agrees with some of the findings and recommendations, but thinks that the GAO could have considered other options before suggesting that Congress reopen TSCA to make it easier for EPA to issue more regulations. EPA and other stakeholders in the U.S. have moved toward more cooperative, inclusive and transparent approaches to chemical risk management, so advising Congress to change TSCA seems premature, given that the new approaches have not been given an adequate amount of time for evaluation, nor the opportunity to become fully realized. SOCMA believes that the GAO letter from November 2005, *Chemical Regulation: Approaches in the United States, Canada, and the European Union*, however, is not of the same objectivity and quality as the June 2005 report.

In its November 2005 letter, GAO attempts to compare the two established statutes in North America and the proposed European statute, but the explanations and visual treatments in tables and matrixes demonstrate an observable bias against TSCA. SOCMA is surprised by the presentation of information in this letter and has submitted detailed comments to GAO. Given its history of not wanting to reverse its earlier findings on issues, SOCMA does not expect GAO to give serious consideration to SOCMA's comments. To avoid duplicative work, SOCMA's comments on the GAO letter are attached as an addendum to this testimony.

## **VII. The Effects of Regulations on Small Business Decisions**

Most small chemical companies are batch producers that can make just about any type of chemical substance on short notice. The specialty chemical business is typically driven by customers seeking specific performance from a substance at a reasonable price. Different molecules can provide similar functions at varying degrees of performance, which makes the specialty chemical sector very competitive. Profit margins are usually thin in specialties markets and the protection of sensitive business information is critical

to the survival of a small company, because is it one of the only economic advantages a small player can obtain over its larger competitors.

Proponents of TSCA reform claim that a change in regulations can somehow change the demand for goods and services. SOCMA believes that short of a ban, even when environmental attributes are considered, the fundamental, economic principles of supply and demand for chemicals will continue to be driven by performance and price. This is readily demonstrated on a daily basis in households throughout the country. Many consumer cleaning products contain well-known hazardous ingredients, such as sodium hypochlorite, caustic soda or various strong mineral acids. Yet, they are properly used by consumers every day, because the U.S. public is willing to accept certain degrees of risk to achieve a higher standard of living.

Business decisions made by U.S. chemical companies are, and will continue to be, driven by consumer demand, whether the consumer is another company or the general public. The fundamental principles of supply and demand have been followed for millennia, but various parties have tried to manipulate those principles throughout history, without much luck. Businesses that follow sound economic principles are better positioned to succeed than those that do not.

A small chemical business, which can make anything at any time, will respond to exhaustive regulatory pressures, such as increasing testing costs, by leaving a particular market and moving to another that is less restrictive or costly. This type of decision will not reduce the demand for the chemical they were producing, it will just shorten the supply. According to economic principles, the supply shortage will actually result in an increase in prices for that chemical.

Innovation of new, and often safer, chemical will also suffer due to several factors beyond the demand for a particular substance. First, as the barrier of entry into the marketplace increases, the number of entrants tends to decrease, as does competition. If the barrier is attributable to increasing costs related to government decisions, then there is



incentive for companies to move operations to areas of less government intervention and less operating costs. Second, most costs associated with chemical testing come from R&D budgets. As R&D budgets dwindle, fewer resources will be dedicated to the discovery of new substances.

Small business decisions in the chemical industry follow the principles of economics. Any attempt to cater to an artificial demand is doomed to fail, which has been demonstrated throughout history.

### **VIII. Conclusion**

TSCA is a typical example of how the founding fathers envisioned the operations of our government. A thorough study of the TSCA statute and the Congressional Record clearly reflects that Congress has given EPA broad authority to regulate chemicals in commerce. The intent of Congress, protection of human health and the environment, while maintaining an appropriate system of checks-and-balances, is also clear in both the statute and the Record.

While TSCA is not necessarily a perfect statute, SOCMA believes it has allowed small chemical businesses to survive in an increasingly competitive market. SOCMA also believes that it is premature to reform TSCA and make it more like the approach proposed by the European Commission. REACH is a regulatory concept that has never been attempted anywhere in the world. The economic consequences of such an approach are predicted to be very significant and raise the barriers of entry into the European marketplace. REACH will also make it difficult for small businesses to survive in Europe. SOCMA urges Congress and EPA to continue chemical risk management with TSCA as it is currently written, and wait until the effects of REACH can be evaluated before venturing down a similar path.

Mr. Chairman, members of the Committee, thank for the opportunity to submit these comments.

## **Addendum 1**

**Synthetic Organic Chemical Manufacturers Association**

COMMENTS

on

*Chemical Regulation: Approaches in the United States, Canada,  
and the European Union  
November 4, 2005*

James R. Cooper  
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March 16, 2006

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**Introduction**

Since 1921, the Synthetic Organic Chemical Manufacturers Association (SOCMA) has been the leading trade association representing approximately 300 specialty and batch chemical manufacturers and importers—an innovative, entrepreneurial and customer-driven sector of the chemical industry. Around 75% of SOCMA members are small businesses, according to the Small Business Administration. While large companies are also members of the association, primarily represented through their specialty chemical divisions and related businesses, SOCMA principally speaks for and serves batch, custom and small chemical companies.

**Specialty chemicals** are materials with highly specialized physical or performance functions, which are the result of certain atoms being attached to a molecule in very specific locations. The specialty chemical economic sector is critical to most other manufacturing industries and, therefore, all regional economies. Specialty chemicals are used in the development of most every other type of product, whether as a building block, raw material, performance additive, ingredient or processing material.

Specialty chemicals differ from commodity chemicals in that each one may have only one or two uses, while commodities may have dozens of different applications for each chemical. While commodity chemicals make up most of the production volume (by weight) in the global marketplace, specialty chemicals make up most of the diversity (number of different chemicals) in commerce at any given time.

Another term associated with SOCMA is **batch manufacturing**. Commodity chemicals are typically produced in continuous processes, 24 hours a day, 7 days a week. Specialty chemicals, because of their complex chemistries and narrowly focused applications, are frequently produced batch-by-batch in a reaction vessel. Since continuous processes employ continuous feeds and yields, the production volume is usually far greater, per chemical, than for batch processes. The main difference, however, is that a batch process is not necessarily automated, and the chemical reaction (which yields the desired product) has a distinct beginning and ending for each batch.

SOCMA is in the unique position of representing the most diverse chemistries in the industry. This technical expertise allows SOCMA to provide insights that are scientifically based and drawn from real-world experience, not just theory. SOCMA's staff and member company representatives are routinely consulted for their unique technical perspectives and practicality. SOCMA avails its resources to industry partners, government and other stakeholders interested in chemistry and engineering.

#### **General Observations**

SOCMA appreciates the opportunity to provide comments on your letter to Senators Jeffords, Lautenberg and Leahy, dated November 4, 2005. While preparing these comments, SOCMA tried to look at several different perspectives. First, SOCMA attempted to put itself into the shoes of an uninitiated person, not familiar with the intricacies of chemical controls. Also, SOCMA tried to read the letter from an EPA perspective to get a better feel for the language and balance. In addition to those perspectives, SOCMA looked at the letter from a technical perspective as well.

SOCMA views the expanded work on this letter as very important to the future of chemical controls in the United States. SOCMA urges the Government Accountability Office to convey to the requestors that great care, and possibly more time, must be taken in the current work because of its potential impact on chemical and downstream manufacturing. TSCA is one of the few laws in the United States that directly impacts a company's ability to sell goods in the marketplace. The importance of this and other chemical control practices cannot be overemphasized.

Innovation has been fostered in this country because our chemical controls are based on risk, sound science and fundamental economic principles. The number of new and often safer chemicals introduced into the US marketplace is orders of magnitude higher than in other developed economies. Innovations in commercial chemistry are directly attributable to the original intent of Congress when drafting TSCA and EPA's implementation of the statute. While innovation has continued, TSCA and other chemical control practices, both regulatory and voluntary, have also served to protect

human health and the environment as well as other chemical control laws. Please consider the comments offered here when updating the GAO report to Congress.

Because the tone and language varies for each different law's descriptions found in the GAO letter, dated November 4, 2005, a person who does not have a great deal of experience in these matters will walk away with a bias against TSCA. In addition, because the report does not address peripheral statutes, regulations and practices that also serve as chemical controls and the very nature of law in each of the different regions, there are inherent gaps in the overall discussion of how chemicals are controlled in each region.

One significant item missing from the letter is the fact that a system like REACH has never been implemented anywhere in the world. The report should mention the extreme difficulty in comparing a system that is still in development and has yet to be implemented with those that are well-established over decades. The realities of REACH, such as the timing for evaluations, regulatory actions and enforcement, may be much different than what is being touted by its proponents. In fact, the report pays little attention to enforcement history under the different laws and regulations, which has great bearing on measuring the success of a given law. Without a comparison of enforcement approaches and history, it is very difficult to provide an objective evaluation of the effectiveness of different laws.

#### **Comments on Differences in Regional Governance and Law**

Because the GAO letter is a comparison between different laws in different regions (US, Canada, EU), it would benefit readers to add a section on the various methods to write federal-level legislation and implementing regulations. For example, the political systems in the US, Canada and EU are quite different, which can help explain why the approaches to writing federal statutes is different. The federal statutes in Europe tend to be much more detailed than in the US; in fact, the proposed language for REACH also contains the actual regulatory requirements. In the US, on the other hand, federal statutes

tend to give broad discretion to the implementing authority and are generally not as detailed.

An additional factor that should be briefly explored in the letter is the difference in tort law between regions. Liability is a significant determinant in how federal laws are written. Because the US has such a comprehensive tort history, laws can afford to appear less protective than in regions where those subject to regulations are not as affected by liability. Liability in the US is every bit as protective as any environmental or health statute.

#### **Comments on the Introductory Section**

In the introductory section that introduces the different laws—specifically, paragraphs 1 through 5 on Pages 2 and 3—statistical data is presented on how often EPA has required testing or taken risk reduction actions on chemicals in commerce. There is no such information provided in the CEPA and European Union descriptions. For a more adequate comparison, there should be similar data provided on the number of chemicals for which testing has been required under each of the laws and, the number of risk reduction actions taken under each law. Without the numbers to allow for a direct comparison, it could be perceived that TSCA or EPA's implementation of TSCA is ineffective, which is not an appropriate depiction.

In the text and footnotes of the introductory paragraphs, the author gives the approximate number of chemicals on each of the different inventories. The actual number of chemicals in commerce at volumes above research and development during any given year, however, is only a subset (for the US, approximately 8,000 to 10,000) of the total inventory. These figures can be derived from the required reporting of production and importation volumes to government authorities.

In the third paragraph on Page 4, the author attempts to compare requirements on authorities to determine the costs of regulatory actions. The author uses an opinion of the Court of Appeals for the Fifth Circuit to demonstrate differences between the laws. The

example given was a supposed finding, which states that costs are a factor in determining whether or not action should be taken by EPA. The author may have misinterpreted the opinion of the court. The court concluded that EPA did not fully evaluate the cost of alternative actions, nor did the Agency effectively quantify the benefits of the regulatory action. The court did not express an opinion that costs must be a factor in deciding whether or not any action should have been taken at all.

A more appropriate method to analyze cost-benefit requirements among different laws is by comparing the actual statutory language, not a court's interpretation of that language. Under TSCA Section 6(c), the statute states that EPA must consider "the reasonably ascertainable economic consequences" when promulgating a rule. When risks can be mitigated through a different statute, the Administrator is required to compare the costs of action (i.e., cost of action under TSCA versus under a different law). There is nothing in Section 6 that requires EPA to use cost as a determining factor for regulatory action. In fact, the well-established chemical control laws in the US, Canada and EU are similar in this regard. They all require cost-benefit analysis when authorities propose restrictive regulatory actions.

In the last paragraph of Page 4, the author states that EPA is not required to prioritize existing chemicals for risk assessment. This statement is not entirely accurate. Under TSCA Section 4(e), a committee (Interagency Testing Committee) is established to advise EPA on which chemicals—in the form of a list—should take priority for testing, evaluation and potential regulatory action. EPA is required to either take action on those substances or publicly state why it is not taking action, which is an open process subject to public comment.

When discussing how statutes treat new chemicals (1<sup>st</sup> Paragraph, Page 5), the author only mentions whether or not each law requires test data. A more complete depiction of how new chemicals are treated should include a comparison of the evaluation processes, not just whether or not measured data are required. For example, EPA uses very conservative modeling to evaluate new chemicals. In a report to one of the National



Pollution Prevention and Toxics Advisory Committee's (NPPTAC) work groups, EPA analyzed Section 8 risk notifications for chemicals on the inventory that went through the new chemicals process and readily demonstrated that the Agency's evaluations are as protective of human health and the environment as the new chemicals processes under other regions' laws.

**Comments on *Approaches to Controlling Chemical Risks***

In this section, the author goes into detail on requirements EPA must meet and studies it must conduct under TSCA before taking risk management actions. The brief paragraphs describing the other laws do not go into such detail, nor do they mention the findings the authorities must meet and analyses (i.e., cost-benefit) that they must conduct under similar circumstances. Rather, the author lists the options available to authorities under the different laws. This makes TSCA appear much more burdensome than the other laws. Also, the purported "high evidentiary burden" under TSCA relies primarily on a single court opinion. There is no mention of court cases or decisions regarding the other regions' laws, which may bias the reader's conclusions. The laws in Canada and Europe (including REACH) also have certain risk thresholds that the authorities must meet to take risk management actions, as well as requirements for consideration of cost-benefit and evaluation of potential alternatives. In this regard, the laws are more similar than the report would imply.

As previously stated, the author may have misconstrued the opinion of the Court of Appeals for the Fifth Circuit. The court did not say that cost should be a factor in determining risk. Rather, the opinion stated that EPA failed to compare the costs of intermediate alternatives and did not quantify the benefits of the action. The statement under the CEPA description that costs and benefits "are not factors in determining...risk" is misleading. EPA scientists consider inherent hazards, such as toxicity, and the potential for exposure when determining risk, not regulatory costs. US, Canadian and European authorities, however, are all required to compare the costs and benefits of their regulatory actions and the cost of alternatives. This is also true under the proposed REACH system.

One important aspect missing is no mention of the Enforceable Consent Agreement (ECA), which is a legally binding instrument used by EPA to obtain risk information and require risk management actions. While ECAs may not be part of the TSCA language, they are not precluded by the statute and are a common control measure used by EPA.

**Comments on *Approaches to Reviewing Existing Chemicals***

The first paragraph of this section states that “TSCA does not require EPA to prioritize and review existing chemicals.” Under TSCA Section 4(e), a committee (Interagency Testing Committee) is established to advise EPA on which chemicals—in the form of a list—should take priority for testing, evaluation and potential regulatory action. EPA is required to either take action on those substances or state why it is not taking action, which is an open process subject to public comment.

In general, while the use of tables can assist readers in quickly comparing different programs, their use may be inappropriate in this report because of the complexities surrounding the approaches used by each of the authorities. Relegating the complete descriptions to footnotes gives the appearance that these details are less important than the information found in the tables.

The first row in Table 1 (Page 8) further illustrates the potential appearance of bias in the GAO letter, especially Columns 1 and 2. For the TSCA column, the author’s simple answer was “No, [u]nless EPA promulgates a test rule...” In the second column is a more thorough explanation that the authorities in Canada “may publish a notice requiring submission of existing information” and, if appropriately determined, the authorities can require testing. In actuality, EPA also has the authority under TSCA Section 8 to require submission of existing data, which are then used to determine if further testing is necessary under Section 4. There is little difference between a “notice” being published in the Canada Gazette and a notice appearing in the US Federal Register. Both are similar in this regard, but the Table entries do not reflect the similarities.

The second row in Table 1 asks about data requirements for existing chemicals. The entry for TSCA is simply “[n]o, unless EPA promulgates a test rule,” while the entries for Canada and the EU are no, but are accompanied by explanations of how the governments can require the submission of existing data and subsequent testing to fill in data gaps. The same is true for TSCA, but this fact is not reflected in the table. Under Section 8, EPA can require companies to submit existing data. Section 4 of TSCA can be used to fill data gaps. In reality, voluntary programs in the US, such as the HPV Challenge, have resulted in more publicly available data than in Canada and the EU combined.

In the third row in Table 1, which discusses prioritization and assessment of existing chemicals, the answer in the TSCA column should be yes. TSCA requires the formation of the ITC and mandates a response to the ITC priority list. These are legal requirements built into the statute; therefore, there is a requirement for prioritizing and assessing chemicals. The entry for Canada fails to mention the fact that Canada uses simple models to conduct the categorization and assessment of its inventory of existing chemicals. The entry for the EU goes into detail about how the authorities draw up lists for the submission of existing data. This approach is similar to the ITC approach and the use of Section 8 to require the submission of existing data under TSCA, but again the table does not reflect this.

The fourth row of Table 1 exemplifies the potential for the appearance of bias. Columns 1 and 2 say essentially the same thing (except for the IUR); however, the tone is quite different. The entry for Canada is softer in tone because the sentence states that companies are not “generally” required to report new uses unless they are “specified” on the DSL. There is no explanation of how a substance gets specified (i.e., the regulatory process). The TSCA entry, on the other hand, is much more direct and states simply that “[c]ompanies are not required to notify” the agency of new uses, unless EPA promulgates a rule. The difference in language gives the appearance that it is more difficult to mandate new use notifications under TSCA than it is under CEPA, which may not be the case.

The entry under TSCA does include a brief statement that uses will be reported under the updated IUR. Since it is now 2006, perhaps this should be the lead sentence for the entry.

In the fifth row of Table 1, under the TSCA column, there should be mention of the Pollution Prevention Act, using similar language to that of the Canadian column. Relegating information on the P2 Act to footnotes does not give readers the impression that there are strong P2 programs in the US. The Integrated P2 and Control Directive should also be mentioned in the EU column.

#### **Comments on *Approaches to Reviewing New Chemicals***

In the first paragraph of this section, there is actually little attention paid to the review processes practiced by the authorities. Rather, the report focuses mainly on whether or not hazard data are required along with the new chemical notification. Generation of hazard data is only a small part of the review process. Because TSCA does not require the generation of new hazard data for new chemicals notifications, it gives the appearance that EPA has little information from which to make decisions. This is not the case. EPA uses data from analogous molecules and very conservative (i.e., protective) modeling, in addition to the information on manufacturing, use and disposal on the premanufacture notice (PMN), when evaluating new chemicals for risks. More details on the actual review processes would provide a more balanced view of how new chemicals are treated in each region.

The last row in Table 2 (Page 14) also reveals a difference in tone. All entries, except for the TSCA column, begin with "However," which softens the tone considerably. The author also missed a key element on the PMN form (Page 7, Section C, Number 1), which asks for an estimate of subsequent maximum annual production. In addition, the TSCA column should describe reporting for chemicals on the inventory in a similar fashion to the descriptions in the other columns. Because the column only mentions that substances on the inventory are subject to the IUR, and the other columns provide details on how production is reported to authorities, it gives the impression that under TSCA companies are not required to submit quantities at all. In fact, under the IUR companies

are now required to submit information related to use and exposure (for volumes greater than 300,000 pounds per year), in addition to production and importation volumes. EPA has found that annual reporting of production is not necessary because production does not change dramatically from year to year. The Agency has data to demonstrate, however, that production does change over the course of a few years.

***Comments on Approaches to Confidential Business Information***

The lead-in sentence for the second paragraph is unnecessarily strong and its claim questionable. Health and safety information submitted under TSCA cannot be claimed as CBI and, therefore, is routinely made available to the public through a variety of means. Most of the information claimed as confidential, on the other hand, would not further inform the public of the risks that a particular chemical may pose. Confidential information typically relates to specific chemical identities and their manufacturers, processing descriptions and other information that would allow others to usurp the intellectual property of their competitors. The second sentence in the same paragraph makes it sound like the other authorities are not required to protect “trade secrets and privileged or confidential or financial information,” which is clearly not the case. All chemical control laws in economies with well-established chemical industries have CBI provisions because they protect small businesses from predatory behavior. It is one of the only means in which a small firm can gain a competitive advantage in the marketplace. In fact, the US has strong CBI protection, which is the lifeblood of innovation in this country. A plausible measurement of innovation can be derived from the number of new molecules submitted under the different laws. The average number of new substances submitted annually in the US is orders of magnitude higher than in Canada or the EU.

The description of the Canadian and European treatment of CBI can also be said for TSCA. Under Section 14(a), the Administrator can disclose certain information to protect human health and the environment from unreasonable risks. Also, generic names and generic use descriptions cannot be claimed as CBI, nor can data from health and safety studies.

Readers of this section would find value in an explanation of why confidentiality is built into chemical control laws, how it impacts small businesses and how it can affect innovation.

**Conclusion**

An uninitiated reader of this GAO letter will be left with the impression that chemical controls in the US are more burdensome to implement and not as effective as laws in Canada or Europe. While TSCA does impose certain requirements on EPA before it can take substantial risk reduction actions, the same holds true for the laws in Canada and Europe. Even the proposed REACH system requires the weighing of cost and benefit, as well as an evaluation of potential substitutes.

SOCMA urges the GAO to reconsider the tone and specific language used to describe certain aspects of the chemical control laws in a subsequent report to the Senate requestors. Additionally, SOCMA believes it necessary to provide more background information regarding governance, tort law, confidential business information and other circumstances that can help explain the differences in the ways laws are written in the covered regions. Without such explanations, this report will not be able to achieve the balance necessary for truly informed decision-making.

Again, SOCMA appreciates the opportunity to provide comment on this and other reports related to chemical controls.



The Deirdre Imus Environmental Center for Pediatric Oncology®

Testimony of Deirdre Imus  
President/Founder of The Deirdre Imus  
Environmental Center for  
Pediatric Oncology,  
Hackensack University Medical Center  
To Environment & Public Works Committee  
S.1391 – Bill to Amend the TSCA  
August 2, 2006

Good morning, I am Deirdre Imus, president and founder of the Deirdre Imus Environmental Center for Pediatric Oncology at Hackensack University Medical Center, a not-for-profit 501-(C) 3 corporation. Thank you for the opportunity to speak today.

Our Center's mission is to identify, control, and ultimately prevent environmental factors that may cause adult, and especially, pediatric cancer, as well as other health problems with our children.

The facts are shocking. Chronic diseases have increased sharply in incidence and have become the leading causes of childhood illness: Children's cancer is still the leading cause of death by disease. We've seen a six-fold increase in attention deficit disorder, a condition almost unknown a generation ago. An appalling diet has produced an epidemic in childhood obesity, and diabetes is at nearly epidemic proportions. The rate of premature births increased 21% between 1981 and 2001 and the third most common chronic disease in childhood is arthritis. Respiratory problems such as asthma are the leading cause of absenteeism in schools. One in every 166 children in this country is diagnosed with autism. One of every six kids is diagnosed with a learning disability. And the list goes on.

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Although much still remains to be learned about the causes of these trends, evidence is accumulating that environmental factors such as toxic chemicals found in our soil, air, water, food, building materials and clothing, may be a contributing factor. We witness everyday the serious consequences caused by these chemical toxins and how they threaten the health of our children. Pound for pound of body weight children take in more air, water and food than adults do. They also play close to the ground, and have frequent hand-to-mouth activity, which makes them more susceptible than adults to environmental toxins. Unfortunately, this means proportionally our children absorb more toxins than we adults. This presents us with a huge responsibility and important opportunity to do more for our children.

Typically, ingredients in industrial products that have been tested are based on an adult male and never consider the potential impact on children. Over 82 thousand chemicals are present in our environment and fewer than two percent have been fully checked by the EPA for safety. This must change.

The Toxic Substances Control Act gives the EPA the ability to track these industrial chemicals currently produced or imported into the U.S. Despite the Act's intent to protect the public from harmful chemicals, none have been reviewed for their toxic effect on our children, who are far more vulnerable. The TSCA also does not consider the health effects of exposures to multiple chemicals from a single product, or the cumulative health affects of exposures to multiple chemicals over time, also known as "body burden".

We want to eliminate where possible, these exposures to carcinogens, neurotoxins, hormone disruptors and endocrine disruptors that are making our kids sick. It makes common sense to do this. What doesn't make sense is to unnecessarily expose our kids to these toxins.

In conclusion, the TSCA has not delivered on its objective to protect the public, especially children, from the serious and even potentially deadly affects of toxins in everyday consumer products. We fully support Senator Lautenberg's efforts to amend this act requiring chemical manufacturers to prove a substance's safety before it is allowed on the market.

After all, children are our most precious natural resource.

Thank you for the opportunity to speak today.



**DRAFT – DRAFT – DRAFT**  
**IN DEFENSE OF TSCA SECTION 6:**  
**AN EXPLANATION OF *CORROSION PROOF FITTINGS***

By

**William K. Rawson**  
**Latham & Watkins LLP**

**July 26, 2006**

EPA's ability to regulate effectively under Section 6 of TSCA<sup>1</sup> has been called into question over the years because of the Fifth Circuit's decision in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5<sup>th</sup> Cir. 1991), which overturned EPA's ban on certain asbestos-containing products. Some have argued that Section 6 of TSCA places too heavy a burden on EPA to justify its regulations. If EPA cannot ban asbestos, the argument goes, then what can it ban? A recent U.S. Government Accountability Office ("GAO") report suggests ways that the legal requirements of TSCA Section 6 might be loosened, ostensibly to make EPA's job easier.<sup>2</sup> A close examination of the court's opinion in *Corrosion Proof Fittings*, however, shows that the failures in the asbestos rulemaking were failures in implementation, and not caused by deficiencies in the statute. EPA's experience in that rulemaking does not warrant changes to TSCA Section 6. To the contrary, EPA's successful regulation of other compounds under Section 6 of TSCA demonstrates that it can be done. Moreover, the suggested changes to TSCA Section 6 would not provide an improved basis for regulatory decision-making.

**TSCA Section 6**

Section 6(a) of TSCA<sup>3</sup> gives EPA authority to regulate the manufacture, processing, distribution, use or disposal of a chemical if the Agency has a "reasonable basis" to believe the chemical "presents or will present an unreasonable risk to health or the environment."<sup>4</sup> Section 6 enumerates various regulatory options -- from an outright ban to warning and labeling requirements -- and provides that EPA may impose one or more of the enumerated requirements "to the extent necessary to protect adequately against such risk *using the least burdensome*

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<sup>1</sup> 15 U.S.C. § 2605.

<sup>2</sup> GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* (June 2005) [hereinafter "GAO Report"].

<sup>3</sup> 15 U.S.C. § 2605(a). Separate authority to regulate polychlorinated biphenyls (PCBs) is contained in TSCA Section 6(e), 15 U.S.C. § 2605(e). This article addresses EPA's general authority set forth at Section 6(a-d).

<sup>4</sup> 15 U.S.C. § 2605(a), (a)(1)(A-B).

*requirements.*<sup>5</sup> When promulgating rules under Section 6, EPA must take into account the health and environmental effects of the substance, the magnitude of exposure, the benefits of the substance, the availability of substitutes, and the reasonably ascertainable economic consequences of the proposed rule.<sup>6</sup> A rule promulgated under Section 6 of TSCA must be supported by “substantial evidence” in the rulemaking record considered as a whole.<sup>7</sup>

Further, before EPA can regulate under Section 6(a), the Agency must determine whether the problem could be better addressed under another statute. If the risk of injury to health or the environment can be eliminated or reduced under a statute administered by EPA other than TSCA, then EPA must utilize the other statute unless the Agency determines that it is in the public interest to act under TSCA.<sup>8</sup> Additionally, if the chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA, the Agency must refer information on the chemical’s risk to the agency administering the other law. EPA may not take action under TSCA Section 6 if the other agency finds no unreasonable risk or initiates regulatory action.<sup>9</sup>

#### **Regulation of Other Compounds Under TSCA Section 6**

In the early years of TSCA, EPA regulated several substances under TSCA Section 6(a). The rules described below provide evidence that Section 6(a) can work.

**Halogenated chlorofluoroalkanes.** Starting in 1978, EPA used TSCA Section 6(a) to ban nonessential uses of fully halogenated chlorofluoroalkanes, which were used primarily as propellants for aerosols.<sup>10</sup> The final rule prohibited almost all manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes, because the chemicals

<sup>5</sup> 15 U.S.C. § 2605(a) (emphasis added). The specific regulatory options include: an outright ban on all manufacturing, processing and distribution; a ban on particular uses; production volume limits generally or for specific uses; concentration limits generally or for specific products; specifying warnings and instructions that must accompany the substance or any article containing the substance; restrictions on any method or manner of commercial use; regulations pertaining to disposal of the substance or any article containing the substance; and a requirement that manufacturers and processors of the substance give warning of the unreasonable risk of injury to distributors or others in possession of the substance, give public notice of the unreasonable risk, and replace or repurchase the substance at the election of the person(s) receiving the warning. *Id.*

<sup>6</sup> 15 U.S.C. § 2605(c)(1).

<sup>7</sup> 15 U.S.C. § 2618(c)(1)(B)(i).

<sup>8</sup> 15 U.S.C. § 2605(c).

<sup>9</sup> TSCA Section 9(a), 15 U.S.C. § 2608(a).

<sup>10</sup> See 42 Fed. Reg. 24542, 24545 (May 13, 1977) (proposed rule); 43 Fed. Reg. 11318 (March 17, 1978) (final rule). In 1995, EPA banned fully halogenated chlorofluoroalkanes under the Clean Air Act and the TSCA Section 6 regulation was made obsolete. 60 Fed. Reg. 31917 (June 19, 1995).

contributed to the depletion of the stratospheric ozone layer, thereby increasing UV radiation exposure which in turn had been shown to cause increased skin cancer.<sup>11</sup> EPA determined that the stratospheric ozone depletion caused by fully halogenated chlorofluoroalkanes presented an “unreasonable risk of injury to health and the environment”.<sup>12</sup> EPA considered but rejected less burdensome alternatives, such as labels, and reduced the economic impact of the regulations by delaying implementation of the manufacturing ban for 18 months.<sup>13</sup>

**TCDD.** In 1980, EPA issued a rule under TSCA Section 6(a) regulating disposal of wastes containing 2,3,7,8-Tetrachlorodibenzo-p-dioxin (“TCDD”, a form of dioxin).<sup>14</sup> The final rule required Vertac Chemical Company (“Vertac”) to keep and monitor wastes produced and contaminated with TCDDs before implementation of the final rule at Vertac’s facility in Arkansas, but allowed Vertac to dispose of any TCDD-contaminated wastes generated after the date of the final rule in landfills meeting EPA’s approval.<sup>15</sup> The rule also required any entity desiring to dispose of waste containing TCDDs to notify EPA of such intent at least sixty days before the disposal.<sup>16</sup> EPA considered the economic impact of its final rule on Vertac and other potential disposers of TCDD-contaminated waste, and, based on economic considerations, allowed TCDD-contaminated waste created after the rule was issued to be stored in landfills.<sup>17</sup>

**Hexavalent chromium.** In 1990, EPA issued a final rule prohibiting the use of hexavalent chromium-based water treatment chemicals in comfort cooling towers.<sup>18</sup> The rule required water treatment chemical distributors to label hexavalent chromium-based water treatment chemicals with a warning that hexavalent chromium air emissions increased the risk of lung cancer when inhaled, and that use of water treatment chemicals containing hexavalent chromium in comfort

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<sup>11</sup> 43 Fed. Reg. 11318 (Mar. 17, 1978).

<sup>12</sup> 43 Fed. Reg. at 11319.

<sup>13</sup> *Id.*

<sup>14</sup> 45 Fed. Reg. 32676 (May 19, 1980). This regulation was superseded by the enactment of a regulation under the Resource Conservation and Recovery Act in 1985 that made the TSCA regulation obsolete. 50 Fed. Reg. 2003 (Jan. 14, 1985).

<sup>15</sup> At the time of the final rule, Vertac had 3200 drums of TCDD-contaminated wastes stored on a diked concrete slab covered by a fixed metal roof, and pursuant to state administrative order Vertac was required to monitor the drums for any potential leakage. 45 Fed. Reg. at 32677. EPA determined that disposal of the drums in landfills would present risks to human health and the environment because the drums would not be under a roof or monitored for leakage. *Id.* at 32677-78.

<sup>16</sup> 45 Fed. Reg. at 32677.

<sup>17</sup> *Id.* at 32680-81.

<sup>18</sup> 55 Fed. Reg. 222 (Jan. 3, 1990). Comfort cooling towers are “dedicated exclusively to and are an integral part of heating, ventilation and air conditioning or refrigeration systems.” 40 C.F.R. § 749.68(d)(4). EPA amended its hexavalent chromium regulation in 1994 to clarify that only hexavalent chromium chemicals that are used for water treatment were the subject of EPA’s regulation. 59 Fed. Reg. 42769 (Aug. 19, 1994).

cooling towers was prohibited. Although EPA acknowledged that it would be possible to regulate the use of hexavalent chromium in comfort cooling towers under the Clean Air Act, it determined that it was more efficient to regulate the chemical under TSCA Section 6.<sup>19</sup>

**PMN Substances.** In 1984, EPA issued three immediately effective proposed rules under TSCA Section 6(a) to address unreasonable risks identified during the review of premanufacture notices (PMNs) for three new chemical substances under TSCA Section 5.<sup>20</sup> The chemical substances affected by the rule were: triethanolamine salt of tricarboxylic acid, tricarboxylic acid, and triethanolamine salt of a substituted organic acid. These chemical substances were intended for use in metalworking fluids. In each case, EPA was concerned that the addition of certain nitrosating agents to metalworking fluids containing the PMN substances could lead to the formation of nitrosodiethanolamine (NDELA), which has been shown to be carcinogenic in animals.<sup>21</sup> Accordingly, EPA's proposed rules banned the use of nitrosating agents in metalworking fluids containing the PMN substances. Moreover, EPA used its authority under TSCA Section 5(f)(2) to make the proposed rule under Section 6(a) effective immediately.<sup>22</sup> EPA also required the distributors of the PMN substances to notify customers of the restrictions of the rule. Distributors also were also required to notify machine shop workers of the potential health hazard through labels on metalworking fluids containing the regulated substances. These proposed rules remain in effect today.

Each of the above-described rulemakings was unique, and it is probably fair to say that none presented the complexity and challenges of the asbestos rule, which is described below. Also, none were challenged judicially. Nevertheless, they provide examples of successful regulation under TSCA Section 6.

#### **EPA Asbestos Rule**

EPA's asbestos rule under TSCA Section 6 was promulgated in 1989 and banned most uses of asbestos still in commerce, including asbestos-containing floor materials, clothing, roofing and other building materials, pipeline wrap, friction products (e.g. brakes), and other automotive products.<sup>23</sup> EPA made a determination that regulation under TSCA Section 6 would be more effective than relying on other federal agencies to address the health risks posed by the

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<sup>19</sup> 55 Fed. Reg. at 230.

<sup>20</sup> 49 Fed. Reg. 2762 (Jan. 23, 1984); 49 Fed. Reg. 24658 (June 14, 1984); 49 Fed. Reg. 36846 (Sept. 20, 1984).

<sup>21</sup> 49 Fed. Reg. at 2763-64, 24659, 36848.

<sup>22</sup> TSCA Section 5(f)(2) provides that if EPA determines a new chemical substance "presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 2605 [Section 6] of this title can protect against such risk," the Agency may issue a proposed rule under TSCA Section 6(a) that is effective upon its publication in the Federal Register. 15 U.S.C. § 2604(f)(2).

<sup>23</sup> 54 Fed. Reg. 29460, 29461 (July 12, 1989).

manufacture and use of asbestos.<sup>24</sup> The bans were to take place in three stages over a period of seven years.<sup>25</sup> EPA also banned all new uses of asbestos, and all existing uses that were not currently in production in the U.S.<sup>26</sup> These latter bans were effective immediately.<sup>27</sup>

EPA's final asbestos rule was the culmination of more than 10 years of effort.<sup>28</sup> The rulemaking record consisted of more than 45,000 pages of analysis, comments, testimony and other materials.<sup>29</sup> EPA held hearings in July 1986, and an additional hearing in October 1986.<sup>30</sup> EPA presented the testimony of numerous witnesses, and heard testimony from many more witnesses presented by interested parties.<sup>31</sup> In all, at least 200 interested parties submitted comments on the proposed rule.<sup>32</sup>

### Court Decision

The court upheld EPA's determination to proceed under TSCA Section 6, instead of deferring to other federal agencies under TSCA Section 9.<sup>33</sup> The court also upheld EPA's ban on products not being produced in the United States currently, and the ban on unknown, future uses of

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<sup>24</sup> At the time of EPA's proposed asbestos regulation, asbestos-related regulations had been promulgated by OSHA, FDA, Mine Safety and Health Administration, and the CPSC. *See* 29 C.F.R. §§ 1910.1001, 1926.1101 (OSHA workplace exposure limits); 16 C.F.R. § 1500.17 (FDA ban on general-use garments containing asbestos unless used for protection against fire); 30 C.F.R. § 56.5001 (regulations pertaining to asbestos exposure in mines); 16 C.F.R. §§ 1304-05 (CPSC ban on consumer patching compounds containing respirable asbestos, and requires labeling for other products containing respirable asbestos). EPA also had regulated asbestos under the Clean Air Act. *See* 40 C.F.R. Part 61.

<sup>25</sup> 54 Fed. Reg. at 29461.

<sup>26</sup> *Id.* at 29462.

<sup>27</sup> *Id.* at 29461.

<sup>28</sup> 54 Fed. Reg. 29460 (July 12, 1989) (final rule); 51 Fed. Reg. 3738 (Jan. 29, 1986) (proposed rule); 47 Fed. Reg. 33207 (July 30, 1982) (rule under TSCA Section 8(a) requiring the reporting to EPA of information on the quantity of asbestos used in making products, employee exposure data, and waste disposal and pollution control equipment data – to assist EPA in its asbestos rulemaking); 44 Fed. Reg. 60061 (Oct. 17, 1979) (advance notice of proposed rule).

<sup>29</sup> 54 Fed. Reg. at 29461.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Corrosion Proof Fittings*, 947 F.2d at 1216. EPA rejected deferring to other government agencies because EPA believed no other agency could effectively regulate "throughout the life cycle" of asbestos. *Id.*

asbestos.<sup>34</sup> Concerning the bans on existing asbestos-containing products, the court articulated a “presumption of validity” in favor of EPA’s rule,<sup>35</sup> and rejected a number of arguments advanced by industry petitioners challenging the bans.<sup>36</sup> However, the court found such fundamental errors in EPA’s methodology and rationale for banning asbestos-containing products that all product-specific bans were struck down in their entirety.<sup>37</sup>

**Failure to Provide Notice and Opportunity to Comment on a Key Justification for the Rule**

Petitioners alleged numerous procedural flaws in EPA’s asbestos rulemaking, in what the court characterized as a “protest everything” approach.<sup>38</sup> The court limited its discussion to the two actions “of most concern to us [the court]” – the failure of EPA to allow cross-examination of some of its own witnesses, and its failure to provide prior notice of its intent to use “analogous exposure” data to estimate potential benefits of its product bans.<sup>39</sup> With regard to the first point, TSCA Section 6(c)(3) allows for the cross-examination of witnesses, and Section 19(c)(1)(B)(ii) requires that a rule promulgated under Section 6 be set aside if denial of cross examination precluded disclosure of material facts.<sup>40</sup> The court expressed sympathy for petitioners’ argument, stating, “[c]onsidering the importance TSCA accords to cross-examination, the EPA should have afforded interested parties with full cross-examination on all of its major witnesses.”<sup>41</sup> The court admonished EPA that “[p]recluding cross-examination of EPA witnesses ... is not the proper way to expedite the finish of a lengthy rulemaking procedure.”<sup>42</sup> However, the court found that the “general failure” to allow cross-examination was not sufficient by itself to require that the rule be overturned.<sup>43</sup>

The court reached a different conclusion with respect to EPA’s use of “analogous exposure” data – exposure data obtained under comparable circumstances to the circumstances being addressed – to calculate expected benefits of the asbestos bans. Use of the analogous exposure estimates “increase[d] the purported benefits of the rule by more than one-third.”<sup>44</sup> For some products, use

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<sup>34</sup> *Id.* at 1229.

<sup>35</sup> 947 F.2d at 1214 (“We [the court] note that in undertaking our review, we give all agency rules a presumption of validity, and it is up to the challenger to any rule to show that the agency action is invalid.”).

<sup>36</sup> See, e.g., 947 F.2d at 1229 (rejecting various science-based arguments).

<sup>37</sup> *Id.* at 1215.

<sup>38</sup> *Id.* at 1211.

<sup>39</sup> *Id.* at 1211.

<sup>40</sup> 15 U.S.C. §§ 2605(c)(3), 2618(c)(1)(B)(ii).

<sup>41</sup> 947 F.2d at 1211.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 1212 n.10.

of the analogous exposure estimates constituted the bulk of EPA's analysis,<sup>45</sup> and in some cases the analogous exposure analysis "completely altered the EPA's calculus and multiplied four-or five-fold the anticipated benefits."<sup>46</sup> In the case of gaskets, roofing, shingles, and paper products, EPA's analogous exposure estimate constituted almost eighty percent of the anticipated total benefits from the asbestos rule for those products.<sup>47</sup> Yet EPA did not disclose that it was relying on "analogous exposure" data until after the hearings were closed.<sup>48</sup> The court found that the "failure to seek public comment on such an important part of the EPA's analysis deprived its rule of the substantial evidence required."<sup>49</sup> The court held further, "[t]his was a change sufficient to make the proceedings unfair to the petitioners and was of sufficient importance that the EPA's failure to afford any cross-examination on this issue was an abuse of discretion."<sup>50</sup>

#### **Failure to Consider Less Burdensome Alternatives**

Perhaps the court's greatest concern with the asbestos rule pertained to EPA's inadequate consideration of less burdensome alternatives, and its consequent failure to demonstrate that product bans were the "least burdensome requirements" necessary to protect against unreasonable risks. EPA did give some consideration to less burdensome options, such as labeling asbestos products and stricter workplace rules.<sup>51</sup> However, the court found EPA's analysis inadequate, because EPA "rejected calculating how many lives a less burdensome regulation would save, and at what cost."<sup>52</sup> "Furthermore the EPA, when calculating the benefits of its ban, explicitly refused to compare it to an improved workplace in which currently available control technology is utilized."<sup>53</sup> Rather, EPA "jumped immediately to the ban provision, without calculating whether a less burdensome alternative might accomplish TSCA's goals."<sup>54</sup> "[A]lthough the EPA mentions the problems posed by intermediate levels of regulation, it takes no steps to calculate the costs or benefits of these intermediate levels."<sup>55</sup>

EPA failed to consider adequately the less burdensome options because it believed there was no level of asbestos exposure that would pose zero risk.<sup>56</sup> However, as the court correctly noted,

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<sup>45</sup> *Id.* at 1212.

<sup>46</sup> 947 F.2d at 1213 n.11.

<sup>47</sup> *Id.* at 1228.

<sup>48</sup> *Id.* at 1212.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 1213 n.11.

<sup>51</sup> 947 F.2d at 1216. EPA also evaluated several different ban options. *Id.* at 1217.

<sup>52</sup> *Id.* at 1216.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 1228.

<sup>55</sup> *Id.*

<sup>56</sup> 947 F.2d at 1216; 54 Fed. Reg. at 29,462, 29,474.

“[r]educing risk to zero . . . was not the task that Congress set for the EPA in enacting TSCA.”<sup>57</sup> In short, EPA misconstrued its authority under TSCA Section 6 – aiming for zero risk instead of eliminating “unreasonable risk”<sup>58</sup> -- and as a result failed to address adequately the statutory requirement that it employ the *least burdensome* alternative necessary to protect against *unreasonable* risks.

The court stated that when considering a complete ban on a chemical, “the proper course for the EPA to follow is to consider each regulatory option, beginning with the least burdensome, and the costs and benefits of regulation under each option.”<sup>59</sup> On first impression, this might seem like a heavy burden, but this statement must be considered in context -- the court had significant misgivings concerning EPA’s assessment of the costs and benefits of the regulatory action chosen (see discussion in the next section regarding inflated benefits, failure to consider harm from substitute products, and failure to consider the costs of the bans). The court’s opinion should not be construed to require a *quantitative* assessment of the costs and benefits of every regulatory option, starting with the least burdensome, in every section 6 rulemaking. Indeed, in other successful TSCA Section 6 rulemakings, EPA has considered and rejected less burdensome alternatives without undertaking such a quantitative analysis.

#### **Flawed Methodology and Skewed Reasoning**

Throughout the opinion, it is clear that the court was very troubled by EPA’s “flawed methodology” and skewed reasoning in support of its rule.<sup>60</sup> Three examples are described below. Additional examples are discussed in the court’s opinion.

**Inflated Estimates of Benefits.** When calculating the workplace benefits, EPA refused to consider currently available control technologies that could have provided improved workplace conditions.<sup>61</sup> As the court stated, “[t]his decision artificially inflated the purported benefits of the rule by using a baseline comparison substantially lower than what currently available technology could yield.”<sup>62</sup> Additionally, the court criticized EPA’s method of calculating the present value of future health benefits. “Instead of using the time of injury as the appropriate time from which to discount [costs or benefits], as one might expect, the EPA instead used the time of exposure.”<sup>63</sup> Because asbestos-related disease typically occurs long after initial exposure, EPA’s approach produced a much higher estimate of potential health benefits from the proposed bans. As already noted, EPA’s late switch to analogous exposure data also led to significantly higher

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<sup>57</sup> 947 F.2d at 1217.

<sup>58</sup> *Id.* at 1215.

<sup>59</sup> *Id.* at 1217.

<sup>60</sup> *Id.* at 1229.

<sup>61</sup> *Id.* at 1216.

<sup>62</sup> *Id.* at 1216-17.

<sup>63</sup> *Id.* at 1218.



estimates of potential benefits. The court clearly was troubled by EPA's methodologies that appeared to inflate potential health benefits from the product bans.<sup>64</sup>

**Failure to Consider Harm From Use of Substitutes.** EPA refused to consider the harm that might flow from use of substitute products, including substitutes that were themselves known carcinogens.<sup>65</sup> The court was troubled by this failure to consider impacts from substitute products, explaining that "[c]onsidering that many of the substitutes that the EPA itself concedes will be used in the place of asbestos have known carcinogenic effects, the EPA not only cannot assure this court that it has taken the least burdensome alternative, but cannot even prove that its regulations will increase workplace safety."<sup>66</sup> The court disavowed any intention to require EPA "to seek out and test every workplace substitute,"<sup>67</sup> but stated,

We do not think it unreasonable, however, once interested parties introduce credible studies and evidence showing the toxicity of workplace substitutes, or the decreased effectiveness of safety alternatives such as non-asbestos brakes, that the EPA then consider whether its regulations are even increasing workplace safety, and whether the increased risk occasioned by dangerous substitutes makes the proposed regulation no longer reasonable.<sup>68</sup>

In the case of asbestos-containing friction products (primarily drum and disk brakes for after-market use)<sup>69</sup> which accounted for "the lion's share of the proposed benefits of the asbestos regulation,"<sup>70</sup> a study commissioned by EPA raised significant concerns about the effectiveness and potential health risks of substitute products.<sup>71</sup> One of the study authors testified that the "replacement/substitution of asbestos-based with non-asbestos brake linings will produce grave risks," and that "the expected increase of skid-related highway accidents and resultant traffic deaths would certainly be expected to overshadow any potential health-related benefits of fiber substitution."<sup>72</sup> Further, many of the EPA's own witnesses conceded on cross-examination that

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<sup>64</sup> *Id.* at 1229

<sup>65</sup> *Id.* at 1218.

<sup>66</sup> *Id.* at 1221.

<sup>67</sup> *Id.* at 1221.

<sup>68</sup> *Id.* at 1221.

<sup>69</sup> Notably, the court's opinion related to after-market brakes and the difficulty of installing non-asbestos replacement brakes in vehicles designed to use asbestos brakes. At the time, most new cars were already being engineered to use non-asbestos brakes.

<sup>70</sup> *Id.* at 1224.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 1224 n.25 (citing written testimony).

the non-asbestos fibrous substitutes would pose cancer risks upon inhalation.<sup>73</sup> The court summed up EPA's failure to consider this evidence:

What we cannot ignore is that the EPA failed to study the effect of non-asbestos brakes on automotive safety, . . . and that the EPA failed to evaluate the toxicity of likely brake substitutes . . . . EPA, in its zeal to ban asbestos, cannot overlook, with only cursory study, credible contentions that substitute products actually might increase fatalities.

. . . . Despite this credible record evidence, by a study specifically commissioned by the EPA, that substitute products actually cause more deaths than those asbestos deaths predicted by the EPA, the agency did not evaluate the dangers posed by the substitutes, including cancer deaths from the other fibers used and highway deaths occasioned by less effective, non-asbestos brakes. This failure to examine the likely consequence of the EPA's regulation renders the ban of asbestos friction products unreasonable.<sup>74</sup>

Ultimately, the court concluded that "a death is a death, whether occasioned by asbestos or by a toxic substitute product, and the EPA's decision not to evaluate the toxicity of known carcinogenic substitutes is not a reasonable action under TSCA."<sup>75</sup> EPA could not ignore the possible toxic effects of the proposed substitutes for asbestos once the potential concerns were brought to the Agency's attention.

**Failure to Consider Costs.** EPA projected very high costs for implementation of its asbestos bans, and then effectively ignored those costs, rendering its economic analysis, in the court's words, "cavalier" and "meaningless."<sup>76</sup>

EPA estimated that its ban of asbestos pipe would save three lives over thirteen years, at a cost of \$128-227 million (\$43-76 million per life saved); that its ban of asbestos shingles would cost \$23-34 million to save 0.32 statistical lives (\$72-106 million per life saved); that its ban of asbestos coatings would cost \$46-181 million to save 3.33 lives (\$14-54 million per life saved); that its ban of asbestos paper products would save 0.60 lives at a cost of \$4-5 million (\$7-8 million per life saved);<sup>77</sup> and, that its ban of friction products, including automatic transmission components and clutch facings, would cost \$15-28 million to save 1.45 lives (\$10-19 million per

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<sup>73</sup> *Id.* at 1225.

<sup>74</sup> *Id.* at 1224.

<sup>75</sup> *Id.* at 1221.

<sup>76</sup> *Id.* at 1223.

<sup>77</sup> *Id.* at 1222.

life saved).<sup>78</sup> The court noted that EPA “regularly rejects” as unjustified, regulations that would save more lives at less cost.<sup>79</sup>

The court found that EPA, “in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation.”<sup>80</sup> As the court stated:

The EPA’s willingness to argue that spending \$23.7 million to save less than one-third of a life reveals that its economic review of its regulations, as required by TSCA, was meaningless. As the petitioners’ brief and our review of EPA caselaw reveals, such high costs are rarely, if ever, used to support a safety regulation. If we were to allow such cavalier treatment of the EPA’s duty to consider the economic effects of its decisions, we would have to excise entire sections and phrases from the language of TSCA. Because we are judges, not surgeons, we decline to do so.<sup>81</sup>

#### **Lessons Learned from *Corrosion Proof Fittings***

The asbestos rule did not fail because of the requirements of TSCA Section 6. Rather, as the court stated in its conclusion, EPA’s product-specific bans were rejected because of “the agency’s reliance upon flawed methodology and its failure to consider factors and alternatives that TSCA explicitly requires it to consider.”<sup>82</sup> The examples described in this article are not the whole; other flaws in EPA’s reasoning and methodology are detailed in the court’s opinion. One gets the impression, from reading the opinion, that the court was deeply troubled by the number of ways the reasoning in the final rule was skewed in favor of the proposed outcome, as reflected by the court’s repeated references to “flawed methodology” and “cursory,” “cavalier” and “meaningless” treatment of data.

The court did not reach its conclusions lightly and certainly did not act on technicalities. As already noted, the court upheld EPA’s decision to proceed under TSCA and its decision banning new and discontinued uses of asbestos, and also rejected many individual arguments advanced by petitioners. Still, the court could not overlook the fundamental errors in EPA’s asbestos rulemaking. In overturning the final rule, however, the court did not presume that EPA would be unable to regulate asbestos under TSCA Section 6 in the future. Rather, the court remanded the rule to EPA for further proceedings consistent with the court’s opinion.<sup>83</sup> The court presumed that EPA could act under TSCA Section 6, provided it adhered to the requirements of the statute and adequately explained its decisions.

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<sup>78</sup> 54 Fed. Reg. at 29,484-85.

<sup>79</sup> 947 F.2d at 1223 n.23.

<sup>80</sup> *Id.* at 1223.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 1229.

<sup>83</sup> *Id.* at 1230.

Thus, the lesson learned from *Corrosion Proof Fittings* is not that TSCA Section 6 does not work. EPA's successes regulating other compounds under Section 6 prove that the statute can work. The lesson is that no matter what the product, when acting under Section 6, EPA must adhere to the statutory requirements. As the court said, "[t]he requirements of TSCA, however, are plain, and the EPA cannot deviate from them to reach its desired result."<sup>84</sup>

#### **What About the GAO Recommendations?**

In June 2005, the U.S. General Accountability Office ("GAO") released a report to Congressional requesters entitled "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program." The report suggested some legislative options that would purportedly strengthen EPA's ability to assess and regulate chemicals under TSCA, including some suggested revisions to TSCA Section 6. As explained below, however, the suggested revisions to TSCA Section 6 would not provide an improved basis for regulatory decision making.

**"Least Burdensome Requirements" test.** GAO has suggested that TSCA Section 6 might be amended to eliminate the requirement to demonstrate that the regulatory option chosen is the "least burdensome requirement" necessary to address the identified health or environmental risks.<sup>85</sup> However, before EPA bans the use of a product, it is not unreasonable to require the Agency to show that there is no less burdensome alternative that would be sufficient to protect human health and the environment. Stated differently, if there is a less burdensome alternative that would be adequately protective of human health and the environment, there would seem to be no justification for not using it, and no justification for banning a product that has proven to be valuable in commerce. Further, notwithstanding the result in *Corrosion Proof Fittings*, if EPA determines that a ban is the least burdensome requirement, the Agency should not be concerned that its judgments will be easily second-guessed by the courts. To the contrary, if regulations imposed under TSCA Section 6 are based on consideration of the relevant factors, adequately explained and promulgated through proper procedures, they will receive deferential treatment by courts.<sup>86</sup> EPA made the "least burdensome requirement" determination successfully in each of its other Section 6(a) final rules.

**"Unreasonable Risk" standard.** GAO also has suggested that TSCA Section 6 might be amended to replace the requirement to demonstrate an "unreasonable risk" with a requirement to

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<sup>84</sup> *Id.* at 1230.

<sup>85</sup> GAO Report at 50.

<sup>86</sup> *Corrosion Proof Fittings*, 947 F.2d at 1214 (citing *Environmental Defense Fund v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980) ("Under the substantial evidence standard, a reviewing court must give careful scrutiny to agency findings and, at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise."). See also *Ausimont U.S.A. Inc. v. U.S.E.P.A.*, 838 F.2d 93, 98 (3<sup>rd</sup> Cir. 1988) (upholding test rule under TSCA Section 4 and finding that EPA has "fairly broad discretion in exercising its expertise...").

show a “significant risk.”<sup>87</sup> GAO indicates that finding “significant risk” would require EPA to show that the “risks are substantial or serious.”<sup>88</sup> Moving from “unreasonable” to “significant” risk, however, would make Section 6 inconsistent with other provisions of TSCA.

Congress used the phrase “unreasonable risk” throughout TSCA,<sup>89</sup> reflecting congressional intent that EPA consider health and environmental impacts and social *and* economic impacts when regulating under TSCA. This congressional intent is stated explicitly in TSCA Section 2(c), which states, “[i]t is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter.”<sup>90</sup> Furthermore, Section 2(b)(3) states that it is the policy of the United States that,

authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an *unreasonable risk* of injury to health or the environment.<sup>91</sup>

Further still, Section 6(c) expressly requires EPA to consider not only the health and environmental effects of the substance and the magnitude of exposure, but also the benefits of the substance, the availability of substitutes, and the reasonably ascertainable economic consequences of the proposed rule.<sup>92</sup> Congress could not have been more explicit in directing EPA to consider social and economic impacts as well as potential effects on health and the environment.

The “unreasonable risk” standard requires a balancing of the nature of the potential harm, the probability of the harm occurring, and the harm that would result from the rule.<sup>93</sup> Thus, full

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<sup>87</sup> GAO Report at 50.

<sup>88</sup> *Id.*

<sup>89</sup> *See, e.g.*, 15 U.S.C. §§ 2601(b)(3) (statement of policy), 2603(a) (testing authority), 2604(e) (allowing regulation of new chemicals pending development of information), 2604(f) (allowing immediate regulation to prevent against unreasonable risk).

<sup>90</sup> 15 U.S.C. § 2601(c).

<sup>91</sup> *Id.* § 2601(b)(3) (emphasis added).

<sup>92</sup> *Id.* § 2605(c).

<sup>93</sup> *Corrosion Proof Fittings*, 947 F.2d at 1222 (citing 15 U.S.C. § 2601(c)) (“In evaluating what is ‘unreasonable’, the EPA is required to consider the costs of any proposed actions and to ‘carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.’”); 54 Fed. Reg. at 29467 (asbestos final rule) (“EPA must balance the probability that harm will occur from the

consideration is given to the nature of the potential adverse health or environmental effects being addressed, and the likelihood of that harm occurring. To suggest, however, that EPA might consider imposing a ban on valuable commercial products without any consideration of the potential social or economic impacts of the ban clearly is not consistent with congressional intent for how EPA should implement its authority under TSCA. As was seen in the asbestos rule, a product ban can have significant adverse impacts that need to be considered. Indeed, as described above, there was credible evidence, supported by an EPA-sponsored study and testimony of EPA witnesses, that use of substitute products actually might cause more deaths than those asbestos deaths predicted by the EPA.

TSCA is by no means unusual in requiring EPA to consider potential social and economic impacts of its regulatory actions. For example, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") requires EPA to consider "any unreasonable risk to man or the environment" and take "into account the economic, social, and environmental costs and benefits of the use of any pesticide."<sup>94</sup> Pesticides are subject to very rigorous scrutiny, perhaps more so than any other category of products, and the "unreasonable risk" standard has not prevented EPA from exercising its authority in a prudent and health-protective manner. Indeed, over the years many pesticide products have been removed from the market by EPA action or in response to EPA concerns expressed to the product manufacturers.

In short, GAO's suggestion that the "unreasonable risk" standard in Section 6 be replaced with a "significant risk" standard would be inconsistent with other provisions of TSCA and contrary to clear congressional intent, and also does not appear necessary to protect human health or the environment.

**"Presents or Will Present" Test.** GAO also suggested that TSCA might be amended to require that EPA demonstrate only that a chemical "may present" an unreasonable risk, rather than requiring a demonstration that a chemical "presents or will present" an unreasonable risk.<sup>95</sup> However, experience under Section 4 of TSCA does not support this recommendation. Under that section, EPA has authority to require testing of a chemical that "may present an unreasonable risk" to health or the environment. In that context, the "may present" standard has proven to be a very low threshold. The court in *Chemical Manufacturers Ass'n v. U.S. Environmental Protection Agency* explained that the "may present" standard only requires a "more-than-theoretical basis for suspecting that some amount of exposure takes place."<sup>96</sup> Furthermore, under TSCA Section 4, EPA has indicated that a determination that a chemical *may present* an unreasonable risk may be based on hazard information that supports merely a suspicion of toxicity.<sup>97</sup> Such a low standard may be entirely appropriate when EPA is deciding

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activities against the effects of the proposed regulatory action on the availability to society of the benefits of asbestos.").

<sup>94</sup> 7 U.S.C. § 136(bb); *see also* 7 U.S.C. § 136a(c)(5).

<sup>95</sup> GAO Report at 51.

<sup>96</sup> 859 F.2d 977, 984 (D.C. Cir. 1988).

<sup>97</sup> 45 Fed. Reg. 48,524, 48,528 (July 18, 1980) (Chloromethane and Chlorinated Benzenes Proposed Test Rule; Amendment to Proposed Health Effects Standards) ("EPA's

whether additional data is needed to determine whether the manufacture or use of a chemical presents unreasonable risks to human health or the environment. However, such a low standard would be inappropriate under Section 6, where the Agency has the ability to ban a chemical. Moreover, if the “may present” standard were incorporated into TSCA Section 6, it would be possible for the Agency to skip the testing step and proceed directly to a ban merely on the suspicion of a hazard and a “more-than-theoretical basis” for believing that exposure might be occurring, rendering Section 4 meaningless. Such an approach clearly was not what Congress had in mind.

**Substantial Evidence Test.** GAO also has suggested that the standard for judicial review of rules promulgated under Section 6 might be relaxed somewhat by replacing the “substantial evidence” test with the “arbitrary and capricious” standard of review.<sup>98</sup> The standard of review was not a decisive factor in the asbestos case. Given the number and nature of EPA’s errors in that rulemaking, it seems clear that the rule would not have survived even under the arbitrary and capricious standard of review. More generally, it is noteworthy that the substantial evidence test also applies to action taken under TSCA Section 4, and the few cases that have been decided under that section have affirmed EPA’s broad discretion to require testing, and have reflected considerable deference to EPA’s judgments and expertise. See *Ausimont U.S.A. Inc. v. U.S.E.P.A.*, 838 F.2d 93, 98 (3<sup>rd</sup> Cir. 1988); *Chemical Manufacturers Ass’n v. U.S. Environmental Protection Agency*, 859 F.2d 977, 984 (D.C. Cir. 1988). Thus, there does not appear to be any compelling reason to alter the standard of review that applies to EPA actions taken under Section 6. At the end of the day, EPA’s scientific judgments and decisions will be respected by the courts if proper procedures are followed, relevant factors are considered, and the Agency’s decisions are adequately explained.

### Conclusion

TSCA Section 6 is not the only mechanism for addressing unreasonable risks. Good product stewardship by industry is the first line of defense, and this will often occur in collaboration with EPA. Nor should EPA’s performance under TSCA be judged by the number of chemicals that have been banned under Section 6. For example, EPA’s proposed ban on the manufacture and use of acrylamide grout was ultimately withdrawn because the development of personal protective equipment (PPEs) made the rule unnecessary – that outcome should be deemed a success, notwithstanding that no ban was imposed.<sup>99</sup>

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conclusion that the chemical may present a hazard will not be based on definitive scientific data. This is inevitable; if EPA knew in detail the types of hazards a chemical posed, there would be no need to test. Thus, determinations of hazard potential under Section 4 by their very nature must involve reasonable scientific assumptions, extrapolations, and interpolations.”)

<sup>98</sup> GAO Report, at 51 (“The Congress could amend the standard for judicial review to instead reflect a rational basis test to prevent arbitrary and capricious administrative decisions.”).

<sup>99</sup> 56 Fed. Reg. 49,863 (Oct. 2, 1991) (Proposed Ban on Acrylamide and N-methylolacrylamide Grouts) (“EPA has concluded that avoidance of the significant

Additionally, EPA also has exercised its authority to issue Significant New Use Rules (SNURs) under Section 5(a)(2) to address chemical risks. A prominent example is EPA's relatively recent use of SNURs in connection with the voluntary phase-out of perfluoroalkyl sulfonate (PFAS) substances. In May 2000, the sole U.S. manufacturer announced it would voluntarily withdraw production of PFAS. The phase-out was completed in 2002. Following this, the EPA issued 13 SNURs in March 2002 limiting any new manufacturing or importing of these substances.<sup>100</sup> In December 2002, the EPA added 75 additional chemicals, but excluded from the definition of *significant new use* specifically defined "low volume, controlled exposure uses in: semiconductor manufacture, aviation hydraulics, and photography."<sup>101</sup> Thus, through close cooperation with industry and use of its authority under section 5(a)(2), the EPA was able to extend the voluntary phase-out by the sole manufacturer to all prospective producers and importers of the subject compounds.

Having said that, Section 6 remains an important part of TSCA, and therefore it is important that the decision in *Corrosion Proof Fittings* not be misunderstood. EPA's asbestos rule was struck down because EPA used flawed methodology and made other errors, not because of problems with TSCA Section 6 itself. GAO's suggested revisions of TSCA Section 6 are not necessary to support effective regulation, and would not improve the statutory framework for regulatory decisions. TSCA Section 6 can work in its current form, as demonstrated by EPA's successes under Section 6 during the first decade after TSCA was enacted. The language of Section 6

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individual cancer risks at the current exposure levels and the serious neurotoxic risks associated with grouting operations outweigh the cost to society of the proposed regulation. Therefore, EPA finds that the use of acrylamide and NMA grouts presents an unreasonable risk of injury to human health."); 67 Fed. Reg. 71524 (Dec. 2, 2002) (Acrylamide and N-methylolacrylamide Grouts; Withdrawal of Proposed Ban) ("EPA is withdrawing the 1991 proposal to ban the manufacture, importation, distribution, and use of acrylamide and NMA grouts. This action reflects the Agency's conclusion that affordable and effective PPE is now available, and that workers who properly use such equipment can be adequately protected while using acrylamide and NMA grouts. The Agency no longer believes that it is necessary to ban acrylamide and NMA grouts to protect workers.").

<sup>100</sup> 67 Fed. Reg. 11,014, 11,020 (Mar. 11, 2002) (Perfluoroalkyl Sulfonates. Proposed Significant New Use Rule) ("EPA determined that the proposed SNUR should be promulgated as final for the 13 chemicals, employed principally in coatings for textiles, carpet, apparel, leather, and paper, on which no comments were received and which 3M, the sole manufacturer, confirmed were discontinued from manufacture before Dec. 31, 2000.").

<sup>101</sup> Battelle, Overview: Office of Pollution Prevention and Toxics Programs, at 18 (Dec. 24, 2003); *see also* 67 Fed. Reg. 72,854, 72,859 (Dec. 9, 2002) (Perfluoroalkyl Sulfonates; Significant New Use Rule.) (Commenters identified "specific PFAS chemicals that were essential to their specific uses in the semiconductor, aviation hydraulics, and imaging industries" and "[b]ased on the information presented by these commenters about the limited volume of their uses, the extent of controls on exposure and releases, and the absence of viable alternatives for these specific chemicals . . . [m]anufacture or importation of these chemicals for these uses is thus not subject to this SNUR.").



provides a sound basis for EPA decision-making, and does not impose unreasonable burdens on the Agency. To the contrary, it highlights the key factors that should be considered by EPA when contemplating whether to ban or restrict the use of products.

**SPECIAL REPORT**

**Green Chemistry in California:  
A Framework for Leadership in  
Chemicals Policy and Innovation**

*Michael P. Wilson  
with Daniel A. Chia and Bryan C. Ehlers*

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Prepared for:  
The California Senate Environmental Quality Committee  
The California Assembly Committee on Environmental Safety and Toxic Materials



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UNIVERSITY OF CALIFORNIA

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**About the California Policy Research Center and This Report**

The California Policy Research Center (CPRC), a University of California program under the aegis of the Office of the President, applies the UC system's extensive research expertise to analysis, development, and implementation of state policy as well as federal policy on issues of statewide importance. CPRC provides technical assistance to policymakers, commissions policy-relevant research, and disseminates research findings and recommendations through publications and special briefings.

This report was prepared in response to a January 2004 request for technical assistance in the area of chemicals policy from California State Senator Byron Sher, chair of the Senate Environmental Quality Committee, and Assembly Member John Laird, chair of the Assembly Committee on Environmental Safety and Toxic Materials. The request was prompted by the committees' interest in a California chemicals policy that would address public and environmental health concerns while also building long-term capacity in the design, production, and use of chemicals that are safer for humans and the environment. The committees were also interested in the implications for California of chemicals policy developments occurring in the European Union.

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The views and recommendations expressed are those of the principal author and do not necessarily represent the opinions of the sponsors or funders or the Regents of the University of California.

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A 13-member Advisory Committee (see following page) provided technical oversight for the report. The full committee was convened one time. Committee members provided individual consultation to the primary author and written comments on three drafts of the report. The report, however, is not a consensus document; final responsibility for the report content rests with the primary author, not with the committee, individually or collectively.

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*Going forward, the chemical industry is faced with a major conundrum—the need to be sustainable (balanced economically, environmentally, and socially in order to not undermine the natural systems on which it depends)—and a lack of a more coordinated effort to generate the science and technology to make it all possible.*

Committee on Grand Challenges for Sustainability in the Chemical Industry  
The National Academy of Sciences  
December 2005<sup>1</sup>

*For 25 years, the Golden State has led the nation in programs to save energy; these, in turn, reduce the greenhouse-gas emissions that contribute to global warming. California now uses half as much energy per capita as the nation as a whole, saving the average household \$1,000 each year, with total savings now more than \$56 billion.*

Hal Harvey  
Director of Environment Programs  
The Hewlett Foundation  
February 2006<sup>2</sup>

## **Executive Summary**

By 2050, California's population is expected to grow by about 50%, from 36 to 55 million residents. This expansion will be accompanied by a growing set of social, economic, and environmental problems whose *magnitude* will be determined in large part by the policy decisions California makes now and in coming years. In charting a course to a sustainable future, policymakers will need to guide industrial development in such a way that it fully integrates matters of environmental quality and human health. In practice, if California is to create a future characterized by improving social, environmental, and economic conditions, industrial development will need to *solve*, not exacerbate, the public and environmental health problems facing the state today. To move California in this direction, policymakers need the support of research that links the science of public and environmental health to innovative policy solutions. This report serves that purpose in the area of chemicals policy.

The report makes the case that a modern, comprehensive chemicals policy is essential to placing California on the path to a sustainable future. Problems associated with chemicals are already affecting public and environmental health, business, industry, and government in California. On the current trajectory, the coming years will see these problems broaden and deepen. Correcting these problems will require much more than isolated chemical bans and other piecemeal approaches that currently characterize the Legislature's efforts in this arena. Rather, a comprehensive approach is needed that corrects long-standing federal chemicals policy weaknesses and builds the foundation for new productive capacity in green chemistry—the design, manufacture, and use of chemicals that are safer for biological and ecological systems. This approach to chemicals policy will link economic development in California with improved health and environmental quality, but it will require a long-term commitment to leadership on the part of California policymakers.

We describe initiatives by leading California businesses and the European Union (E.U.) that are already driving interest by industry in cleaner technologies, including green chemistry. Given California's unparalleled capacity for innovation and its scientific, technical, and financial resources, a proactive response to these developments in the form of a modern, comprehensive chemicals policy could position California to become a global leader in green chemistry innovation. The report illustrates that to do so, California will need to adopt a chemicals policy that greatly improves chemical information, regulatory oversight, and support for green chemistry research, development, technical assistance, and education.

### **Methods**

We used four research methods in preparing this report: a literature review, interviews with key informants, participation in chemicals policy meetings, and peer review. Over a two-year period, the primary author held discussions with chemicals policy experts affiliated with academic institutions, scientific bodies, governmental agencies, chemical producers, downstream users of chemicals, entities within the European Union, small and medium-sized enterprises, environmental organizations, and labor organizations. In addition, between April 2003 and February 2006, the primary author participated in 35 meetings and conferences pertaining

expressly or in part to chemicals policy matters; he presented the report's key concepts at 17 of these meetings. The report reflects feedback produced throughout this process.

### **Major Findings**

#### ***The scale of chemical production is immense and will continue to expand globally.***

Every day, the U.S. produces or imports 42 billion pounds of chemicals, 90% of which are created using oil, a non-renewable feedstock. Converted to gallons of water, this volume is the equivalent of 623,000 gasoline tanker trucks (each carrying 8,000 gallons), which would reach from San Francisco to Washington, D.C., and back if placed end-to-end. In the course of a year, this line would circle the earth 86 times at the equator. These chemicals are put to use in innumerable processes and products, and at some point in their life cycle many of them come in contact with people—in the workplace, in homes, and through air, water, food, and waste streams. Eventually, in one form or another, nearly all of them enter the earth's finite ecosystems.

Global chemical production is expected to double every 25 years for the foreseeable future. Between now and 2033, the U.S. EPA expects 600 new hazardous waste sites to appear each month in the U.S. and require cleanup, adding to 77,000 current sites. Efforts at site mitigation are expected to cost about \$250 billion. Given the scale, pace, and burden of chemical production, the toxicity and ecotoxicity of chemicals are of great public importance.

#### ***Many chemicals that are useful to society are also hazardous to human biology and ecological processes.***

There is growing scientific concern over the biological implications of chemical exposures that occur over the human lifespan, particularly during the biologically sensitive period of fetal and child development. Hundreds of chemicals that are released into the environment are accumulating in human tissues; the U.S. EPA found just under 700 such chemicals in a nationwide survey of Americans in 1987. Many of these chemicals enter the developing organ systems of fetuses and infants through the maternal bloodstream and through breast milk. Animal studies indicate that some can interact with and disrupt the development of these systems, such as the endocrine system, at very low doses. Among children, chemical exposures are estimated to contribute to 100% of lead poisoning cases, 10% to 35% of asthma cases, 2% to 10% of certain cancers, and 5% to 20% of neurobehavioral disorders.

Occupational disease continues to exact a tremendous toll in California. Each month, an estimated 1,900 Californians are diagnosed with a preventable, deadly chronic disease that is attributable to chemical exposures in the workplace; another 540 Californians die as a result of a chronic disease linked to chemical exposures in the workplace. The U.S. Occupational Safety and Health Administration (OSHA) has adopted workplace exposure limits for only 193, or about 7%, of the 2,943 chemicals produced or imported in the U.S. at more than one million pounds per year. Immigrants, minorities, and lower-income groups—as workers and as residents—are at particular risk of exposure to hazardous chemicals.

***There are extensive deficiencies in the federal regulation of chemicals.***

Of all federal environmental statutes, the Toxic Substances Control Act of 1976 (TSCA) is the only law that is intended to enable regulation of chemicals both before and after they enter commerce. However, studies conducted by the National Academy of Sciences (1984), the U.S. General Accounting Office (1994), the Congressional Office of Technology Assessment (1995), Environmental Defense (1997), the U.S. EPA (1998), former EPA officials (2002), and the U.S. Government Accountability Office (2005) have all concluded that TSCA has not served as an effective vehicle for the public, industry, or government to *assess* the hazards of chemicals in commerce or *control* those of greatest concern.

- The TSCA inventory lists 81,600 chemicals that are registered for commerce in the U.S., 8,282 of which are produced or imported at 10,000 pounds or more per year.
- TSCA does not require chemical producers to generate and disclose information on the health and environmental safety of these chemicals—or on the approximately 2,000 new chemicals that enter the market each year. The result is that there is an enormous lack of information on the toxicity and ecotoxicity of chemicals in commercial circulation.
- TSCA places legal and procedural burdens on the EPA that have constrained the agency's capacity to act. Since 1979, the EPA has used its formal rule-making authority to restrict only five chemicals or chemical classes, though the agency reported in 1994 that about 16,000 chemicals in the U.S. were of some concern on account of their structure and volume in commerce.
- TSCA has not provided a vehicle for channeling federal support to research in cleaner chemical technologies, including green chemistry.

Voluntary initiatives on the part of the chemical industry to correct some of these weaknesses are positive but do not make up for TSCA's structural weaknesses. Other federal laws that pertain to chemicals are essentially "end-of-pipe" statutes that do not allow for review of chemicals prior to their introduction into commerce. Together, five major federal statutes apply to only 1,134 chemicals and pollutants. The weaknesses of TSCA and the other federal statutes have produced three fundamental problems in the U.S., which we refer to as the chemical Data Gap, Safety Gap, and Technology Gap.

***TSCA's weaknesses are adversely affecting California.***

The chemical Data Gap, Safety Gap, and Technology Gap have created a broad set of problems for public and environmental health, industry, business, and government in California.

***The Data Gap:*** Without comprehensive and standardized information on the toxicity and ecotoxicity for most chemicals, it is very difficult even for large firms to identify hazardous chemicals in their supply chains. Along with consumers, workers, and small-business owners, they do not have the right kinds of information to identify safer chemical products. The lack of chemical information weakens the deterrent function of the product liability and workers' compensation systems.

**The Safety Gap:** Government agencies do not have the information they need to systematically identify and prioritize chemical hazards, nor the legal tools to efficiently mitigate known hazards.

**The Technology Gap:** The lack of both market and regulatory drivers has dampened motivation on the part of U.S. chemical producers and entrepreneurs to invest in new green chemistry technologies. There has been virtually no government investment in green chemistry research and development.

Meanwhile, evidence of public and environmental health problems related to chemicals continues to accumulate. Each year the California Legislature faces numerous bills related to public concerns over chemicals; on the current trajectory, the number of such bills is likely to grow. Correcting the chemical Data, Safety, and Technology Gaps engendered by TSCA will require a modern, comprehensive approach to chemicals policy in California.

***Developments in the European Union and among leading California businesses are driving interest in cleaner technologies, including green chemistry.***

Facing a similar set of problems, the European Union is implementing sweeping new chemicals and materials policies that are driving global changes in ways that will favor cleaner technologies, including green chemistry.

- The E.U. *Restriction of Hazardous Substances in Electrical and Electronic Equipment* (RoHS) directive will prohibit the use of lead, cadmium, mercury, certain flame-retardant chemicals, and other toxic materials in electronic and electrical equipment sold in the E.U.
- The *Waste Electrical and Electronic Equipment* (WEEE) directive requires electronics producers to “take-back” their products at the end of their useful life.
- The proposed *Registration, Evaluation and Authorization of Chemicals* (REACH) initiative will require chemical producers to register most chemicals that are widely used and will place restrictions on the use of about 1,400 chemicals of very high concern.

It is becoming clear that cleaner technologies will play an increasingly important role in industrial activity globally—among both developed and developing nations. The E.U. government’s policies to motivate investment in cleaner technologies, though difficult for some E.U. producers in the short term, are expected to lead to a long-term E.U. competitive advantage in this arena.

Lacking similar government leadership in the U.S., a number of large U.S. businesses have been working independently to implement strategies for identifying hazardous chemicals in their supply chains and removing those chemicals from their operations. California businesses at the forefront of this effort include Kaiser Permanente, Catholic Healthcare West, Intel, Hewlett-Packard, IBM, Bentley Prince Street, and Apple. These developments signal a growing demand among U.S. businesses for safer chemicals and better chemical information; these efforts,

however, are constrained by the Data, Safety, and Technology Gaps. Effective leadership in chemicals policy to close these Gaps is now called for in the U.S.

***California needs a modern, comprehensive chemicals policy to address pressing public and environmental health problems and to position itself as a global leader in green chemistry innovation.***

These developments have opened an opportunity for California to position itself as a leader in green chemistry science and technology. To do so, California will need to correct the Data, Safety, and Technology Gaps, which have given rise to conditions in the U.S. chemicals market that favor *existing* chemicals and discourage investment by chemical producers in new green chemistry technologies. Large “sunk” investments by industry in existing chemical technologies will make it difficult to transition to an industrial system based on cleaner technology, including green chemistry; this transition, however, will have to be made if California is to respond proactively to developments in the E.U. and address a host of chemical problems affecting public and environmental health, business, industry, and government in the state.

We propose three chemicals policy goals that will move California in this direction:

***Close the Data Gap:*** Ensure that chemical producers generate, distribute, and communicate information on chemical toxicity, ecotoxicity, uses, and other key data.

***Close the Safety Gap:*** Strengthen government tools for identifying, prioritizing, and mitigating chemical hazards.

***Close the Technology Gap:*** Support research, development, technical assistance, entrepreneurial activity, and education in green chemistry science and technology.

Because many policy mechanisms could be employed to reach these goals, we recommend that as a first step the Legislature establish a chemicals policy task force to explore various mechanisms and develop a legislative proposal for a comprehensive policy based on the findings of this report. We recommend that the task force be charged with developing the proposal for the 2007 legislative session.

## 1. Background

### 1.1 Methodology

We used four research methods in preparing this report: a literature review, interviews with key informants, participation in chemicals policy meetings, and peer review. Over a two-year period, the primary author held discussions with chemicals policy experts affiliated with academic institutions, scientific bodies, governmental agencies, chemical producers, downstream users of chemicals, entities within the European Union, small and medium-sized enterprises, environmental organizations, and labor organizations. In addition, between April 2003 and February 2006, the primary author participated in 35 meetings and conferences pertaining expressly or in part to chemicals policy matters (listed in Appendix A) and presented the report's key concepts at 17 of these meetings. The report reflects feedback produced throughout this process.

### 1.2 Scope

For purposes of this report, *chemicals* refers to organic (carbon-based) chemicals, metals, and inorganic chemicals created by humans through chemical processes. The report pertains to chemicals at all points in their life cycle, including (1) feedstock supply chains leading to chemical processing facilities, (2) research, development, design, and manufacture of chemicals and chemical products, and (3) distribution, use, disposal, and recycling of chemicals and chemical products.<sup>3</sup> *Chemical industry* refers to the business and industrial entities involved in the design, production, and distribution of chemicals and chemical products.

The report pertains to chemicals in three market classifications: consumer products, basic chemicals, and specialty chemicals (Figure 1).<sup>4,6</sup> The report does not address pesticides, pharmaceuticals, cosmetics, or food products.

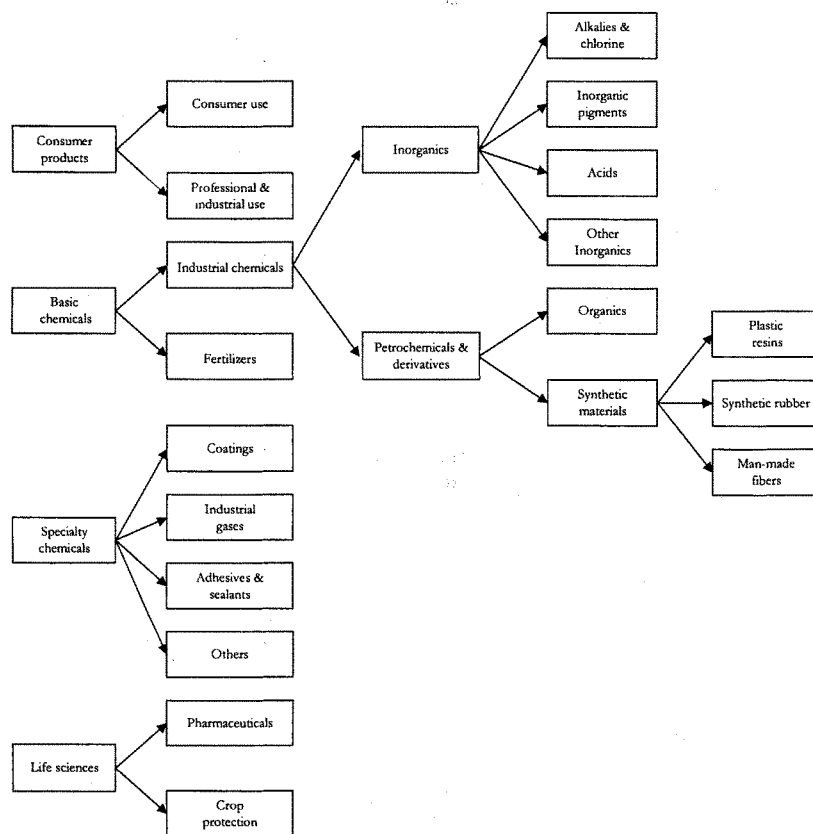
### 1.3 Report Overview

For purposes of this report, public policy is defined as a plan of action to guide decision-making that is based on an agreed-upon set of goals. Goals, in turn, are determined by the ways in which problems are defined. A large portion of the report is therefore dedicated to an analysis of chemical problems in the U.S. and California. Following an introduction (Section 2), the report describes the federal regulatory origins of the Data, Safety, and Technology Gaps (Section 3) and the problems these gaps have created for public and environmental health, business, industry, and government in California (Section 4). The report then describes chemicals policy

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<sup>3</sup> Of the 81,600 chemical substances listed in the inventory of the federal Toxic Substances Control Act (TSCA), 34,000 are discrete chemicals having a definite structure (Class I Substances); 20,000 are complex reaction products, biological materials, and chemical substances having indefinite structures (Class II Substances); and 27,600 are polymers.<sup>4</sup> There are 8,282 chemicals in commercial circulation in the U.S. that are produced or imported at 10,000 pounds or more per year, according to data from TSCA's 2002 Inventory Update Rule (IUR).<sup>5</sup> Of these, over 99% are produced or imported at one million pounds or more per year; these are known as High Production Volume (HPV) chemicals. There are 2,943 HPV chemicals in the U.S. A total of 15.2 trillion pounds of chemicals was produced or imported in the U.S. in 2001, or about 42 billion pounds per day.

Figure 1. The chemical industry's four primary sectors as classified by the American Chemistry Council.





developments occurring in the European Union and efforts by U.S. businesses and non-governmental organizations to “clean” industrial supply chains of hazardous chemicals (Section 5). The report proposes that these developments present a unique opportunity for California to consider a new approach to chemicals policy that addresses public and environmental health problems, supports entrepreneurial activity in green chemistry, and responds proactively to developments in the E.U. The report describes a case study of a reasonably successful, if limited, chemicals policy implemented in Massachusetts in 1989 and discusses its relevance to California (Section 6). The report recommends three overarching goals for a modern, comprehensive chemicals policy in California and explores a number of issues related to each goal (Section 7). The report concludes that a chemicals policy based on these goals is timely and necessary in California, given the state’s expanding population, its health and environmental problems, and the pressures of an increasingly competitive global economy (Section 8).

The report is not intended to be an exhaustive study of chemicals policy. It does not present cost-benefit analyses of differing policy approaches, nor does it compare health and environmental risks associated with chemicals against other risks. The development of the report included a cost-benefit analysis of a California chemical reporting system, an analysis of voluntary initiatives by industry, and an analysis of 10 federal and state chemicals policies, but for brevity only the key points of these analyses are summarized in the report.

#### **1.4 Definition of Terms**

*Adverse health effects:* The continuum of health and disease, from early indicators of biochemical disruption (resulting from chemical exposure) to the presence of overt health damage. The definition reflects the fact that health and disease are manifested in degrees, not simply as “either/or.”

*Bioaccumulative and persistent chemicals:* Chemicals that, by virtue of their structure are very slowly metabolized or excreted and therefore increase in concentration in the tissues and fluids of organisms.<sup>7</sup> Some bioaccumulative chemicals are known to exert toxic effects; for most, toxicity is unknown. The exposure pathways for most bioaccumulative chemicals are also unknown. Many bioaccumulative chemicals are resistant to natural degradation processes, such as those induced by sunlight and bacterial activity, and therefore tend to *persist* in the environment. Some persistent chemicals can remain in the atmosphere for decades or centuries (Table A).<sup>8</sup> Chemicals that are bioaccumulative, persistent, and toxic are particularly problematic because they can give rise to toxic effects over a greater period of time and over larger geographic regions.

*Biobased material:* Chemical products composed wholly, or in significant part, of renewable agricultural, forestry or waste materials.<sup>9</sup> Corn, soybeans, vegetable oils, and wood are currently the main sources used in creating biobased materials (Table B).<sup>10</sup> Some biobased products are processed with other materials, including petrochemicals, to manufacture the final product, while others are derived entirely from plant feedstock. Biobased *processes* utilize enzymatic and other biological mechanisms to generate chemical reactions. A sizeable industry in biobased industrial materials emerged in the U.S. in the 1930s and 1940s.<sup>11</sup>

Table A. Persistence in the atmosphere of some chlorinated organic molecules.\*

Chemical	Atmospheric half-life (yrs)
Tetrachloroethylene	0.3
Dichloromethane	0.4
Dichloroethane	0.4
Chloroform	0.4
Chloromethane	1.0
Dichlorotrifluoroethane (HCFC-22)	1.2
Dichloropentafluoropropane (HCFC-115ca)	1.9
Trichloroethane	3.3
Chlorotetrafluoroethane (HCFC-124)	4.8
Dichloropentafluoropropane (HCFC-225-cb)	5.5
Dichlorofluoroethane (HCFC-141b)	6.2
Dichlorofluoromethane (HCFC-22)	8.3
Bromochlorodifluoromethane	11.1
Chlorodifluoroethane (HCFC-142b)	13.2
Carbon tetrachloride	24.3
Trichlorofluoromethane	31.2
Trichlorotrifluoroethane	58.9
Dichlorodifluoromethane	69.3
Dichlorotetrafluoroethane	152.5
Chloropentafluoroethane	381.2

\* The atmospheric half-life is the time required for a substance to degrade to 37% of its original concentration.

Table B. Common nonfood biobased commercial and consumer products, 2003.

Source	Chemical products
Corn	Solvents, pharmaceuticals, adhesives, starch, resins, binders, polymers, cleaners, ethanol
Soybeans	Paints, toiletries, solvents, inks, pharmaceuticals, lubricants, biodiesel fuel, carpet backing, foam insulation.
Vegetable oils	Surfactants in soaps and detergents, pharmaceuticals, inks, paints, resins, cosmetics, fatty acids, lubricants.
Wood	Paper, cellulose for fibers and polymers, resins, binders, adhesives, coatings, paints, inks, fatty acids, road and roofing pitch.

*Exposure:* Contact between a chemical and a target.<sup>12</sup> Contact takes place at an exposure surface (such as the lungs, skin or digestive tract) over an exposure period.

*Exposure assessment:* The process of estimating or measuring the magnitude, frequency, and duration of exposure to a chemical, along with the number and characteristics of the population exposed.<sup>13</sup> Ideally, it describes the sources, pathways, routes, and uncertainties in the assessment. Chemicals enter the environment as vapors, gases, liquids, and particles; they do so through intentional and unintentional releases from chemical processes and products; and they enter the body through the lungs (inhalation), the gastrointestinal system (ingestion), and the skin (dermal absorption).<sup>14</sup>

*Green chemistry:* The design, development, and implementation of chemical processes and manufactured products that are intended to reduce or eliminate substances hazardous to human health and the environment.<sup>15</sup> Green chemistry can be applied in at least three major areas: raw materials, processes, and products. Green chemistry *raw materials* include renewable biobased feedstocks, new chemical building blocks using biobased materials, and the design (or mimicking) of chemicals that exist in nature. Green chemistry manufacturing *processes* use safer solvents or solvent-less systems, alternative reaction pathways, novel catalysts, ultra-thin membrane technologies, and other processes. Some processes harness biological processes (e.g., fermentation) to make chemicals at ambient temperature and pressure.<sup>16-18</sup> Relative to products made through standard chemical processes, green chemistry *products* are less reactive in biological systems; they are less toxic and do not persist in the environment or accumulate in the human body. In 2003, three Nobel prizes were awarded to chemists working in the area of green chemistry.<sup>19</sup>

Twelve principles of green chemistry have been proposed to serve as a guide for measuring progress toward the adoption of green chemistry:<sup>15, 20</sup>

- *Prevent waste:* Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.
- *Design safer chemicals and products:* Design chemical products to be fully effective, yet have little or no toxicity.
- *Design less hazardous chemical syntheses:* Design syntheses to use and generate substances with little or no toxicity to humans and the environment.
- *Use renewable feedstocks:* Use renewable materials and feedstocks. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or are obtained by mining.
- *Use catalysts, not stoichiometric reagents:* Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times, unlike stoichiometric reagents, which are used in excess and work only once.

- *Avoid chemical derivatives:* Avoid using blocking or protecting groups or any temporary modifications if possible. Derivatives use additional reagents and generate waste.
- *Maximize atom economy:* Design syntheses so that the final product contains the maximum proportion of the starting materials.
- *Use safer solvents and reaction conditions:* Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use innocuous chemicals.
- *Increase energy efficiency:* Run chemical reactions at ambient temperature and pressure whenever possible.
- *Design chemicals and products to degrade after use:* Design chemical products to break down to innocuous substances after use so that they do not accumulate in humans or the environment.
- *Analyze in real time to prevent pollution:* Include in-process, real-time monitoring and control during synthesis to minimize or eliminate the formation of byproducts.
- *Minimize the potential for accidents:* Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents, including explosions, fires, and releases to the environment.

*Hazard:* The inherent property of a chemical having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that chemical.<sup>13</sup>

*Public health:* The protection and enhancement of human health and well-being by preserving the integrity of the biological, ecological, and social systems on which human life depend.<sup>21-23</sup>

*Risk:* The probability of an adverse effect in a person, system or (sub)population caused under specified circumstances by exposure to a chemical.<sup>13</sup> Conceptually, risk has also been defined as a function of hazard and exposure:  $Risk = f(hazard, exposure)$ , where “hazard” is intended to refer to chemical toxicity.<sup>24</sup> Strategies to reduce risk by reducing *exposure* include, for example, preventing escape of chemical emissions from a process, minimizing the volume of chemicals used in a process, setting permissible public and worker exposure limits, using local exhaust ventilation systems, or requiring workers to wear personal protective equipment. These strategies have characterized the great majority of environmental policy activities in the U.S. and California to date. Strategies to reduce risk by reducing *hazards* are oriented toward the *design* of safer chemicals and chemical processes, such as green chemistry.

*Sustainability:* The condition resulting from industrial processes and products that meet the economic, social, and environmental needs of the present generation without compromising those of future generations.<sup>25</sup> The *Committee on Grand Challenges for Sustainability in the Chemical Industry* of the National Academy of Sciences proposed eight major research objectives “to enable the ongoing transition toward chemical products, processes, and systems that will help achieve the broader goals of sustainability” in the U.S. chemical industry.<sup>26</sup>

- *Green and sustainable chemistry and engineering*: Discover ways to carry out fundamentally new chemical transformations.
- *Life cycle analysis*: Develop tools to compare the total environmental impact of products generated from different processing routes and under different operating conditions through their full life cycle.
- *Toxicology*: Understand the toxicological fate and effect of all chemical inputs and outputs of chemical bond-forming steps and processes.
- *Renewable chemical feedstocks*: Derive chemicals from biomass—including any plant-derived organic matter available on a renewable basis, dedicated energy crops and trees, agricultural food and feed crops, agricultural crop wastes and residues, wood wastes and residues, aquatic plants, animal wastes, municipal wastes, and other waste materials.
- *Renewable fuels*: Lead the way in the development of future fuel alternatives derived from renewable sources such as biomass as well as landfill gas, wind, solar heating, and photovoltaic technology.
- *Energy intensity of chemical processing*: Continue to develop energy-efficient technologies for current and future sources of energy used in commercial processing.
- *Separation, sequestration and utilization of carbon dioxide*: Develop more-effective technology and strategies to manage the resulting carbon dioxide from current and future human activity.
- *Sustainability education*: Improve sustainability science literacy at every level of society—from informal education of consumers, to the practitioners of the field, and the businesses that use and sell these products.

*Toxic and ecotoxic*: Inherent properties that cause an agent to produce an adverse biological effect. Not all chemicals are toxic or ecotoxic; those that are, are not equally so. Some chemicals can produce death in humans in microgram doses, for example, while others appear to be relatively harmless at doses in excess of several grams (Table C).<sup>27</sup> The toxic effects of chemicals in the human body and in ecosystems can be local or systemic, immediate or delayed, reversible or irreversible, as well as combinations of these attributes.<sup>27</sup> For the great majority of chemicals, the full range of toxic and ecotoxic effects is unknown. The health effects of exposure to chemical *mixtures* are largely unknown; it is well-established, however, that chemical mixtures can amplify or dampen the toxic effects of individual chemicals.<sup>28-30</sup>

*Table C. Examples of the toxicity range for some chemical and biological agents.\**

<b>Agent</b>	<b>LD<sub>50</sub>, mg/kg</b>
Ethyl alcohol	10,000
Sodium chloride	4,000
Ferrous sulfate	1,500
Morphine sulfate	900
Phenobarbital sodium	150
Picrotoxin	5
Strychnine sulfate	2
Nicotine	1
d-Tubocurarine	0.5
Hemicholinium-3	0.2
Tetrodotoxin	0.1
Dioxin (TCDD)	0.001
Botulinum toxin	0.0001

\*LD<sub>50</sub> is the dosage (mg/kg body weight) that causes death in 50% of exposed experimental animals. LD<sub>50</sub> reflects only the acutely lethal dose and does not reflect the spectrum of toxic effects associated with a chemical. Some chemicals may produce cancer or birth defects at doses that produce no evidence of acute toxicity. Note that some chemicals in the table are synthetic and some are naturally occurring, and both types occur at each extreme of toxicity.

## 2. Introduction

### 2.1 Green Chemistry Technology Innovation in California

By 2050, California's population is expected to grow by about 50%, from 36 to 55 million residents. This expansion will be accompanied by a growing set of social, economic, and environmental problems; the *magnitude* of these problems, however, will be determined in large part by the kinds of policy decisions California makes now and in coming years. In finding the path to a sustainable future, it will be increasingly important to make decisions that link economic development with measures that support environmental sustainability and human society. A decision-making framework is therefore needed in California that will allow policymakers to guide the transformations of industrial development in ways that simultaneously *solve* health and environmental problems.

This report makes the case that chemicals policy is a key element in California's transition to a sustainable future. Problems associated with society's current approach to chemical design, use, and management represent one of the major challenges of the 21<sup>st</sup> century, and reorienting this approach will require a long-term commitment to the development of a modern, comprehensive chemicals policy. In California, chemical problems are already affecting public and environmental health, business, industry, and government. On the current trajectory, these problems will broaden and deepen. Altering this course will require a chemicals policy that motivates industrial investment in the design, manufacture, and use of cleaner chemical technologies, known collectively as green chemistry.

Green chemistry represents a primary, long-term solution to many of the chemical problems facing California, and it is a key element of an industrial development strategy that is environmentally, socially, and economically sustainable. Green chemistry *products* are less toxic, they do not accumulate in the body, and they break down more readily in the environment. Green chemistry *processes* use safer materials and less energy and produce less hazardous waste.

As detailed in this report, however, weaknesses in the design and implementation of the federal Toxic Substances Control Act of 1976 (TSCA), together with the narrow scope of other U.S. environmental statutes and a lack of government support for basic research in cleaner technology, have discouraged U.S. chemical producers, product manufacturers, and entrepreneurs from investing in green chemistry on a scale commensurate with the nature of chemical problems facing society. As a consequence, the science of green chemistry remains in its infancy in the U.S., and the U.S. market for green chemistry products has yet to be established. The European Union and other nations, meanwhile, are moving rapidly ahead with chemicals policy changes and public investments in green chemistry science and technology.

To be effective, chemicals policy in California will need to address the weaknesses in federal chemical statutes by implementing improvements in three key areas: chemical information flows, regulatory oversight and investment in green chemistry research and development. A properly conceived chemicals policy will enable California to mobilize its unparalleled capacity for innovation and could position the state to become a global leader in green chemistry science and technology.

## 2.2 Chemicals: A Key Industry

Over the last 150 years, the U.S. chemical industry has played a key role in the U.S. and global economy. The industry's contributions to economic growth, employment, and improvements in life expectancy, health, and living conditions in Western-style societies are widely acknowledged.<sup>31-34</sup> Chemicals are a basic feedstock to nearly all industrial and productive activity in the U.S., and they appear in thousands of consumer and commercial products. In 2002, the American Chemistry Council (ACC) reported that U.S. businesses purchased \$288 billion (Table D) in U.S. chemical products, and industry exports totaled \$81 billion—larger than either agriculture or aircraft/aerospace.<sup>35</sup> The ACC reports that the industry contributed directly or indirectly to 5.5 million U.S. jobs, or about 5% of the total U.S. workforce in 2002, and it paid \$24.5 billion in federal, state, and local taxes.<sup>35</sup>

Table D. Direct purchases of U.S. chemicals and chemical products in 16 U.S. industry sectors, 2002.

Industry sector	U.S. billions
Health care	106.1
Consumer products	43.1
Rubber and plastic products	35.6
Furnishings, textiles, and apparel	16.4
Services and other	14.6
Agriculture	14.1
Paper and printing	10.0
Construction	10.4
Electrical and electronic equipment	5.4
Motor vehicles	4.6
Nonmetallic mineral products	3.4
Primary metals	3.3
Petroleum refining	3.0
Mining	2.3
Instruments	1.7
All other manufacturing	13.8
<b>Total</b>	<b>288.0</b>

In California, the ACC reports that the chemical industry employed about 81,000 people in 2004,<sup>B</sup> and that another 505,000 jobs were produced in the state indirectly by chemical industry activity in California and other states.<sup>36</sup> Together, this produced \$28.6 billion in worker earnings and \$1.7 billion in state and local tax revenues. The ACC reports that industries for which 10% or more of material inputs is derived from chemicals employ more than 4.3 million Californians (Table E). California consumers and businesses purchase 164 million pounds of chemical products each day, or about 4.5 pounds per capita.<sup>37</sup>

<sup>B</sup> Includes pharmaceuticals and pesticide producers; disaggregated employment information for the four industry sectors illustrated in Figure 1 is not available.



Table E. California employment in industry sectors for which 10% or more of material inputs is derived from chemicals.

Industry	California employment, 2004
Health care	1,179,304
Durable goods	710,892
Construction	683,437
Services	609,038
Nondurable goods	450,517
Agriculture	363,496
Information	263,486
Mining and utilities	54,024
Wholesale	38,776
<b>Total</b>	<b>4,352,970</b>

Both directly through its employment and indirectly through its impact on other industries, the chemical industry makes significant contributions to the economic well-being of citizens in the U.S. and California.

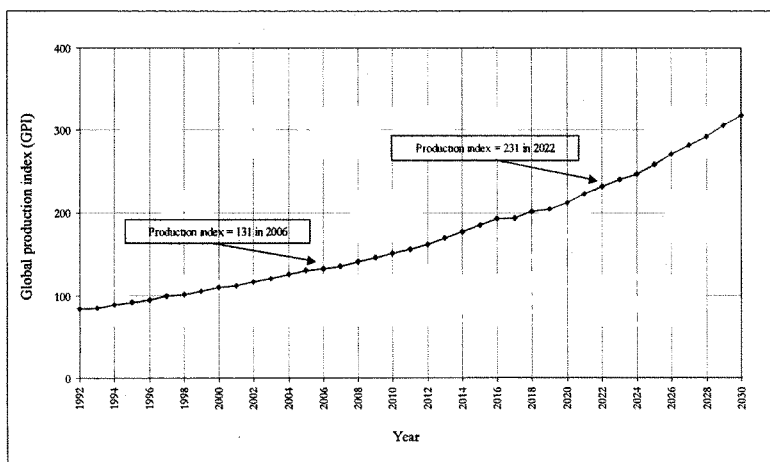
The chemical industry is also important because its products are ubiquitous; in roughly the last 50 years, chemicals have come to constitute the primary material base of society. The chemical industry has grown enormously in the last century and will continue to do so in the future, concomitant with expansion in the global consumer economy. In 2001, the U.S. produced or imported 42 billion pounds of chemicals each day,<sup>38</sup> the equivalent (if converted to gallons of water) of about 623,000 gasoline tanker trucks per day, each carrying 8,000 gallons.<sup>C</sup> If placed end-to-end, this number of trucks would extend 6,000 miles from San Francisco to Washington, D.C., and back; in the course of a year, it would circle the earth 86 times at the equator. The equivalent of about 2,700 such trucks are sold each day in California in consumer and commercial products alone.<sup>D</sup>

These chemicals are used in innumerable processes and products, and at some point in their life cycle many of them come in contact with people—in the workplace, in homes and through air, food, water, and waste streams. Eventually, in one form or another, nearly all of them enter the earth's finite ecosystems. On the current trajectory, global chemical production is expected to grow about 3% per year, such that it will double in size every 25 years for the foreseeable future (Figure 2). Given the scale and pace of chemical production, the toxicity and ecotoxicity of chemicals are of great public importance.

<sup>C</sup> An MC-407 gasoline tanker carries about 8,000 gallons of fuel. Estimates in this paragraph are based on the following:  $(1.52 \times 10^{13} \text{ pounds/year}) \times (0.016 \text{ ft}^3/\text{lb water}) \times (7.48 \text{ gallons/1 ft}^3) \times (1 \text{ truck/8,000 gallons}) \times (1 \text{ year/365 days}) = 623,000 \text{ trucks/day}$ . Assuming each truck is 50 feet in length:  $(1 \text{ mile/5280 ft.}) \times (50 \text{ ft./truck}) \times (623,000 \text{ trucks/day}) \times (365 \text{ days/year}) = 2,153,000 \text{ miles/year}$ . The earth's diameter at the equator = 7,926 miles and its circumference at the equator =  $7,926\pi = 25,000 \text{ miles}$ .  $(2,153,000 \text{ miles}/25,000 \text{ miles}) = 86$ .

<sup>D</sup> For California:  $(1.64 \times 10^8 \text{ pounds/day}) \times (0.016 \text{ ft}^3/\text{lb water}) \times (7.48 \text{ gallons/1 ft}^3) \times (1 \text{ truck/8,000 gallons}) \times (1.11 \text{ for 11\% population growth from 1997-2004}) = 2,723 \text{ trucks/day}$ .

Figure 2. Estimated projection of the global production index (GPI) of chemical production to 2030.\*<sup>E</sup>



\* 1997 = 100 and production is assumed to follow the trajectory defined by the period 1992–2002.

### 2.3 Closing the Gaps: The Challenge for Chemicals Policy in California

The size, complexity, economic importance, and rapid growth of the chemical industry have made it very difficult for countries around the world to implement effective chemicals policies. The U.S. is no exception. Of all the federal environmental statutes, the Toxic Substances Control Act (TSCA) of 1976 is the only U.S. law that is intended to enable regulation of chemicals both before and after they enter commerce. It has become clear, however, that TSCA has not provided an effective vehicle for the public, government, or industry to *assess* the hazards of the great majority of chemicals in commerce (the Data Gap), to *control* those that are known to be hazardous to public and environmental health (the Safety Gap), or to stimulate government and industry investment in green chemistry research and development (the

<sup>E</sup> This estimate was derived using a statistical model in which random samples were drawn from a distribution consisting of 10,000 random samples drawn from values representing the percent change per year in the global chemical production index for the period 1992 to 2002 (range 0.015 to 0.052; mean 0.032; standard deviation 0.015).<sup>39</sup> The model thus assumes continued global production to 2030 at the 1992–2002 rate. This rate is similar to that of previous years. This projection is similar to that of the Organization for Economic Cooperation and Development (OECD), UK Chemicals Industry Association and the American Chemistry Council, which predict an annual growth rate ranging from 0.026 to 0.035 leading up to 2020.<sup>40</sup> Indexed to 1995, the OECD expects non-OECD countries to experience 200% growth in chemical production by 2020 (from 0.5 to 1.5 trillion US\$) compared to 75% growth for OECD countries (2.0 to 3.5 trillion US\$).

Technology Gap). In California, the problems resulting from these three gaps are affecting public and environmental health, business, industry, government, and chemical producers themselves—especially those seeking to innovate green chemistry. Addressing these problems will require a modern, comprehensive approach to chemicals policy in California.

Other U.S. statutes have not remedied the deficiencies of TSCA and are surprisingly narrow in their scope. Combined, five major U.S. environmental and occupational statutes cover only 1,134 chemicals and pollutants.<sup>41</sup> The U.S. Occupational Safety and Health Administration, for example, has adopted workplace exposure limits for only 193, or about 7%, of the 2,943 chemicals produced or imported at more than one million pounds per year in the U.S.<sup>42</sup>

TSCA's weaknesses have far-reaching effects. Lacking comprehensive and standardized information on toxicity and ecotoxicity for most chemicals, it is very difficult for businesses and industry to choose safer chemicals or to identify and reduce the use of hazardous chemicals in their supply chains. Government agencies do not have the information they need to systematically identify and prioritize chemical hazards, nor the legal tools to efficiently mitigate known hazards. Consumers, workers, and small-business owners do not have the right kinds of information to identify and use safer chemical products. The lack of chemical information weakens the deterrent function of the product liability and workers' compensation systems. The lack of both regulatory and market drivers has dampened motivation on the part of U.S. chemical producers and entrepreneurs to invest in new green chemistry technologies. Meanwhile, evidence of public and environmental health problems related to chemicals continues to accumulate. The California Legislature faces numerous bills each year related to chemical problems, and on the current trajectory, the number of bills is likely to grow.

Leaders in the U.S. chemical industry have responded to these problems with a number of voluntary initiatives, including the *Responsible Care* program (of the ACC), the *High Production Volume* chemical program (ACC), the *Long-Range Research Initiative* (ACC), and the *Responsible Distribution Process* (of the National Association of Chemical Distributors). These efforts have undoubtedly produced improvements in environmental performance by leading firms in the chemical industry, and they will continue to do so. In particular, the HPV program is expected to produce basic screening level data for the great majority of the 2,943 chemicals in the U.S. that are produced or imported at more than one million pounds per year and that currently constitute about 99% of chemicals in commercial circulation, by volume. When combined with basic measures of exposure, these data could provide a useful, if limited, foundation for chemical data reporting in California. On the other hand, it is clear that California cannot rely on voluntary initiatives by industry as the basis for a comprehensive chemicals policy.<sup>F</sup>

<sup>F</sup> We evaluated a number of voluntary initiatives, including the U.S. chemical industry's *High Production Volume (HPV)* program, the *Responsible Care* program, the semiconductor industry's *Semiconductor Equipment and Materials International S2 Standard (SEMI)*, California's *Hazardous Waste Source Reduction and Management Review Act* (SB 14),<sup>43</sup> and an analysis of the mining and forestry sectors conducted by the Organization for Economic Cooperation and Development (OECD).<sup>44</sup> We found that while these efforts were generally positive, they were intended to incrementally improve the performance of existing industrial systems, not to transform those systems through technological change, as will be needed for the broad adoption of green chemistry. The *Responsible Care* program, for example, has sought to reduce environmental impacts among participating firms but has avoided confronting the health, environmental and economic problems associated with continued reliance on

On the current trajectory, problems related to the design, use, and regulation of chemicals in California will only expand. Federal regulatory weaknesses have given rise to conditions in the chemicals market that favor *existing* chemicals and discourage investment by chemical producers in green chemistry innovation and technological change. Large “sunk” investments by industry in existing chemical technologies will make it difficult to transition to an industrial system based on cleaner technology, including green chemistry; this transition, however, will have to be made if California is to respond proactively to developments in the E.U. and address a host of chemical problems affecting public and environmental health, business, industry, and government in the state. A California chemicals policy will enable more of the state’s businesses to “clean” their supply chains and implement green chemistry technologies, and it could position California to become a global leader in green chemistry technology innovation. The primary challenge of chemicals policy in California will be to motivate producers, distributors, and users of chemicals to invest in green chemistry and other practices that contribute to a developmental path in California that is environmentally, socially, and economically sustainable.

The analysis presented in the report is intended to help policymakers:

- understand the key weaknesses of federal statutes, particularly TSCA, that have given rise to the Data, Safety, and Technology Gaps (Section 3);
- understand the problems the three Gaps have created in California for public and environmental health, business, industry, and government (Section 4);
- recognize the need for a green chemistry technology transition in the chemical industry (Section 4);
- understand the basis for resistance by chemical producers to policies that would induce this transition (Section 4);
- recognize the significance of chemicals policy developments occurring in the European Union and among U.S. businesses and nongovernmental organizations (Section 5);
- recognize the relevance of the Massachusetts Toxics Use Reduction Act to chemicals policy in California (Section 6); and
- craft a chemicals policy that addresses health and environmental problems and motivates industry to invest in green chemistry technologies by closing the Data Gap, the Safety Gap, and the Technology Gap (Section 7).

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petroleum feedstock; *SEMI* induced positive changes in the environmental performance of numerous actors in the semiconductor industry but did not address the problems associated with the use of lead, cadmium, mercury and other hazardous materials in electronics, which are now being addressed by regulations in the European Union. Under SB 14, the California Department of Toxic Substances Control (DTSC) found that 29 of 40 California firms evaluated in 1998 in the Chemicals and Allied Products sector were significantly out of compliance. DTSC concluded “the underlying problem may be that company management lacks commitment to devoting the necessary resources to evaluate source reduction options.” Without a robust market or regulatory driver, most firms seek to avoid the disruption and costs that can accompany technological change, even when such changes are necessary for the long-term viability of the industry as a whole. As a result, we found that policies that could induce technological change were largely absent from voluntary initiatives.

### **3. The Federal Origins of the Data, Safety, and Technology Gaps**

#### **3.1 Overview**

This section describes the structural weaknesses in federal statutes that have produced a chemical Data Gap, Safety Gap, and Technology Gap in the U.S. The Data Gap refers to the absence of publicly available, standardized, robust information about the hazards and uses of chemicals in commerce, which impedes businesses, industry, government, consumers, and workers from identifying and acting on chemical hazards. The Safety Gap refers to legal and procedural barriers that prevent government agencies from mitigating known hazardous chemicals or preventing the introduction of new ones. The Technology Gap refers to the absence of proactive government efforts to support research, development, education, and technical assistance in green chemistry science and technology. California has not developed remedies to these three chemicals policy gaps.

Of all federal statutes, the federal Toxic Substances Control Act (TSCA) of 1976 (P.L. 94-469) is the only law that is broadly intended to enable regulation of chemicals both before and after they enter commerce.<sup>9</sup> As detailed in this section, weaknesses with TSCA lie at the heart of the Data, Safety, and Technology Gaps. The majority of chemical problems facing public and environmental health, business, industry, and government in California trace their roots to these weaknesses.

Other federal and state laws that pertain to chemicals are essentially “end-of-pipe” statutes that do not allow review of chemicals prior to their introduction into commerce. The section illustrates that the narrow scope and downstream orientation of these statutes prevent them from remedying the weaknesses of TSCA. Conversely, the weaknesses of TSCA have limited the potential effectiveness of these statutes.

#### **3.2 The Toxic Substances Control Act**

TSCA’s passage in 1976 resulted from widespread concern about the absence of public oversight over the proliferation of chemicals in commerce. At the time, this situation was not unique to the U.S.; internationally, the introduction of tens of thousands of chemicals into the market preceded regulation of any kind.

In enacting TSCA, Congress had three major policy objectives:<sup>45</sup>

- Those who manufacture and process chemical substances and mixtures should develop adequate data with “respect to the effect of chemical substances and mixtures on health and the environment.”

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<sup>9</sup> The 1996 *Food Quality Protection Act* addresses pesticides used in food production, and the 1997 *Food, Drug and Cosmetic Act* addresses the use of chemicals in food, drugs, and cosmetics. The 1990 federal *Pollution Prevention Act* addresses chemicals at the point of production and use but its applications are strictly voluntary.

- The government should have adequate authority to regulate chemical substances and mixtures that present “an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards.”
- The government’s authority over chemical substances and mixtures should be exercised “in such a manner so as not to impede unduly or create unnecessary economic barriers to technological innovation.”

TSCA represented an important step forward in the U.S. in the regulation of chemicals. Prior to its passage, for example, the U.S. had no inventory of chemicals in commercial circulation, and there was no vehicle for a public agency to conduct pre-market evaluation of chemicals. On the other hand, it is clear that TSCA is need of modernization. Studies conducted by the National Academy of Sciences (1984),<sup>46</sup> the U.S. General Accounting Office (1994),<sup>47</sup> the Congressional Office of Technology Assessment (1995),<sup>48</sup> the nongovernmental organization Environmental Defense (1997),<sup>49</sup> the U.S. EPA (1998),<sup>50</sup> the U.S. Government Accountability Office (2005),<sup>51</sup> former EPA officials,<sup>52</sup> and researchers<sup>53</sup> have concluded that TSCA has fallen short of its objectives and has not provided an effective vehicle for the public, industry or government to *assess* the hazards of chemicals in commerce or *control* those of greatest concern. As a consequence, it has not served to motivate industry investment in cleaner technologies, including green chemistry.

These studies point to TSCA’s three overarching weaknesses in design and implementation that we have designated the Data Gap, the Safety Gap, and the Technology Gap.

### **3.2.1 The Data Gap**

For the great majority of chemicals in commercial circulation, TSCA has provided EPA with insufficient authority to require the *generation* of information on chemical toxicity and ecotoxicity and the *distribution* of that information to state governments, businesses, industry, and the public. In 1979, at the time TSCA was implemented, there were about 62,000 chemicals in commercial circulation in the U.S.—often described as “1979 existing chemicals.”<sup>54</sup> These chemicals were “grandfathered” under TSCA; chemical producers were not required to disclose information on their toxic and ecotoxic properties, and they were generally considered to be “safe.” TSCA assigned the EPA responsibility for assessing the risks associated with these chemicals.

TSCA erected a number of barriers that have prevented the EPA from fulfilling this responsibility. Before the EPA is able to require a chemical producer to generate the test data necessary for assessing risks, TSCA requires the agency to show, on a chemical-by-chemical basis, that a chemical either (a) may present an unreasonable risk to human health or the environment, or (b) that the chemical is produced or imported in substantial quantities, *and* enters the environment in substantial quantities, *or* there is or may be significant or substantial human exposure to the chemical. The EPA must also demonstrate that existing health and environmental information about the chemical is insufficient, and that testing by the producer is

necessary to fill the information gaps. If the EPA cannot meet these requirements, it cannot act under TSCA to require generation of safety information about a chemical.

This legal burden has created a “logical paralysis” for the EPA: to assess chemical risks, the EPA needs toxicity and exposure data that producers are not required to provide unless the EPA can first show that such a risk may in fact exist. Not surprisingly, this has turned out to be a significant barrier for the EPA. In 1994, the GAO found that the EPA had managed to review the risks of about 1,200 (2%) of the 62,000 “1979 existing chemicals.”<sup>54</sup> The EPA reported to the GAO, however, that about 16,000 (26%) of these chemicals were potentially of concern on account of their production volume and chemical design.<sup>54</sup>

Though the TSCA inventory has grown to 81,600 chemicals, this body of 62,000 “1979 existing chemicals” continues to constitute the great majority of chemicals in commercial circulation in the U.S. (by volume), many of which have reached high levels of use despite very little information about their toxicity or ecotoxicity.<sup>38</sup> Currently, 8,282 chemicals are produced or imported in the U.S. at more than 10,000 pounds per year, and 2,943 are produced or imported at more than one million pounds per year, known as High Production Volume (HPV) chemicals (Table F).<sup>38</sup> Ninety-two percent of HPV chemicals in commercial circulation today consist of “1979 existing chemicals”; only 248 (8%) new chemicals introduced since 1979 have reached HPV status.<sup>38</sup>

*Table F. Distribution of chemicals produced or imported in the U.S. in 2001, as reported under the 2002 TSCA Inventory Update Rule.\**

Distribution of chemicals produced or imported in the U.S.			
	U.S. production & import range, lbs	Number of chemicals in the production range	Percentage of chemicals in the production range
<b>Non-HPV</b>	10K to 500K	4,670	56%
	>500K to 1M	669	8%
	>1M to 10M	1,548	19%
	>10M to 50M	577	7%
<b>HPV</b>	>50M to 100M	153	2%
	>100M to 500M	273	3%
	>500M to 1B	77	9%
	>1B	315	4%
	Total pounds reported	15,208,921,689,779	
	Total HPV pounds	15,207,877,185,511	
	HPV as percent of total		99.99%

\* Chemicals produced or imported at less than 10,000 pounds per year are not subject to reporting under the Inventory Update Rule except under certain conditions, such as an order under Section 5(e). HPV chemicals constitute about 35% of the *number* of chemicals produced or imported at 10,000 pounds or more per year, but over 99% by *volume*, according to Inventory Update Rule reporting data.

Given its constraints under TSCA, the EPA has opted for voluntary approaches to generating chemical toxicity and ecotoxicity data, beginning in 1997 with an effort to gather screening-level data on the HPV chemicals.<sup>55</sup> As of 2003, chemical producers had voluntarily submitted

screening-level data for about 90% of these chemicals.<sup>56</sup> <sup>H</sup> Because HPV chemicals account for over 99% of chemicals in commercial circulation in the U.S., these data could provide a foundation for chemical reporting in California, assuming they can be linked to basic measures of exposure (Section 7).

On the other hand, while the HPV program represents an important beginning, it will not provide enough information to support chemical decision-making by businesses, industry, government, and the public. The U.S. EPA has recommended that more extensive toxicity testing would be needed beyond screening-level tests to “adequately assess the hazards of higher-exposure chemicals (e.g., chemicals in consumer products, chemicals to which children may be exposed, high-release TRI chemicals, chemicals with large numbers of exposed workers etc.).”<sup>57</sup> The EPA, however, presently has no systematic efforts under way to obtain more extensive toxicity data on the HPV chemicals or to gather screening-level data on the 5,339 chemicals produced or imported in the range of 10,000 to one million pounds per year.<sup>58</sup>

For the great majority of chemicals in commercial circulation, there is insufficient publicly available information about the toxicological properties and uses that is necessary for determining whether these chemicals are safe for human health and the environment; this can be characterized as a chemical Data Gap.

### 3.2.2 The Safety Gap

In addition to giving the EPA limited authority for requiring the generation and distribution of chemical information, TSCA makes it very difficult for the EPA to take regulatory *action* on chemicals. To regulate a chemical, TSCA requires EPA to provide “substantial evidence” that (1) the chemical presents or will present an “unreasonable” risk to health and the environment, (2) the benefits of regulation outweigh both the costs to industry of the regulation and the lost economic and social value of the product, and (3) EPA has chosen the least burdensome way to eliminate only the unreasonable risk. In considering regulatory actions, the EPA is required to “consider the environmental, economic, and social impact of any action” it proposes to take.<sup>59</sup>

Faced with this burden of proof, the EPA has been able to use its formal rule-making authority to regulate only five existing chemicals (or chemical classes) since the passage of TSCA in 1979: polychlorinated biphenyls (PCBs), chlorofluorocarbons (CFCs), dioxins, asbestos, and hexavalent chromium.<sup>60</sup> Of these, TSCA itself required regulation of PCBs, and EPA’s regulation of asbestos, promulgated after the agency spent 10 years gathering evidence, was overturned in its most significant aspects by the 5<sup>th</sup> Circuit Court of Appeals, which concluded that EPA had failed to meet its burdens of proof.<sup>62</sup>

TSCA enables the EPA to be somewhat more active under the provisions of the statute that pertain to “new” chemicals introduced since 1979.<sup>1</sup> As noted above, these chemicals comprise

<sup>H</sup> Since the program’s launch in 1997, about 700 additional chemicals have reached HPV status in the U.S. Chemical producers have voluntarily submitted information for about 100 of these, and the industry has announced an “Extended HPV Challenge” to address the remainder.

<sup>1</sup> These provisions also apply to a small number of “existing” chemicals in the original 1979 TSCA inventory for which the EPA has issued Significant New Use Rules.



248 HPV chemicals and a number of other smaller-volume chemicals.<sup>5</sup> Using information submitted by producers on “pre-manufacturing notices” (PMNs), the EPA has acted in various ways to restrict 3,500 (10%) of the 36,600 chemicals that producers proposed to introduce into commercial circulation between 1979 and 2004.<sup>61</sup>

TSCA thus enables EPA to take steps to control *new* chemicals before they are marketed; on the other hand, it only requires that producers submit toxicity testing information that is “in their possession” when they file the PMN; it does not require new testing.<sup>62</sup> This has created a disincentive for producers to conduct toxicity testing. For example, the EPA has reported that 85% of PMNs lack data on chemical health effects, and 67% lack health or environmental data of any kind.<sup>61</sup> In addition, once new chemicals are placed on the TSCA inventory, EPA may regulate them only under the standards and burdens it carries for “1979 existing chemicals.” Producers are not required to generate *tiered* health and environmental data on new chemicals as their production volume increases over time, such as the 248 new chemicals that have reached HPV status.

Finally, TSCA contains confidential business information (CBI) provisions that have prevented the EPA from *distributing* the chemical information it obtains through the PMN process and Inventory Update Rule. In 1998, the EPA reported that 65% of information filings submitted under TSCA were claimed by businesses as CBI.<sup>62</sup> The EPA determined that 22% of these claims were invalid.<sup>63</sup> In 2005, the EPA reported that 95% of PMNs contained some information that chemical companies claimed as confidential.<sup>64</sup> California state agencies, businesses, and nongovernmental organizations have no more access to chemical information classified as CBI under TSCA than do private citizens.<sup>62</sup> State agencies in California are therefore currently unable to determine the toxicity, ecotoxicity, identity, volume in commerce, locations of use, or potential routes of exposure of chemicals used in the state (Section 4).

The U.S. EPA has been unable to regulate “1979 existing chemicals” and it has had to rely on limited information and tools to regulate “new chemicals”; this has produced a chemical Safety Gap in the U.S.

### **3.2.3 The Technology Gap**

By not requiring the generation and disclosure of the toxicity of chemicals on the market, and by erecting barriers to chemical regulation, TSCA has given rise to conditions in the market that have favored *existing* chemicals and dampened industry motivation to invest in green chemistry technology innovation (Section 4). In addition, TSCA was not intended as a vehicle for the federal government to support research, development, and education in cleaner chemical technologies, including green chemistry. Although practical developments in green chemistry are occurring among a number of leading U.S. chemical producers,<sup>65-67</sup> government support for green chemistry research in the U.S. is lagging behind initiatives in Japan, Italy, China, and Australia.<sup>68, 69</sup> Together, these conditions may be producing a green chemistry Technology Gap in the U.S. that could have long-term implications for U.S. competitiveness in the chemicals market.

### 3.3 Federal Pollution Control Statutes

There are a number of federal statutes oriented to chemical pollution and exposure *control*. These statutes have produced improvements in environmental and occupational health performance by industry.<sup>70</sup> The American Chemistry Council, for example, reports that the industry spent \$10 billion per year between 1995 and 2002 (about 3% of sales) on efforts to abate air pollution, water pollution, and other pollution (43%); capital costs for pollution abatement (27%); hazardous waste cleanup (16%); and worker health and safety (14%) related to the industry's current choice of chemical technologies.<sup>71</sup>

On the other hand, the narrow scope of federal statutes has prevented them from functioning as a "safety net" against the deficiencies of TSCA. Five major federal statutes regulate emissions or exposure levels for only 1,134 chemicals and pollutants (Table G).<sup>72</sup> Adding, deleting, or otherwise changing listed chemicals requires extensive justification—at public expense—and typically engenders a legal challenge. These statutes have therefore not kept pace with developing scientific knowledge of chemical toxicity that is reflected, for example, in the *Hazardous Substances Data Bank* of the U.S. National Library of Medicine, which contains entries for about 4,800 potentially hazardous chemicals.<sup>73</sup>

Table G. The number of chemicals listed under five major federal statutes. \*

Federal statute	Number of chemicals listed
Clean Water Act (CWA) <sup>74</sup>	148
Resource Conservation and Recovery Act (RCRA) <sup>75</sup>	502
Clean Air Act (CAA) <sup>76</sup>	189
Occupational Safety and Health Act (OSH Act) <sup>77</sup>	453
Emergency Planning and Community Right-to-Know Act; the Toxics Release Inventory (EPCRA – TRI) <sup>78</sup>	600

\*With overlap, the total number of regulated chemicals is 1,134.

The number of regulated chemicals, as well as the chemicals themselves, varies considerably from statute to statute (Table H). Chemicals that appear in any pair of the five statutes range from only 13% to 29% of the total number.<sup>72</sup> This variability results primarily from the fact that the lists were derived independently for different reasons; some of the statutes are concerned entirely with human health, for example, while others also address ecosystem effects.<sup>79</sup>

Because the scope of the statutes is constrained, they have not served to motivate broad investment by chemical producers in green chemistry technologies. In theory, if they are sufficiently stringent and adaptable to new technology developments, pollution control strategies can motivate investment by industry in new pollution prevention technologies, including green chemistry. For example, a standard that prohibits the discharge of certain hazardous chemicals into wastewater (but leaves industry responsible for developing the means for achieving the

standard) can in principle lead to industrial innovations that include green chemistry solutions. Although the federal pollution control statutes have achieved this objective in isolated cases, they have not motivated industry to invest broadly in green chemistry and other cleaner technologies, which has contributed to the Technology Gap.

Table H. Comparison of chemicals listed under the five statutes in Table G.

Comparison	Number of chemicals listed
Regulated under all five statutes	49
Regulated under at least four statutes	119
Regulated under three or more statutes	210
Regulated under two or more statutes	371
Regulated under only one of the five statutes	768

### 3.4 California Pollution Control Statutes

California has established a number of its own efforts to regulate chemicals that appear in air, water, workplaces, and consumer products (Table I). These efforts have led to improved practices in California. Under Proposition 65 (the *Safe Drinking Water and Toxic Enforcement Act* of 1986), for example, California is able to notify the public of certain carcinogenic or reproductive chemical hazards where the state can demonstrate a potential risk of exposure. The state has assigned workplace permissible exposure limits (PELs) to nearly 700 substances, compared to 453 under federal OSHA.<sup>80</sup> Many of California's PELs are more protective of workers than those of federal OSHA. California has developed a number of community-based exposure limits for chemicals and is pursuing innovative strategies to encourage the use of green building materials.<sup>81</sup> Like the federal statutes, however, California's laws capture a very small number of chemicals and pollutants, and updating them is constrained by legal and procedural barriers.

Other chemical regulatory efforts in California that do not involve lists of chemicals include the *Certified Unified Program Agencies* (CUPAs) of 1993 (SB 1082), the *Hazardous Waste Source Reduction and Management Review Act* of 1989 (SB 14), and the *Hazardous Substances Information and Training Act* of 1986. These laws and programs have produced improvements in the management and communication of some chemical hazards; however, with the possible exception of Proposition 65, however, California's environmental laws—like those at the federal level—are too constrained to enable California to effectively identify, prioritize, and mitigate chemical hazards, nor have they served to motivate industry investment in cleaner chemical technologies, including green chemistry.

Table I. Numbers of chemicals regulated in California under nine programs.\*

California statute or program	Number of chemicals listed
Permissible Exposure Limit (workplace) (DOSH) <sup>80</sup>	688
Chronic Reference Exposure Levels (air) (OEHHA) <sup>81</sup>	80
Registry for Report of Carcinogen Use (workplace) (DIR) <sup>82</sup>	30
Maximum Contaminant Levels (water) (DHS) <sup>83</sup>	77
AB 2588 – Air Toxics “Hot Spots” (air) (EPA) <sup>84</sup>	80
Drinking Water Action Levels (water) (DHS) <sup>85</sup>	49
Toxic Air Contaminants (air) (EPA) <sup>86</sup>	24
Proposition 65 Chemicals (consumer products) (EPA) <sup>87</sup>	635
Process Safety Management Chemicals (industry) (DOSH) <sup>88</sup>	138

\*DOSH: Division of Occupational Safety and Health  
 OEHHA: Office of Environmental Health Hazard Assessment  
 DIR: Department of Industrial Relations  
 DHS: Department of Health Services  
 EPA: California Environmental Protection Agency

This orientation in California law has emerged in part from a general presumption among California policymakers that federal law, particularly TSCA, provides the U.S. EPA with sufficient authority to assess the hazards of chemicals in commercial circulation and control those of greatest concern, which is not the case, as described above.

### 3.5 Lessons Learned from the Current Regulatory Context

The experience under TSCA since 1979 illustrates three key lessons for chemicals policy in California:

First, it illustrates chemicals policy approaches that are ineffective. These include (1) not requiring chemical producers to generate and disclose toxicity and other information sufficient to evaluate the safety of chemicals (the Data Gap); (2) requiring public agencies to produce extensive evidence of harm and economic analyses before they are able to take actions to protect public and environmental health (the Safety Gap); and (3) neglecting the role of information, regulation, and public investment in spurring research and development in new technologies, such as green chemistry (the Technology Gap). Chemicals policy in California will need to correct these weaknesses.

Second, it illustrates policy approaches that are outmoded. With advancements over the last thirty years in the environmental health sciences, it is clear that many chemicals are hazardous to biological systems, sometimes at very low doses, and they are particularly so during fetal and child development (Section 4). While such chemicals might constitute only a subset of chemicals in commercial circulation, the size of this subset is presently unknown—although the evidence suggests it far exceeds the number of chemicals presently listed under federal and state statutes.

The disconnect between a continually evolving body of knowledge in the environmental health sciences and the static nature of the chemical regulatory system is a source of tension in California that could grow in the future. California journalists are reporting on developments in toxicology and regulatory changes in the European Union, and public-health advocates—as well as a growing number of business leaders in California—are aware that the regulatory system is incapable of responding to these developments in a proactive, deliberative way. California will need to develop mechanisms for decision-making and action in chemicals policy that are better able to respond to evolving knowledge in the environmental health sciences and to developments in the chemicals market (Section 7).

Third, it points to policy flaws that prevent proper operation of the market. The work of Nobel prize-winning economist Joseph Stiglitz suggests that the Data Gap has created a “market failure” in the U.S. that prevents the laws of supply and demand from enabling the market to produce what the public really wants.<sup>89</sup> Because the chemicals market lacks robust, easy-to-use information on chemical toxicity, the prices businesses and consumers pay for chemicals may not reflect their true preferences; they may inadvertently be purchasing hazardous chemicals that they might avoid if they had better information. As a consequence, Guth, Dennison, and Sass argue that “the demand for *safer* products is not adequately expressed or realized in the market.”<sup>90</sup> These conditions disadvantage producers of safer products, and they give rise to commercial interests that are motivated to protect existing products, including those that are hazardous (Section 4). These interests naturally resist information disclosure policies out of concern that they could undercut the market share of existing chemicals if those chemicals are found to be hazardous. A new approach to chemicals policy is needed in California that better uses information to leverage market forces.

Together, weaknesses in the federal regulation of chemicals have created Data, Safety, and Technology Gaps that have dampened the motivation of industry to innovate safer chemical products and processes, including green chemistry. The commercial interests that have grown up within this “economic space” will present a significant challenge to new chemicals policy efforts in California; on the other hand, as described in the following section, the array of problems these three gaps are causing for public and environmental health, business, industry, and government in California are likely to worsen if left uncorrected.

## **4. Chemical Problems in California**

This section describes chemical problems in California from three perspectives: public and environmental health, business and industry, and government. The section illustrates that many of these problems trace their roots to the Data, Safety, and Technology Gaps that have emerged as a result of federal chemicals policy weaknesses, notably those of TSCA (Section 3). The section is organized as follows:

- 4.1 Public and Environmental Health
  - 4.1.1 Environmental Justice
  - 4.1.2 Children
  - 4.1.3 Consumers
  - 4.1.4 Workers
  - 4.1.5 Environment
- 4.2 Business and Industry
  - 4.2.1 Businesses That Use Chemicals
  - 4.2.2 Green Chemistry Leaders
  - 4.2.3 Chemical Producers
- 4.3 Government
  - 4.3.1 State and Municipal Agencies
  - 4.3.2 The Legislature

### **4.1 Public and Environmental Health**

There is growing scientific concern regarding the implications of chemical exposures that occur over the course of the human lifespan—in workplaces and homes and in air, water, food, and waste streams—particularly during the sensitive period of fetal and child development. In considering health effects in relation to chemical exposures, it is important to recognize that, in the great majority of cases, human *disease* results from a combination of environmental, socioeconomic, genetic, and cultural factors, each of which acts over a lifetime.<sup>91-94</sup> Chemical exposures represent one of many environmental factors that can induce disease directly and can also influence the initiation, progression, or recurrence of other disease processes.<sup>95, 96</sup>

On the other hand, there is a substantial body of literature regarding chemically induced diseases among workers and other highly exposed individuals and populations.<sup>97-106</sup> There is growing evidence in animal studies that some chemicals can disrupt biological processes at very low doses. The biological and ecological effects of chemicals are of growing importance given the scale and pace of chemical production globally. In the following subsections we present examples of public and environmental health problems facing California that are related to chemicals; this review, however, is not intended to be a comprehensive examination of these issues.

#### **4.1.1 Environmental Justice**

It is well established that certain populations—immigrants, minorities, and lower-income groups—are at heightened risk of exposure to hazardous chemicals and chemically induced disease. The fact that emissions of chemical pollutants tend to be concentrated in lower-income and minority communities in California is well-documented.<sup>107-110</sup> This reflects earlier research in the area of occupational injuries and illnesses, which showed that Latino males were 80% more likely to suffer a disabling illness or injury than white males (68 vs. 38/1,000), while black males were 40% more likely (53/1,000).<sup>111</sup> Latinas were almost 60% (33/1,000) and African American women were 40% (29/1,000) more likely than their white female co-workers in the same industries (21/1,000) to suffer a disabling illness or injury. In communities and in workplaces in California, immigrants, minorities, and lower-income groups are at disproportionately heightened risk of hazardous chemical exposures.

The California Environmental Protection Agency has adopted an Intra-Agency Environmental Justice Strategy that calls for consideration of environmental justice in the “development, adoption, implementation and enforcement of environmental laws, regulations and policies” in California.<sup>112</sup> Environmental justice matters overlie many of the chemical problems described for children, consumers, and workers in this section.

#### **4.1.2 Children**

The evidence indicates that (1) children are especially vulnerable to the effects of chemical exposures; (2) children are exposed to chemicals during pregnancy, in breast milk, through consumer products, and through food, air, and water; (3) many of these chemicals have properties that can cause them to disrupt biological processes; and (4) some portion of the chronic pediatric conditions of asthma, certain cancers, and autism are related to chemical exposures.<sup>113-117</sup> It is possible that the long-term effects of chemical exposures during fetal, infant, and child development are under-appreciated. Children and their offspring will carry the greatest burden of chemically induced damage to human and environmental health. Chemicals policy strategies are needed that will enable California to proactively identify, prioritize, and mitigate chemical exposures of concern to children’s health, even when the health outcomes resulting from these exposures have not been fully characterized.

#### ***Children are uniquely vulnerable to the effects of chemical exposures.***

In 1993, the National Academy of Sciences reported that children are uniquely vulnerable to the effects of chemical exposures during all periods of fetal, infant, and child development. This vulnerability is attributable to four key factors, as follows:<sup>118</sup>

- Sensitive physiological processes can be disrupted during the rapid growth and development characteristic of embryonic and fetal life and the first year following birth. Development of the brain, for example, requires the formation and interconnection of billions of neurological cells; development of the endocrine system and reproductive organs is guided by a precisely timed sequence of hormones that exert their effects in the parts-per-trillion range.

- Children's metabolic pathways, especially in fetal life and in the first month after birth, are immature. Among other factors, growth of the blood-brain barrier, which can provide protection against some chemicals, is incomplete during fetal and early child development, such that chemicals are able to move directly from the maternal blood stream into the developing fetal brain.
- Relative to their size, children's intake of air, water, and food is far greater than that of adults. The amount of air a resting infant breathes, for example, is twice that of an adult, normalized by body weight. Children therefore experience disproportionately higher doses of environmental agents, including chemicals.
- Children have more years of future life than adults and thus have more time to develop diseases initiated by exposures early in life. Many chronic diseases, including cancer and neurodegenerative diseases, appear to arise as a result of cellular changes that take place many years before the actual manifestation of the disease. Critical windows of exposure to hazardous chemicals *in utero*, during early child development, and during puberty are more likely to produce chronic disease than similar exposures encountered later.

***Chemical exposures take place during fetal development.***

For the reasons outlined above, chemical exposures that occur during fetal development are of special concern.<sup>119, 120</sup> There is evidence that many chemicals reach the fetus.<sup>114, 119, 121-128</sup> A 2005 study reported (for the first time) that the maternal urinary concentration of chemicals used as plasticizers in consumer products—known as phthalates—was associated in a statistically significant dose-response relationship with changes in the sexual characteristics of a study group of 134 boys age 2 to 36 months.<sup>129</sup><sup>J</sup> These changes were consistent with those seen in animal studies and were reported to occur at maternal phthalate metabolite concentrations that were not unusually high compared to the U.S. female population, based on a nationwide sample. While further studies will be needed to validate these findings, the reported effects could represent one outcome in a cascade of other, as yet unidentified, forms of human endocrine disruption by phthalates. Phthalates make up about 87% of the 10.4 billion-pound-per-year world market for plasticizers.<sup>130</sup>

A 2005 report by the Environmental Working Group, a U.S. nongovernmental organization, showed that between 159 and 234 chemicals were present in samples of umbilical cord blood obtained from 10 newborns.<sup>131</sup> Many of these chemicals were reported to be associated with toxic effects in animals or humans, or both.

Among other pathways, fetuses may be exposed to chemicals through parental use of consumer products. A British study of 7,000 families found that women quite commonly used chemical consumer products during pregnancy.<sup>132</sup> The products used (and the percentage of women using them) were disinfectant (87%), bleach (85%), air freshener (68%), window cleaner (61%), carpet

<sup>J</sup> These were decreased anogenital distance and incomplete descent of the testes, both of which are associated with feminization. Plasticizers are introduced into a wide range of consumer and commercial products to improve flexibility.



cleaner (36%), paint or varnish (33%), turpentine (23%), pesticides and insecticides (21%), paint stripper (6%), and dry cleaning fluid (5%).

***Chemical exposures take place during infant and child development.***

There is evidence that children who are nursing are exposed to a significant number of chemicals in breast milk, including some that are known to be toxic, including methylene chloride, styrene, perchloroethylene, toluene, trichloroethylene, 1,1,1-trichloroethane, xylene, dioxins, benzene, polychlorinated biphenyls (PCBs), chloroform, polybrominated diphenyl ethers (PBDEs), and others.<sup>133-140</sup> Over the last 30 years, for example, total PBDE levels in breast milk have shown a doubling time of only five years (Figure 3). While the chemical "body burden" of males slowly increases over a lifetime, it appears to be reduced in nursing mothers through transfer out of fat tissue into breast milk.<sup>141</sup> A study of 800 nursing mothers found that first-born children ingested the highest concentration of chemical contaminants in breast milk, and that contaminant levels decreased during lactation, such that younger children received lower doses than older siblings.<sup>135</sup> While it is widely recognized that breast milk provides overall enhancement of infant health and development, the potential effects of even minute amounts of chemical contaminants in breast milk are of concern to pediatricians and child health researchers.<sup>142-144</sup>

*Figure 3. Flame retardants and children's health.*

Polybrominated diphenyl ethers (PBDEs) are used as flame retardants in consumer products. Because many U.S. states and the federal government require certain products to be flame-resistant, PBDEs have become an important commercial product, with annual global sales of about 70,000 metric tons.<sup>145</sup> Total PBDE levels have increased in human blood, breast milk, and tissues by a factor of about 100 over the last 30 years, with a doubling time of about five years.<sup>145</sup> This same trend is seen in marine mammals throughout the world.

Animal studies have demonstrated a striking array of toxic effects associated with exposure to PBDEs. Single exposures to animals shortly after birth induce permanent impairment of motor behavior in adulthood.<sup>146</sup> Repeated exposures produce neurotoxicity, endocrine disruption (e.g., decreased thyroid hormone levels), immunotoxicity, and other effects.<sup>146-148</sup> Some of the neurotoxic effects of PBDEs appear comparable to those of polychlorinated biphenyls (PCBs), which were finally phased out of use by most countries of the Organization for Economic Cooperation and Development (OECD) in 1989.<sup>148</sup>

***Some portion of childhood asthma, certain cancers, and neurodevelopmental disorders is linked to chemical exposures.***

Establishing a link between chemical exposures and disease trends is difficult given the set of epidemiological and toxicological tools currently available.<sup>149</sup> Nevertheless, there is evidence that chemical exposures play a role in certain diseases among children in the U.S.<sup>113</sup> Landrigan et al. estimate that chemical exposures in air, food, water, and communities contribute to 100% of lead poisoning, 10% to 35% of asthma, 2% to 10% of certain cancers, and 5% to 20% of neurobehavioral disorders among children.<sup>150</sup> These chronic conditions of multifactorial origin have been termed the “new pediatric morbidity.”

The prevalence of asthma among children approximately doubled between 1980 and 1995, from about 4% to 8%.<sup>113</sup> Between 1994 and 1996, asthma caused U.S. children to miss 14 million days of school. The National Academy of Sciences reported in 2000 that, although data are limited, there is evidence suggesting that indoor air pollutants such as volatile organic compounds, plasticizers, nitrogen dioxide, and pesticides may play a role in childhood asthma.<sup>151</sup> A 2005 study of 14,000 children reported a dose-response relationship between childhood wheezing and pre-natal exposure to chemical consumer products.<sup>152</sup>

The prevalence of childhood cancers, including leukemias (acute lymphoblastic and acute myeloid), central nervous system tumors, lymphomas (Hodgkin’s lymphoma, non-Hodgkin’s lymphoma), thyroid carcinoma, and malignant melanoma, appears to have stabilized since 1990 after steady increases since 1975.<sup>113</sup> In absolute numbers, childhood cancer deaths have declined since 1975, largely due to improvements in treatment.<sup>152</sup>

Between 3% and 8% of infants born each year in the U.S. are—or will be—affected by neurodevelopmental disorders, including autism, mental retardation or attention-deficit/hyperactivity disorder (ADHD).<sup>113</sup> The causes of these disorders are unknown in the great majority of cases. It is well-established, however, that at low levels certain industrial chemicals—such as lead, methylmercury, PCBs, and others—disrupt the developing brain and nervous system.

#### **4.1.3 Consumers**

The Data Gap and the Safety Gap are reflected in the fact that there is very little information about chemicals in consumer and commercial products, and there are very few restrictions on the kinds of chemicals that can be used in these products. Some chemicals that are known to be hazardous therefore continue to be used in consumer products; however, for the great majority of chemicals used in millions of pounds of products sold in California, the toxicity and ecotoxicity are unknown. The chemical consumer market is distorted by the fact that there are no criteria—and there is no simple labeling system—that would enable consumers and small-business owners to identify and choose chemical products on the basis of toxicity or ecotoxicity.

***Manufacturers are not required to test the safety of chemicals used in consumer products.***

Manufacturers of chemical consumer products are not required to evaluate and disclose the toxicity and ecotoxicity of their products before placing them on the market. The California Air Resources Board (ARB) reports that 164 million pounds of chemical consumer and commercial products are sold in California each day (Appendix B).<sup>153, 154</sup> Because chemicals in consumer and commercial products are typically released from their container in close proximity to the user, the likelihood of exposure is high. There is some information in publicly available databases on the safety of individual chemicals in consumer products; for the great majority of chemicals, however, there is little to no information. As noted above, the effects of chemical *mixtures*, which constitute most chemical products, are unknown; it is well-established, however, that chemical mixtures can amplify or dampen the toxic properties of individual chemicals.<sup>28-30</sup>

Most Californians probably believe that chemicals in consumer products are somehow “safety tested” before being placed on store shelves, or before being introduced into the workplace. In a 2002 survey of 800 voters in Washington and Maine, for example, 55% agreed with the statement, “Currently, the government carefully tests chemicals used in all major consumer products to make sure they are safe for people to use.” 76% agreed with the statement, “Current regulations require chemical companies to provide information about the health impacts of the chemicals they create.”<sup>155</sup> Both statements are false (Section 3).

***Consumers are unable to choose safer chemical products.***

There is no simple labeling system in California to communicate to consumers that a chemical product contains, for example, “untested,” “hazardous,” “safer,” or “certified green” chemicals. At present, the Data Gap precludes a labeling system of this nature; it is very difficult for manufacturers of chemical products to gather standardized, robust toxicity information on the chemicals they purchase and introduce into their products.<sup>156</sup> Without a simple labeling system for chemical products, however, consumers and business owners cannot make rapid, efficient purchasing choices that reflect their values. This represents a key barrier to the commercial viability of green chemistry consumer products.

***There are hazardous chemicals in consumer products.***

California’s Proposition 65 lists over 600 chemicals that appear in consumer products and are known to cause cancer or harm to reproduction and/or development. Using 1997 data, the California Air Resources Board estimated that about 472,000 pounds of volatile organic compounds (VOCs) are released from consumer and commercial products each day in California.<sup>153</sup> Due to insufficient data on toxicity and chemical usage, however, it is not possible to identify and prioritize the risks associated with hazardous chemicals in consumer products sold in California.

The *Household Products Database* of the National Library of Medicine lists about 2,000 isolated chemical ingredients that are associated with a range of toxic effects and are contained in about 4,000 consumer products.<sup>157</sup> As previously noted, the U.S. EPA reported in 1994 that about

16,000 chemicals in commercial circulation in the U.S. (about 26% of existing chemicals at that time) are potentially of concern to public health on account of their design and volume in commerce (Section 3).<sup>54</sup> The European Environment Commission estimates that about 1,400 “chemicals of very high concern” are produced or imported in the E.U. at significant levels (Section 5). These substances consist of chemicals that are persistent, bioaccumulative, and toxic; chemicals that are “very persistent and very bioaccumulative”, irrespective of toxicity; and chemicals that are carcinogenic, mutagenic, or toxic to reproduction.<sup>158, 159</sup>

***Many chemicals persist in the environment and accumulate in the human body.***

Persistent and bioaccumulative chemicals represent a unique hazard because they can give rise to effects over a greater period of time and over larger distances than other chemicals. Chemicals that are persistent and bioaccumulative *and* toxic are of particular concern in this regard. In 1987, the U.S. EPA reported finding 688 synthetic chemicals and other substances in the adipose tissue of a nationwide sample of Americans.<sup>160</sup> <sup>K</sup> In 2003, the U.S. Centers for Disease Control and Prevention (CDC) looked for, and found, 116 chemicals and other substances in the blood and urine of a representative sample of the U.S. civilian population.<sup>161</sup> In 2005, the CDC added 32 new chemicals to the survey, all of which were subsequently identified in blood and/or urine samples.<sup>162</sup> Other chemicals will likely appear as these lists are expanded.

Chemicals that consist of hydrocarbon molecules attached to one or more atoms of chlorine, bromine or fluorine—known as halogenated molecules—present a unique set of problems because they often exhibit toxicity in addition to persistence and bioaccumulative properties. Combined, several studies have reported the presence of about 200 *chlorinated* hydrocarbons (or organochlorines) in human adipose tissue, breast milk, blood, urine, semen, and exhaled breath.<sup>163-176</sup> Many of these chemicals are associated with toxic effects in animals and/or humans. The American Public Health Association wrote in a 1994 consensus resolution that “Virtually all organochlorines that have been studied exhibit at least one of a range of serious toxic effects, such as endocrine dysfunction, developmental impairment, birth defects, reproductive dysfunction and infertility, immunosuppression and cancer, often at extremely low doses, and many chlorinated organic compounds . . . are recognized as significant workplace hazards.”<sup>177</sup>

*Brominated* hydrocarbons, which have recently appeared in California in cleaning solvents,<sup>178</sup> exert a range of potent toxic effects on the human reproductive, neurological, and other systems.<sup>179-193</sup> Problems associated with the class of flame retardants known as polybrominated diphenyl ethers (PBDEs) are described in Figure 3, above. Among *fluorinated* compounds, perfluorooctane sulphonate (PFOS), which was used in a variety of consumer products for its “non-stick” and water-repellent properties, has appeared in human tissues and in the tissues of birds, fish, and marine mammals around the world.<sup>194-198</sup>

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<sup>K</sup> The EPA identified 288 of these substances at the time of the study; the methods were not available at the time to identify the remaining 400.

#### **4.1.4 Workers**

Because chemicals and chemical products are essential to nearly all forms of industrial activity, the chemical industry is important to employment and economic growth in California. A study of California employment trends during 1999 to 2002 concluded that the primary drivers of job growth are the expansion of existing firms and the birth of startup companies.<sup>199</sup> During this period, California employers created 450,000 new jobs through payroll expansion, and startup firms created 220,000 jobs. About 11,000 jobs left California, representing about 1.6% of job creation during this period.

Changes in the nature and organization of the workplace in California (e.g., decreased job stability and unionization, greater income inequality, lower rates of health insurance coverage) have heightened the vulnerability of certain groups of workers in the state. Work-related diseases continue to exact a tremendous human and economic toll in California, a portion of which is attributable to chemical exposures.

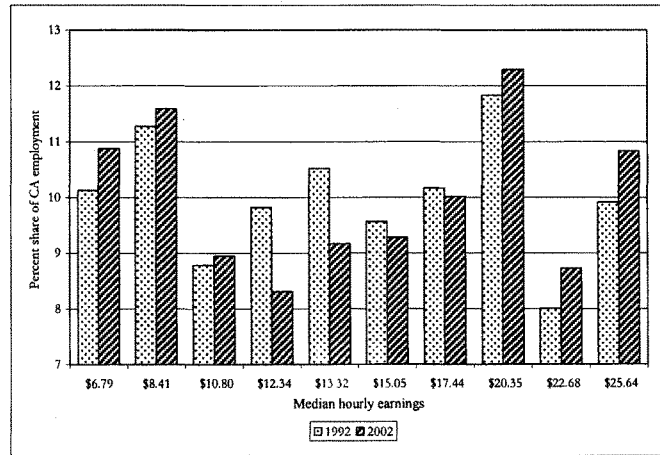
A modern, comprehensive chemicals policy that closes the Data, Safety, and Technology Gaps and motivates industry investment in green chemistry processes and products would begin to address the need for high-quality employment in California as well as the need to protect the health and safety of workers.

#### ***There is growing income inequality in California.***

Income inequality has grown nearly everywhere in the U.S. in recent decades, but it has been more extreme in California, especially in the Los Angeles metropolitan area.<sup>200</sup> Between the late 1970s and late 1990s, average real (before-tax) income for the poorest 20% of California workers dropped 5.5%, while average real income for the state's wealthiest 20% grew by 37.4%. Average real income of the top 5% of income earners in California grew by 50.4% during this period. Employment in California during the economic expansion from 1992 to 2002 showed growth in the bottom and top ends of the income scale, with declines in middle-income jobs (Figure 4). This growth pattern contrasts with that of California's economic expansion during the 1960s, when new jobs were distributed more evenly across the income spectrum.

Lower-wage jobs offer less economic security and are less likely to offer benefits such as health insurance, paid sick days, paid vacation time, and retirement programs. Because economic status is a key driver of health status in the U.S., growth in income inequality in California represents an emerging public-health problem. A chemicals policy that expands productive capacity in green chemistry would contribute to improved employment opportunities in California.

Figure 4. Changes in California job growth by median hourly income, 1992 and 2002.\*



\*In each of the 10 income categories, the income value is the median of the hourly income for six job groups with the largest number of full-time workers in 1992. Growth in the lower-income categories in 2002 occurred among "prime-age" (30 to 55) workers, not in a separate "youth labor market."<sup>200</sup>

#### **Preventable occupational diseases exact a tremendous toll in California.**

Workers are at particular risk of chemically related diseases because chemical exposures in the workplace occur at much higher frequency, intensity, and duration than those that occur in the ambient environment. Each year, about 23,000 Californians are diagnosed with a preventable, deadly chronic disease that is attributable to chemical exposures in the workplace (Table J).<sup>201-205</sup> About 6,500 Californians die each year as a result of a chronic disease attributable to chemical exposures in the workplace (Table K).<sup>201-205</sup> These figures are the equivalent of 1,900 new cases and 540 new disease-related deaths each month in California.

<sup>1</sup> Estimate does not include nonlethal diseases attributable to workplace chemical exposures, such as neurological diseases and skin diseases. For example, the European Union estimates that about 50% of occupational skin diseases are attributable to chemical exposures.<sup>206</sup>

Table J. Estimated annual new cases of deadly chronic diseases in California that are attributable to workplace chemical exposures, 2004.

Disease classification	Estimated annual new disease cases in the U.S., 1992	Estimated annual new disease cases in CA (13%)	Estimated % attributed to occupation	Estimated % attributed to occupational chemical exposures	Estimated % increase in the CA workforce, 1992-2004	Point estimate
Cancer	1,113,100	144,703	6-10%	80-90%	20%	11,808
COPD	1,500,000	195,000	10-20%	20-30%	20%	8,775
Coronary heart disease*	730,000	94,900	5-10%	20-30%	20%	2,135
Cerebrovascular disease*	122,000	15,860	5-10%	20-30%	20%	357
<b>Total</b>						<b>23,075</b>

\* Includes only new and recurrent cases of coronary heart disease and cerebrovascular disease among people between ages 25 and 64, inclusive. Source: Leigh, Markowitz, Fahs, and Landrigan. *Costs of Occupational Injuries and Illnesses*, p. 84. University of Michigan, 2000.<sup>207</sup> J. Paul Leigh, University of California, Davis, personal communication, February 6, 2006: California accounts for about 13% of U.S. chronic disease cases; of occupationally related diseases, about 80–90% of cancers, 20–30% of COPD (chronic obstructive pulmonary disease), and 20–30% of coronary heart disease and cerebrovascular disease are attributable to chemical exposures.

Table K. Estimated annual California deaths in selected disease classes that are attributable to workplace chemical exposures, 2004.

Disease classification	Estimated annual number of deaths in the U.S., 1992	Estimated annual number of deaths in CA (13%)	Estimated % attributed to occupation	Estimated % attributed to occupational chemical exposures	Estimated % increase in the CA workforce, 1992-2004	Point estimate
Cancer	517,090	67,222	6-10%	80-90%	20%	5,485
COPD	91,541	11,900	10-20%	20-30%	20%	536
Cardiovascular and cerebrovascular disease*	101,846	13,240	5-10%	20-30%	20%	298
Pneumoconioses	1,136	148	100%	100%	20%	177
Nervous system disorders	26,936	3,502	1-3%	40-50%	20%	38
Renal disorders	22,957	2,984	1-3%	40-50%	20%	32
<b>Total</b>						<b>6,566</b>

\* Includes only new and recurrent cases of coronary heart disease and cerebrovascular disease among people between ages 25 and 64, inclusive. Source: Leigh, Markowitz, Fahs, and Landrigan. *Costs of Occupational Injuries and Illnesses*, p. 87. University of Michigan, 2000.<sup>207</sup> J. Paul Leigh, University of California, Davis, personal communication, February 6, 2006: California accounts for about 13% of U.S. chronic disease deaths; of occupationally related chronic disease deaths, about 80–90% of cancers, 20–30% of COPD (chronic obstructive pulmonary disease) and cerebrovascular disease, 100% of pneumoconiosis, 1–3% of nervous system disorders, and 1–3% of renal disorders are attributable to chemical exposures.

The total cost of chemically related occupational illnesses and deaths in California is a function not only of medical care and rehabilitation but also of home care, lost wages, effects on the economic security of families, and years of productive life lost.<sup>M</sup> Clearly, the human and financial costs of chemically related diseases are born most immediately by workers. Efforts to prevent occupational disease in California would be greatly enhanced by a comprehensive approach to chemicals policy that closes the Data, Safety, and Technology Gaps.

***Numerous factors contribute to the burden of preventable occupational diseases caused by chemical exposures in California.***

A number of factors contribute to the continuing burden of occupational disease in California. As a group, these factors make it difficult to estimate the true burden of chemically related occupational disease in the population, and efforts to do so, including in this report, most likely underestimate the true rates.

First, as a consequence of the Data Gap, the full scope of health effects associated with the great majority of chemicals in commercial circulation, even as isolated entities, is unknown (Section 3). Likewise, the effects of chemical mixtures, which account for the great majority of workplace exposures, are unknown, though it is well established that chemical mixtures can dampen or amplify the toxic effects of individual chemicals, as noted above.<sup>28-30</sup>

Second, work-related diseases (including those induced by chemical exposures) are generally under-recognized by workers as well as health-care professionals.<sup>209</sup> The current vehicle for communicating chemical hazard information in the workplace, the Material Safety Data Sheet (MSDS), is inadequate for a variety of reasons.<sup>210-212</sup> Board-certified occupational physicians constitute only about 0.2% of U.S. physicians, and only half of U.S. medical schools require instruction in occupational medicine (and an average of only six hours, at that).<sup>213, 214</sup>

Third, the presence of a labor union in the workplace increases the ability of workers to understand, recognize, and take action to correct workplace hazards, and to ensure proper care and compensation in the event of an injury or disease.<sup>215-218</sup> Unionization has declined to about 10% of workers in the private sector in California, down from 20% in 1983.<sup>219</sup> <sup>N</sup> This has probably produced a decline in vigilance in the private sector with regard to work-related diseases, particularly among low-income, minority, and immigrant workers, who are at greatest risk.<sup>220</sup>

Fourth, there are still wide gaps in government protections for workers. There are permissible exposure limits (PELs) in California for about 700 substances, compared to 8,282 chemicals that

<sup>M</sup> The \$140 billion that has been proposed in the U.S. Senate to compensate workers who were exposed to asbestos illustrates the long-term implications of a weak chemicals policy, particularly with respect to occupational health. As former European Commissioner for the Environment Margot Wallström noted in 2004, "Countries all over the world are paying a high price for failures to address chemical safety. For example, asbestos was once seen as a valuable, versatile material and was used extensively in buildings. Every year people are now dying from exposure to asbestos. It is estimated that, in developed countries alone, 100,000 more people will die. The costs of removing asbestos from building and contaminated sites have been enormous."<sup>208</sup>

<sup>N</sup> Unionization among public-sector employees was about 58% during this period; public-sector employees, however, constitute only about 16% of total employment in California.<sup>219</sup>



are produced or imported at more than 10,000 pounds per year in the U.S. As previously noted, only 193 PELs (7%) have been established for the 2,943 chemicals in the U.S. that are produced or imported at more than one million pounds per year.<sup>50</sup> Chemicals lacking PELs are not likely to be monitored in the workplace, and the diseases they produce are not likely to be linked to workplace exposures—either by workers or health-care providers. The California Division of Occupational Safety and Health (DOSH) employs only 200 compliance officers to address worker health and safety matters for the state's 16.5 million workers.<sup>221-223</sup> The Hazard Evaluation System and Information Service (HESIS), a public entity charged with anticipating and preventing chemical exposures in California workplaces, consists of only three full-time scientific staff members.

Finally, the Data Gap weakens the deterrent function of the workers' compensation system and the product liability laws.<sup>224</sup> In order to award workers' compensation benefits, a link must be established between the applicant's symptoms, exposure conditions in the workplace, and the specific toxic end-point(s) of a chemical. The same general principle applies to plaintiffs under the product liability laws. This evidentiary burden cannot be met if toxicity data necessary for doing so are inadequate. More broadly, if workers or members of the public are exposed to chemicals that, unknown to society, are in fact toxic, they are not likely to contemplate a legal remedy; damage caused by unrecognized hazards (due to the Data Gap) simply lies where it falls.

#### **4.1.5 Environment**

Dispersion of chemicals into the environment has produced a number of major ecological disruptions whose effects continue today. These include, for example, the destruction of stratospheric ozone by chlorofluorocarbons (CFCs), chemical contamination of the Great Lakes, contamination of water supplies by methyl tert-butyl ether (MTBE), disruption of aquatic reproductive activity by tributyltin (TBT) anti-foulants, contamination of foods by perchlorate, and other cases. The number of hazardous waste sites in the U.S. is expected to continue to climb. As noted above, there is ongoing concern about the long-term implications of chemicals that persist in the environment and accumulate in the tissues of animals and humans. On the current trajectory, new instances of chemically induced environmental damage will undoubtedly occur in the future. Today's children and their offspring will carry the heaviest burden of this damage, and they will experience the effects, as yet largely unknown, of persistent and bioaccumulative chemicals.

#### ***Environmental damage caused by chemicals can have long-term consequences.***

Releases of organochlorines and other chemicals that destroy stratospheric ozone molecules represent a reasonably well-characterized example of the long-term consequences of chemically induced environmental damage—and the difficulties of correcting them.<sup>o</sup> The ozone layer surrounds the earth at an altitude of 10 to 30 miles and absorbs ultraviolet (UV) solar radiation, which protects the earth's surface from wavelengths of light that cause skin cancer, genetic mutations, immune suppression, and burns to the eyes and skin. As early as the 1970s,

<sup>o</sup> Ozone consists of three oxygen atoms bonded together. Ozone-depleting chemicals that continue to be released include the CFC substitute hydrochlorofluorocarbon (HCFC), halon, methyl bromide and others.

atmospheric scientists recognized that long-lived organochlorine molecules, such as CFCs, could break down ozone molecules, and that industrial releases of organochlorines into the environment could lead to catastrophic damage to the ozone layer. In 1993, the Montreal Protocol was negotiated for the purpose of reducing industrial CFC emissions after evidence indicated that the ozone layer over Antarctica had thinned to about one-third its former concentration.

Despite the Montreal Protocol, damage to health and the ecosystem is expected to continue to unfold over the next 100 years due to past and continuing releases of organochlorines into the atmosphere. The United Nations Environment Programme (UNEP) reports that increased UV radiation reaching the earth's surface during this period will produce a 25% increase in the incidence of nonmelanoma skin cancers, or about 250,000 new cases per year globally. The incidence of melanoma, the more deadly form of skin cancer, will also increase. A 32% increase in UV radiation that damages DNA is expected in northern latitudes.

In December 2005, the National Aeronautics and Space Administration (NASA) announced that recovery of the ozone would not occur until 2065, rather than 2050 as previously estimated, due to continuing releases of ozone-depleting substances by industries around the world, including CFCs, despite the Montreal Protocol.<sup>225</sup>

***Between now and 2033, 600 new hazardous waste sites will appear each month in the U.S. and require cleanup.***

The number of hazardous waste sites in the U.S. continues to rise. Each year, more than \$1 billion is spent on efforts to clean up hazardous waste Superfund sites.<sup>226</sup> Assuming current U.S. regulatory and industrial practices remain the same, the U.S. EPA expects that by 2033, 217,000 new hazardous-waste sites will materialize and require cleanup, on top of 77,000 current sites.<sup>227</sup> <sup>228</sup> The EPA estimates that efforts to cleanup the new sites will cost about \$250 billion.

The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) has identified 275 chemicals present at existing "National Priority" hazardous waste sites and has rated those chemicals on the basis of both toxicity and exposure potential.<sup>229</sup> Of the top 50 chemicals on the list, 38 (76%) are "reasonably anticipated" to cause, or are "possibly" or "probably" capable of causing, cancer in humans; 28 (56%) are expected to cause developmental defects in children; and 27 (54%) are suspected of causing acute and/or chronic neurotoxic effects.<sup>230</sup>

## **4.2 Business and Industry**

### **4.2.1 Businesses That Use Chemicals**

California businesses that use chemicals face significant barriers to improving chemical management practices and to adopting green chemistry technologies. These include a lack of standardized, robust information on chemicals in their supply chains (due to the Data Gap); the continued circulation in commerce of chemicals that pose a potential threat to public and environmental health (due to the Safety Gap); a lack of industry and government investment in green chemistry research and development (the Technology Gap); a lack of comprehensive,

easy-to-use information on chemical regulatory requirements; and a lack of effective regulatory measures and incentives to improve chemical accounting and management (particularly for small and medium-sized businesses).

***Businesses need better information from chemical producers.***

The lack of robust, standardized information on the health and environmental safety of chemicals on the market presents a fundamental problem for California businesses that use chemicals. The Data Gap prevents businesses from identifying and using chemical products that are both efficacious and safer, and it exposes businesses to potential liability related to worker, customer, and product safety. It is very difficult for businesses to identify hazardous chemicals in their supply chains and reduce the use of those chemicals in their operations (Figure 5). Health and environmental information supplied by chemical producers, distributors, or consulting firms on Material Safety Data Sheets is often incomplete and can be inconsistent or conflicting even for the same chemical.

The problems created by the Data and Safety Gaps are experienced most acutely by small and medium-sized businesses, which do not have the resources to conduct their own chemical evaluations but have as large a stake in protecting the health of their workers and customers as do large enterprises. Even large companies, however, find it difficult to sustain their own chemical assessment programs, and some have dropped them altogether. Companies of all sizes would benefit from a California chemicals policy that improves the flow of chemical information in the supply chain and enables a state agency to efficiently identify, prioritize, and reduce the commercial circulation of the most hazardous chemicals.

***Businesses would benefit from better information and technical assistance regarding chemical regulatory requirements in California.***

Some California businesses that use chemicals have expressed frustration in their efforts to gather, comprehend, and conform to chemical regulatory requirements in the state. Businesses that use chemicals can face numerous regulatory requirements that are enforced by local, regional, and state agencies. These agencies are responsible for addressing subsets of chemicals as they appear in different *media*—such as outdoor air, workplace air, surface water, drinking water, solid waste, hazardous waste—and during different *events*—such as routine operations, transportation, storage, minor spills, and emergencies. In general, the regulations governing these differing arenas are not well integrated, and the agencies responsible for enforcing them do not often communicate with each other. As a consequence, some businesses in California experience chemical regulatory requirements as disorganized and confusing.<sup>p</sup>

The frustration on the part of businesses is heightened by two factors. First, while government agencies are responsible for enforcing only those regulations assigned by law to their sector of the chemical universe, businesses often find themselves required to develop and maintain

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<sup>p</sup> This set of conditions was improved with the establishment under SB 1082 (19 CCR, Division 2, Article 4) of the Certified Unified Program Agencies (CUPAs), which consist of 82 regional government agencies that are responsible for collecting chemical and other information from businesses that was previously collected under six different programs involving 1,300 local and state agencies.

expertise across the full scope of that universe.<sup>232</sup> Doing so can be costly and time-consuming, particularly for small and medium-sized firms. Second, while California has developed a few business assistance programs that include aspects of chemical management—such as the Consultation Service of the California Division of Occupational Safety and Health<sup>233</sup>—there is no single public entity that is capable of providing comprehensive, easy-to-use information or technical assistance to help businesses understand and meet chemical regulatory requirements.<sup>Q 234</sup>

Improving the integration and communication of the state's chemical regulatory requirements would benefit businesses and industry throughout the state and would likely lead to closer compliance with existing laws and to improved chemicals management practices generally.

*Figure 5. Kaiser Permanente confronts the Data Gap.*

With 30 hospitals and over 430 medical office buildings nationwide, Kaiser Permanente is the largest private provider of health services in the U.S.; it is also the largest private-sector employer in the San Francisco Bay Area. With the support of Chairman and CEO George Halvorson, the Kaiser Environmental Stewardship Council established a new chemicals policy in April 2004 that called for “avoiding the use of carcinogens, mutagens and reproductive toxins and persistent, bioaccumulative and toxic chemicals (PBTs).”<sup>231</sup> It was Kaiser's intent to “achieve this policy for (their) own facilities and to broadcast (their) intent in order to drive innovation in the marketplace.” As a purchaser of thousands of chemical substances and materials for which little information was available, Kaiser had operated with considerable uncertainty about the safety of its operations; the new policy sought to remedy this condition.

In implementing the new chemicals policy, Kaiser has faced the lack of chemical information on the market—the Data Gap that traces its roots to deficiencies in the design and implementation of TSCA. At considerable cost, Kaiser has shouldered the responsibility of developing screening tools to assess the toxicity and ecotoxicity of the chemicals and materials it purchases.<sup>231</sup>

The chemical Data Gap has made it difficult for even the Bay Area's largest private-sector employer to identify the properties of chemicals in its supply chain, or to identify and purchase chemicals and materials that are less hazardous to workers, the public, and the environment.

<sup>Q</sup> See, for example, technical assistance provided by the Massachusetts Department of Environmental Protection and the University of Massachusetts, Lowell, Toxics Use Reduction Institute pursuant to the Massachusetts Toxics Use Reduction Act of 1989 (Section 6).

**California businesses need greater motivation to account for and reduce their use of hazardous chemicals.**

California law requires businesses to comply with various regulatory requirements in the handling of chemicals, but the state has yet to develop a strategy that would motivate businesses to carefully account for and reduce their use of hazardous chemicals. As a consequence, chemical management practices by many California businesses tend to be undisciplined. An evaluation of 300 California companies conducted by the consulting firm 3E made the following findings:<sup>235</sup>

- About a third of the chemicals and chemical products used at the 300 companies were improperly inventoried, were listed but not used, or were used and unaccounted for.
- Chemical toxicity was “massively overlooked.”<sup>R</sup>
- There was only about 12% commonality in the chemicals used between firms, even when those firms performed the same function and were owned by the same company.
- Combined, the 300 companies were unaware of the presence of about 55 carcinogenic chemicals and over 200 “extremely hazardous substances” used in chemical products.

The experience in Massachusetts under the Toxics Use Reduction Act of 1989 (Section 6) along with that of California chemical management service providers, shows that businesses are often unaware of the management costs associated with the chemicals they use, which can range from seven to 10 times the purchase cost.<sup>236-238</sup> Chemical accounting systems, such as those required in Massachusetts, motivate businesses to quantify and reduce these costs. Developing these systems, however, take time and money, and the experience in Massachusetts and of 3E suggests that businesses will not invest in these systems without a regulatory driver. The Massachusetts experience also illustrates that technical assistance by a state agency in chemical accounting and management systems is useful, particularly for small and medium-sized businesses.

#### **4.2.2 Green Chemistry Leaders**

The Data, Safety, and Technology Gaps represent a barrier to the broad adoption of green chemistry. Due to the lack of robust, standardized toxicity information (the Data Gap), green chemistry leaders find it difficult to differentiate their products in the market; weaknesses in regulatory oversight allow the continued use of hazardous chemicals (the Safety Gap); and there is no substantive public investment in green chemistry research, development, technical assistance, and education (the Technology Gap). Together, these conditions have undermined industry motivation to invest in the technological changes that are necessary for the adoption of green chemistry. This set of conditions broadly characterizes the present status of green chemistry in the U.S. and California.

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<sup>R</sup> In light of the Data Gap, this finding most likely understates true conditions in the surveyed firms.

A 2003 study by RAND identified similar barriers to the development and implementation of green chemistry in the U.S.:<sup>239</sup>

- lack of research, technology development, and new process engineering;
- industrial infrastructure problems and integration barriers;
- the size of up-front investments required; and
- lack of coordinated actions by means of regulations, incentives, and government purchasing.

To establish the technical foundation and market viability of green chemistry, California will need to correct these core chemicals policy weaknesses.

***The Data Gap makes it very difficult for green chemistry leaders to differentiate their products in the market.***

With few exceptions, chemicals and chemical products are differentiated in the market only on the basis of function, price, and performance. The chemicals market is thus unable to select against hazardous chemicals. As a consequence, there is little immediate, compelling *market* advantage to firms that invest time and money in implementing the principles of green chemistry, just as there is very little market disadvantage to firms that gain competitive advantage through the design and manufacture hazardous chemicals. There are no agreed-upon technical criteria or labeling strategies that would allow green chemistry leaders and entrepreneurs to differentiate their products in the market.<sup>5</sup> These market conditions have made it very difficult for both established and new firms to introduce green chemistry products into the market.<sup>240</sup>

***Weak regulatory oversight in the chemicals market has dampened industry motivation to invest in green chemistry.***

As described below, there is very little regulatory oversight of chemicals in commercial circulation in California. Reflecting the Safety Gap, state agencies are unable to identify, prioritize, and reduce the use of hazardous chemicals in the market. Businesses therefore do not face a regulatory barrier to designing, manufacturing, and using hazardous chemicals and chemical products in California, which weakens the competitive advantage of safer, green chemistry products. Combined with the effects of the Data Gap, these conditions have undermined the commercial success of green chemistry.

The role of regulation in motivating technological change in industry is apparent in changes that have occurred in energy consumption per capita in California compared to the rest of the

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<sup>5</sup> The challenges of developing technical criteria for green chemistry products grow as the boundaries of the analysis are extended up the supply chain and through the design and production process. The *California Certified Organic Farmers* (CCOF) label, for example, was based on a fairly narrow set of technical criteria for organically produced foods; it did, however, allow organic growers to differentiate their products in the market. Labeling strategies in the chemicals market are challenging because very few chemicals are sold to end-users; the formulators of chemical products, not chemical producers themselves, play the greatest role with respect to green chemistry product design. In addition, producers and formulators alike often consider green chemistry *processes* to be proprietary.

U.S.<sup>241, 242</sup> Over a period of 25 years, California has adopted some of the strictest energy efficiency requirements in the nation, such that California now uses half as much energy per capita compared to the U.S. as a whole. California's energy efficiency regulations have altered the orientation of the energy market, which, like the chemicals market (with respect to green chemistry), is structured such that it hampers, rather than encourages, energy efficiency.

The important role of regulation in shaping chemicals and materials policy is apparent in changes occurring in the U.S. electronics industry as a result of regulatory developments in the European Union (Section 5). The E.U. directive on the *Restriction of Hazardous Substances in Electrical and Electronic Equipment* (RoHS) will prohibit the use of lead, cadmium, mercury, and other toxic substances in electronic and electrical equipment sold in the E.U. Although the health and environmental effects of these materials have been known for decades—and it has been well known that these materials were dissipating into the environment through electronic waste—most U.S. electronics producers resisted innovating safer materials until they were forced to do so by the RoHS directive. Similarly, the E.U. directive on *Waste Electrical and Electronic Equipment* (WEEE) requires U.S. electronics producers to redesign equipment to facilitate “take-back” at the end of the product's useful life. Most electronics producers resisted similar efforts in California, even though the health and environmental threats of electronic waste (particularly in certain developing countries) have been known for several years.

***There is a lack of attention to green chemistry research and education.***

Without a functioning market or regulatory driver to motivate chemical producers to invest in green chemistry, and without an explicit government commitment to invest in green chemistry research, U.S. universities have seen little reason to direct attention to green chemistry. The University of Massachusetts offers the only chemistry doctoral program in the U.S. that fully integrates the principles of green chemistry.<sup>243</sup> Moreover, very few U.S. universities require undergraduate or graduate students in chemistry to demonstrate an understanding of toxicology.<sup>244</sup> At the University of California, Berkeley, for example, one of the nation's leading chemistry research and teaching institutions, students earning undergraduate and graduate degrees in the College of Chemistry are not required to undertake coursework in the principles of human and environmental toxicology.

The lack of green chemistry educational and research opportunities at leading U.S. universities represents a key impediment to the technical and commercial success of green chemistry; it is also a potential barrier to the long-term capacity for innovation and growth in the U.S. chemical industry more generally.<sup>245</sup> A sustainable future will not be possible in California if the next generation of chemists has little to no understanding of the basic principles of toxicology.

***The broad adoption of green chemistry will require a technological transition in the chemical industry.***

As described below, adopting green chemistry practices will require technological change by industry; technological change, however, introduces new costs and uncertainties, both of which are challenging for industry.<sup>246-248</sup> Without a promising market or an effective regulatory driver, most established firms therefore tend to avoid technological change, or they experiment in niche

markets with spin-off products that do not pose an economic threat to the company's core processes or markets. As a result, technological innovation is often accomplished by new market actors who have less stake in established technologies. However, because the combined effects of the Data, Safety, and Technology Gaps prevent proper operation of the chemicals market in the U.S., entering the chemicals market as an entrepreneur is extremely difficult.<sup>240, 249, 250</sup> Under present conditions, the broad adoption of green chemistry in the U.S. is unlikely in the near term.

A comprehensive chemicals policy in California that closes the Data, Safety, and Technology Gaps will support green chemistry leaders by enabling proper operation of the market and effective regulation, and by supporting research in green chemistry science and technology.

#### **4.2.3 Chemical Producers**

The present position of the U.S. chemical industry with respect to chemicals policy in the U.S. can best be described as a paradox. On one hand, the industry has benefited from the Data and Safety Gaps engendered by TSCA; the industry has not been required to invest substantially in chemical safety testing, and it has not had to contend with a government agency with broad authority to regulate chemicals in the market. Indeed, the American Chemistry Council regularly argues in support of TSCA and advises that changes to the statute are unnecessary.<sup>251</sup> In January 2006, ACC Managing Director Michael Walls noted, "In our opinion, TSCA works and works well."<sup>252</sup>

On the other hand, the weaknesses of TSCA and other federal statutes have dampened the motivation—and perhaps the capacity—of the industry to innovate safer, green chemistry technologies. The websites of the 50 largest U.S. chemical companies all contain a statement of commitment to achieving sustainability goals; at the same time, however, spending on research and development by these companies has decreased or remained flat since about 2000, according to the National Science Foundation.<sup>256, 253</sup> Introducing a new green chemistry product or process has proven to be difficult under the market conditions engendered by TSCA, as previously described. Not surprisingly, the great majority of the chemical processes and chemicals used today have not changed substantially since TSCA was introduced into law nearly 30 years ago (Section 5). Only 248 new chemicals introduced since 1979 have reached High Production Volume (HPV) status, about 8% of the 2,943 HPV chemicals in commercial circulation today (Section 3).<sup>38</sup> <sup>T</sup>

#### ***The U.S. chemical industry faces an array of global and domestic pressures.***

U.S. chemical producers now face a set of market and policy pressures that they may or may not be capable of meeting, assuming they continue along their current path. Given the industry's role as a feedstock to many industrial and commercial sectors in the U.S., the implications of these challenges for economic growth and employment in California could be significant. These pressures include the following:

- For the first time, the U.S. chemical industry is operating with a global trade deficit.
- North American natural gas costs far exceed those of global competitors.
- The price of non-renewable fossil fuel feedstock rose 50% during 2004–2005.

<sup>T</sup> High Production Volume = produced or imported at one million pounds or more per year.



- Under its current technology choices, the industry faces ongoing regulatory compliance costs.
- Many U.S. states, including California, are pursuing chemical phase-outs and other policies.
- The federal government does not have a strategy to spur innovation in green chemistry.
- The European Union is implementing sweeping new chemicals policy reforms (Section 5).
- A growing number of large U.S. and E.U. businesses are seeking to remove hazardous chemicals from their supply chains (Section 5).
- U.S. nongovernmental organizations are involved in campaigns to change chemical markets and policies (Section 5).

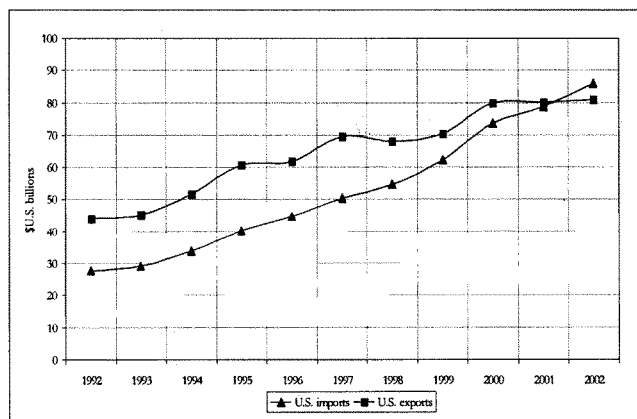
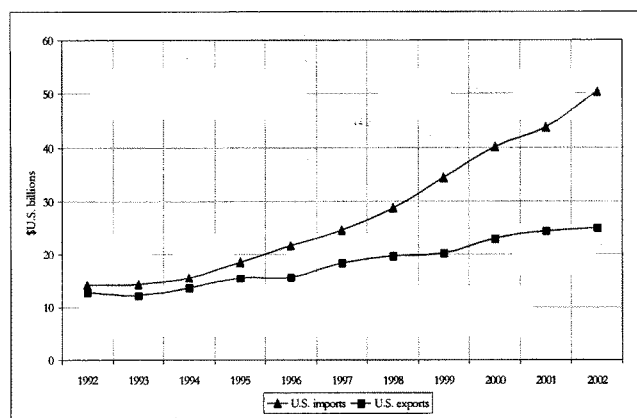
Some of the challenges facing the U.S. chemical industry relate to the pressures of the global economy and to the realities of non-renewable fossil fuels; others signal a demand by the market and the public for safer chemical products and processes, such as green chemistry. Industry leaders recognize that to respond to these challenges, the industry will need to commit itself to a new era of technological change and innovation in which green chemistry will play a significant role. At the same time, the industry's investments in current technologies will likely cause these same leaders to resist policy changes that could bring about a technological transition of this nature. This represents a fundamental dilemma for the U.S. chemical industry and a key challenge for the establishment of a new chemicals policy in California.

***For the first time, the U.S. chemical industry is operating with a global trade deficit.***

For the first time, the U.S. chemical industry is experiencing a trade deficit (Figure 6).<sup>71</sup> In 2002, the deficit was about \$5 billion. This appears to be driven by a widening deficit with the major U.S. chemical trading partner, Western Europe (Figure 7), which highlights the importance of E.U. chemical regulatory initiatives for the U.S. chemical industry and the U.S. economy generally (Section 5).

The U.S. has maintained a trade surplus in chemicals with Asia/Pacific (Figure 8) and with Canada and Mexico (Figure 9). The total value of trade in chemicals between the U.S. and the Middle East, Africa, and Latin America was below \$10 billion in total imports and exports for each of these regions during 1992–2002.<sup>71</sup>

The U.S. chemical industry is experiencing a trade surplus in basic chemicals (Figure 10) and consumer products (Figure 11), and a trade deficit in specialty chemicals (Figure 12) and pharmaceuticals/pesticides (Figure 13).

Figure 6.<sup>U</sup> U.S. global trade in chemicals, 1992–2002.Figure 7.<sup>V</sup> U.S. trade in chemicals with Western Europe, 1992–2002.

<sup>U</sup> For Figures 6, 7, 8, and 9, the data reflect totals for basic chemicals, specialty chemicals, life sciences (pharmaceuticals and pesticides), and consumer products.

<sup>V</sup> In 2002, Western European chemical imports accounted for 60% of total U.S. chemical imports. In these data, Western Europe includes the chemical markets of France, Germany, Ireland, Italy, The Netherlands, Switzerland, United Kingdom, and "Other Western European" countries. Countries in Central and Eastern Europe are not included; however, in aggregate the countries of Central and Eastern Europe accounted for only \$663 million in U.S. chemical exports (2.6% the level of exports to Western Europe) and \$2.3 billion of U.S. chemical imports (4.6% the level of imports from Western Europe) in 2002.

Figure 8. U.S. trade in chemicals with Asia/Pacific, 1992–2002.

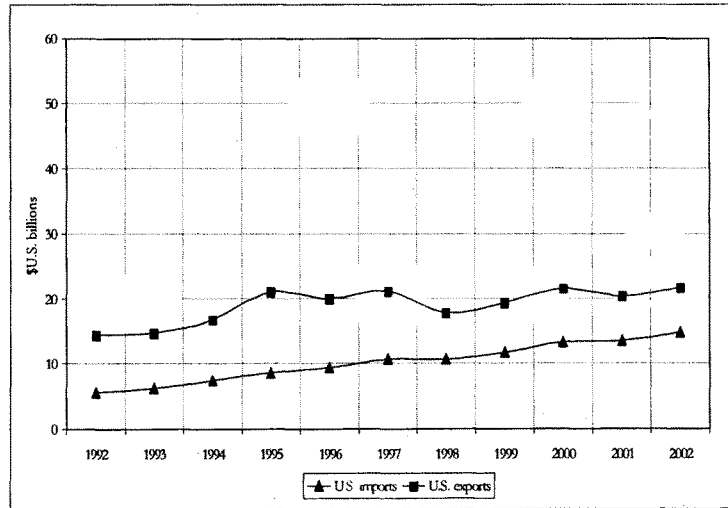


Figure 9. U.S. trade in chemicals with Canada and Mexico, 1992–2002.

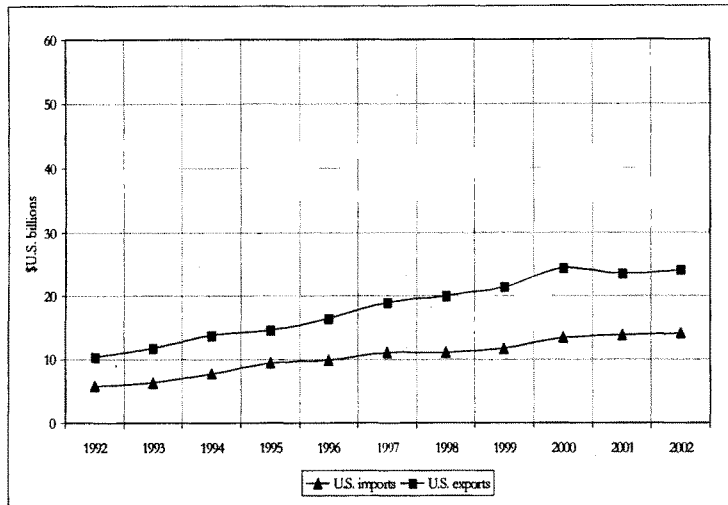


Figure 10.<sup>W</sup> U.S. global trade in basic chemicals, 1992–2002.

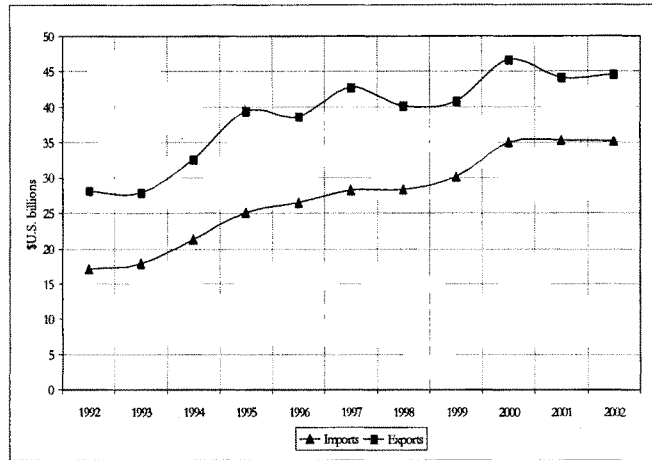
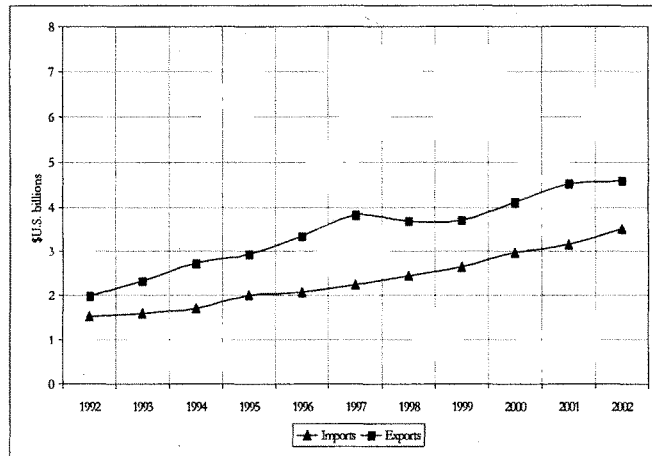


Figure 11. U.S. global trade in consumer products, 1992–2002. (Note scale change.)



<sup>W</sup> Basic chemicals include industrial chemicals (inorganics, bulk petrochemicals and intermediates, petrochemical derivatives and other polymers, surfactants, colorants, printing inks and others) and fertilizers (Figure 1).

Figure 12.<sup>X</sup> U.S. global trade in specialty chemicals, 1992–2002.

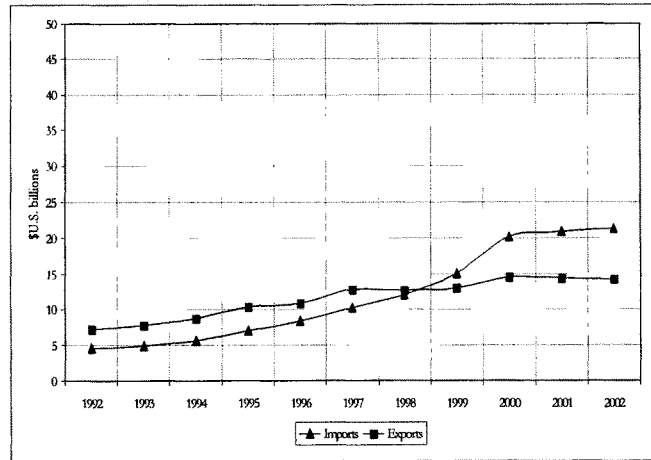
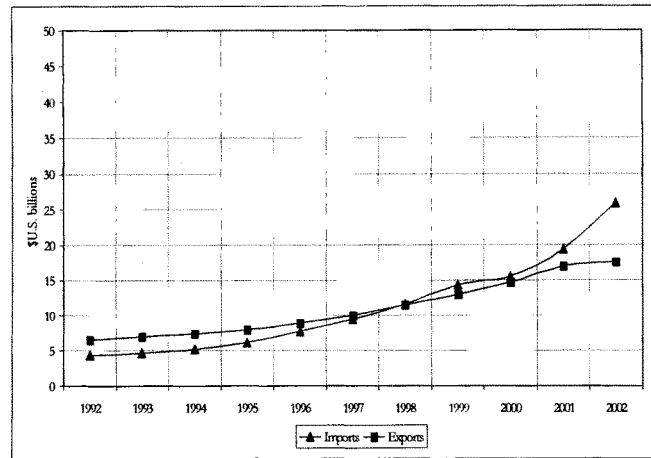


Figure 13.<sup>Y</sup> U.S. global trade in pharmaceuticals and pesticides, 1992–2002.



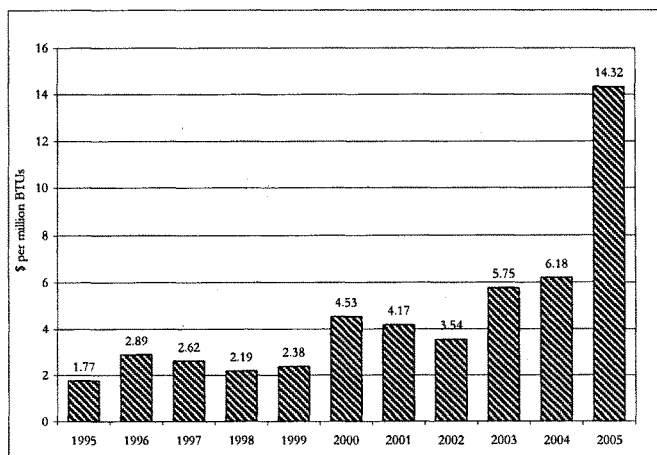
<sup>X</sup> Specialty chemicals include adhesives, catalysts, coatings, electronic chemicals, industrial gases, plastic additives and others.

<sup>Y</sup> These data are dominated by pharmaceuticals. In 2002, U.S. pesticide imports were \$0.5 billion and pharmaceutical imports were \$25.5 billion; pesticide exports were \$1.5 billion and pharmaceutical exports were \$16.2 billion.

**North American natural gas costs far exceed those of global competitors.**

The U.S. chemical industry is the single largest industrial consumer of natural gas in the U.S., accounting for 26% of total consumption for domestic manufacturing.<sup>254</sup> The American Chemistry Council reports that escalating natural gas prices during 2004 and 2005 have sparked an energy crisis in the industry, and that maintaining access to a reliable and affordable supply of energy has become the industry's most important economic issue (Figure 14).<sup>255</sup> Industry analysts note that U.S. electrical utilities are able to pass natural gas price increases onto domestic users, whereas the chemical industry is forced to buy natural gas on a tight North American market and sell its products on a global market, "where they compete with companies whose costs of production, based on natural gas prices, are five times lower."<sup>256</sup> In December 2005, the U.S. Department of Energy reported that after spiking at more than \$14 per thousand cubic feet, natural gas prices will return to less than \$5 in the long term.<sup>257</sup>

Figure 14. U.S. natural gas prices as reported by the American Chemistry Council, 1995–2005.



**Continued reliance on non-renewable fossil fuel feedstock will be increasingly problematic.**

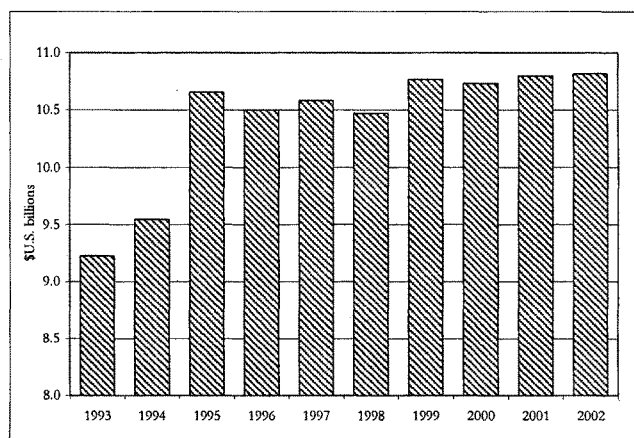
In addition to natural gas prices, the U.S. chemical industry is facing escalating prices and declining availability of fossil-fuel feedstock.<sup>258-260</sup> In 2000, U.S. chemical producers purchased 950 million barrels of oil for organic chemical production, or about 90% of total feedstock.<sup>261, 262</sup> Between June 2004 and July 2005, the price of oil increased from \$40 to \$60 per barrel.<sup>263</sup> As production of non-renewable fossil fuels peaks, the chemical industry is likely to become increasingly vulnerable to price fluctuations and security of supply concerns.<sup>264, 265</sup> The development of alternatives to fossil fuels, such as biobased materials and processes, is therefore considered to be a key feature in the future of the industry (Section 5).<sup>266</sup> In July 2004, for

example, Thomas Connelly, DuPont's chief science and technology officer, noted that "with oil costing as much as \$40 a barrel and being a non-renewable resource, there are all kinds of reasons to say that a market for carbon derived from agricultural materials is viable and will improve over time."<sup>267</sup>

***Under its current technology choices, the chemical industry faces substantial regulatory compliance costs.***

As noted above, the American Chemistry Council reports that the industry spent between \$10 and \$11 billion per year between 1995 and 2002<sup>z</sup> on environmental, health, and safety compliance (Figure 15).<sup>71</sup> As previously noted, these costs were associated with efforts to abate air pollution, water pollution, and other pollution (43%); capital costs for pollution abatement (27%); hazardous waste cleanup (16%); and worker health and safety (14%) related to the industry's current chemical technology choices. The ACC reports that these costs amounted to about 3% of sales, with a slight decline from 1993 to 2002.<sup>AA</sup>

*Figure 15. Spending for environmental, health, and safety compliance in the U.S. chemical industry, 1993–2002.\**



\* For consumer products, basic chemicals and specialty chemicals; excludes pharmaceuticals and pesticides.

<sup>z</sup> Excludes pharmaceuticals and pesticides.

<sup>AA</sup> The ACC reports that these and other factors have led to marked improvements in environmental and occupational health performance. For example, the ACC notes that while the industry's output increased 26% from 1988 to 2002, emissions of certain substances (as listed under the U.S. Toxics Release Inventory) declined 71%, and the prevalence of occupational illness and injury declined 38%.<sup>71</sup> The largest share of regulatory costs have been devoted to environmental regulatory compliance (59%), followed by various economic (15%), tax (14%) and workplace regulations (12%).<sup>268</sup>

**Many U.S. states, including California, are pursuing chemical phase-outs and other policies.**

In 2005, the California Legislature deliberated on about 35 bills related to chemicals (see below). During this same period, about 18 U.S. states considered or passed legislation pertaining to chemicals in at least five areas: brominated flame retardants (BFRs), mercury, methyl tert-butyl ether (MTBE), lead, and arsenic in wood products (Figure 16).

Figure 16. Chemicals policy legislation pending or passed in 18 U.S. states, 2005.

	BFR	Mercury	MTBE	Lead	Arsenic
Alaska					
California					
Connecticut					
Florida					
Hawaii					
Illinois					
Maryland					
Michigan					
Minnesota					
Montana					
New Jersey					
New York					
North Carolina					
Ohio					
Oregon					
Rhode Island					
Vermont					
Wisconsin					

Source: M+R Strategic Services, Bill Wasserman, President. 2120 L Street, NW, Washington, D.C., 20037 (<http://www.mrss.com>) (accessed March 2, 2006). Used with permission.

Like chemicals policy initiatives occurring among some U.S. businesses, state-based chemical initiatives are a natural reaction to the weaknesses of federal chemicals policies, notably TSCA; they reflect ongoing public concern over the health and environmental effects of chemicals. The number of state-based initiatives is likely to grow in the future as the public becomes more aware of developments in the European Union<sup>269, 270</sup> and of chemical problems in the U.S., such as those related to persistent and bioaccumulative substances<sup>BB</sup> and to children's health.<sup>273</sup>

<sup>BB</sup> The U.S. Centers for Disease Control (CDC)<sup>271</sup> reports that the presence of certain chemicals in the body does not necessarily imply an increased risk of disease or the need for policy action; the E.U., however, is moving in a markedly different direction. The U.K. *Royal Commission on Environmental Pollution*, for example, has recommended that "where synthetic chemicals are found in elevated concentrations in biological fluids such as breast milk and tissues of humans, marine mammals or top predators, regulatory steps be taken to remove them from the market immediately."<sup>272</sup> The E.U. REACH authorization process will presumptively remove certain



***For many years the chemical industry has recognized the need for green chemistry innovation, but it has not made substantive progress in this arena.***

The U.S. chemical industry recognizes that the three pillars of economic, environmental, and social sustainability represent the long-term solution to the many challenges it faces. Industry leaders recognize that to remain viable, the industry must commit itself to a new era of innovation in which green chemistry and other cleaner technologies will need to play a significant role.<sup>31, 265, 274-276</sup>

In its 1996 *Vision 2020* report, the U.S.-based Council for Chemical Research, together with the American Chemical Society, the American Institute of Chemical Engineers, the American Chemistry Council, and the Synthetic Organic Chemical Manufacturers Association, wrote that the vast majority of chemical products are manufactured using technologies developed 40 to 50 years ago and that new technologies are needed that incorporate economical and environmentally safer processes, use less energy, and produce fewer harmful byproducts.<sup>277</sup> *Vision 2020* established goals for the chemical industry of reducing feedstock losses to waste and by-products by 90%, energy intensity by 30%, and emissions and effluents by 30% by the year 2020. The report concluded:<sup>CC</sup>

While the challenges of sustainability are significant, there are also major opportunities. . . . The chemical industry now has the opportunity to accelerate its development of advanced manufacturing technologies and new chemistry and related technologies that use materials and energy more efficiently. U.S. companies also have an opportunity to build on their current dominance in the relatively new field of environmental technology. Environmental technologies make sustainable development possible by reducing risk, improving process efficiency, and creating products and processes that are environmentally beneficial or benign.

Ten years after *Vision 2020*, the websites of the 50 largest U.S. chemical companies all contain a statement of commitment to achieving sustainability goals, as previously noted, but their spending on research and development has decreased or remained flat since about 2000.<sup>26, 253</sup>

It is not surprising, therefore, that the Committee on Grand Challenges for Sustainability in the Chemical Industry, convened by the National Academy of Sciences, concluded in its December 2005 report that in “going forward, the chemical industry is faced with a major conundrum—the need to be sustainable (balanced economically, environmentally, and socially in order to not undermine the natural systems on which it depends)—and a lack of a more coordinated effort to generate the science and technology to make it all possible.”<sup>279</sup> The committee included academic scientists as well as representatives of Dow, PPG Industries, ConocoPhillips, and Agraquest.

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bioaccumulative, persistent and toxic substances from the market, along with “very persistent, very bioaccumulative” substances—regardless of toxicity (Section 5).

<sup>CC</sup> The 1996 *Vision 2020* report was in part the result of a request from the White House Office of Science and Technology Policy for advice from U.S. industry on how the U.S. government could better allocate research and development funds to advance the manufacturing base of the U.S. economy. The report did not use the term “green chemistry,” although followup efforts did.<sup>278</sup>

***There are indications that green chemistry, including biobased materials, will become increasingly important in the chemicals market.***

Given the problems associated with non-renewable fossil fuels, together with developments in the E.U. and efforts by some large U.S. companies to clean their supply chains of hazardous chemicals, it is clear that fundamental changes are occurring in the chemicals market (Section 5). The European Social Investment Forum reported in 2005 that “over the next five to ten years, green chemical innovation could be a significant source of competitive advantage for companies manufacturing chemicals used in consumer products, particularly in markets where brand or product differentiation based on green credentials is a key component of value for the final customer.”<sup>266</sup> Great Britain’s Crystal-Faraday Partnership<sup>DD</sup> projected that consumer and commercial demand will grow during 2003–2013 for chemical products that are “more environmentally friendly whilst still delivering high performance,” and for which there is complete “traceability of all raw materials and ingredients.”<sup>280</sup> In California’s Silicon Valley, clean technology in energy and chemicals was projected to be one of “ten key trends that are likely to set the direction for technology in 2006.”<sup>281</sup>

There are indications that the demand for green chemistry processes and products using biobased materials will increase in the U.S. over the next five to 10 years.<sup>264</sup> In 2000, the National Academy of Sciences evaluated biobased materials in the U.S. and proposed national targets for their adoption (Table L).<sup>282</sup>

*Table L. National Academy of Sciences targets for biobased industrial materials, as percent derived from biobased feedstock material.*

Biobased product	2000 level	National targets	
		2020 level	2090 level
Liquid fuels	1-2%	10%	50%
Organic chemicals	10%	25%	90%
Materials	90%	95%	99%

The NAS timeline might be conservative.<sup>283</sup> Sales at NatureWorks, a Cargill, Inc. subsidiary that makes rigid-transparent plastics from corn sugars, grew 200% in the first half of 2005 compared to the same period in 2004.<sup>67</sup> NatureWorks Chairwoman Kathleen M. Bader noted that “the early adopters were more influenced by environmental concerns than costs, but now we’re competitive with petrochemicals, too.”<sup>67</sup> In its October 2005 report, the European Social Investment Forum reported that “the development of alternatives to fossil fuels as a primary input factor to production . . . is a potential source of competitive advantage for chemical companies that are able to make this transition themselves. Leaders in this area will be well positioned to benefit from investment and market opportunities in bio-derived products (e.g. biodiesel) at the expense of laggards, provided stakeholder concerns about genetically modified

<sup>DD</sup> The Crystal-Farraday Partnership is a government-funded consortium of chemical producers and academic researchers in Great Britain. It includes industry participants Proctor and Gamble, GlaxoSmithKline, Protensive and British Petroleum.

organisms (GMOs) can be addressed and required quantities of bio-feedstock can be reliably sourced.<sup>286</sup>

To encourage investment in biobased processes and products, the U.S. Farm Security and Rural Investment Act of 2002 (P.L. 107-171) includes a provision that will require federal agencies (beginning January 2006) to “preferentially purchase” biobased materials—from biodegradable solvents to transmission fluids and synthetic fibers—provided these materials are readily available, efficacious, and cost-effective.<sup>284, 285</sup> <sup>EE</sup>

***Investments in current technologies will cause some members of the U.S. chemical industry to resist policy changes that would spur a technological transition to green chemistry.***

The U.S. chemical industry has the technical capacity and talent to innovate cleaner technologies, including green chemistry, and a chemicals policy should support, motivate, and compel the industry to do so. Ironically, out of rational self-interest, some members of the industry will likely oppose policies of this nature, despite recognizing that over the long term they would benefit the industry as a whole. This is the fundamental dilemma of an industry that finds itself transitioning from one set of technological and social conditions to another.

The challenges facing the chemical industry will require a deep transition to new technologies, including green chemistry. As the U.S. industrial experience has demonstrated, however, making a transition of this type is inherently disruptive.<sup>246-249</sup> Technology transitions produce winners and losers; companies survive the transition by innovating and re-inventing themselves, or they exit the market. This is the juncture that now appears to be facing the Ford Motor Company, for example.<sup>289-291</sup> <sup>FF</sup> As Ford’s case illustrates, a technology transition that occurs in *reaction* to a steady loss of market share can be particularly disruptive. At the same time, for a variety of reasons, industry often finds it difficult on its own to take *proactive* action in the face of imminent changes in the market. The U.S. chemical industry may be beginning to face these conditions in the global chemicals market.

***Proactive technology transitions by industry are preferable to reactive transitions.***

Technology transitions can occur *reactively* in response to a loss of market share—as the experience of the U.S. auto industry illustrates—and they can be spurred *proactively* through

<sup>EE</sup> While there are a number of advantages to moving from a petroleum-based to a biobased chemical production system, it is important to note that the health and environmental implications of biobased materials and processes are not yet well understood.<sup>286-288</sup> These include, for example, concerns over worker health effects associated with the production, processing, and use of biobased materials; environmental impacts of agricultural production for the purpose of producing biobased feedstock, such as pesticide and fertilizer use, energy consumption, farm machinery emissions, and soil erosion; and the use of genetically modified organisms (GMOs). The successful development of biobased materials will require linkage to sustainable agricultural and greenwaste practices and a comprehensive, integrated approach to chemicals policy.

<sup>FF</sup> With increases in fuel costs, Ford’s 10-year resistance to higher fuel economy standards has now produced a dramatic loss of U.S. market share, which has dropped from about 27% to about 18% over a period of 10 years; U.S. sales of Toyota and Honda vehicles continued to climb during the same period.<sup>289</sup> In the third quarter of 2005, Ford lost \$1.2 billion. In 2006, Ford will close 10 of 43 plants and cut 25,000 of 123,000 jobs in North America.

public policy. Industry leaders recognize that technology transitions are inevitable and, in fact, are the driving force of innovation and new growth. Many industry leaders, along with labor and community leaders, also recognize that *proactive* transition strategies provide a margin of protection to the economic security of workers and communities. From the point of view of public health, proactive technology transitions are preferable to reactive transitions, which can be disastrous for workers and communities when they involve an important industry such as the chemical industry. On the current trajectory, however, most U.S. chemical companies will likely continue to rely on existing chemical technologies and products, and some portion of these companies will end up in a reactive transition as they attempt to remain solvent in an increasingly competitive global economy.

***By adopting a comprehensive chemicals policy, California would help drive a proactive technology transition in the U.S. chemical industry.***

Given the important role of the chemical industry and its products in California, the problems facing the industry warrant a concerted policy response. Just as it continues to provide leadership in policies to promote energy efficiency, California has a unique opportunity to take a leadership role in implementing a chemicals policy that lays the groundwork for a proactive transition in the chemical industry to green chemistry technologies.<sup>241, 242</sup>

The developments described above, however, suggest that the U.S. chemical industry may already be entering the early stages of a reactive transition environment, and that the window for implementing a proactive transition in California could begin to close in the near future.

Most U.S. chemical producers recognize that the future of the industry rests not in a “race to the bottom” with other nations in the production of chemicals that are already on the market, but rather in the technological transition we are describing. Though it could be costly in the short term, this transition will improve the capacity of the industry to compete over the long run on the basis of its contribution and dedication to the three primary dimensions of sustainability—often known as the “triple bottom line” of environmental, social, and economic sustainability. This perspective represents the foundation for a new, comprehensive chemicals policy in California.

### **4.3 Government**

#### **4.3.1 Agencies**

As a result of the Data Gap, California state agencies face a fundamental lack of information on the toxicity and distribution of chemicals used in the state, which has prevented them from systematically identifying, prioritizing, and mitigating chemical hazards.

California agencies also face procedural and legal barriers in responding to known chemical hazards; agencies carry the burden of proving that a chemical poses a risk to public health long after it has been introduced into commerce.

In addition to information gaps and regulatory weaknesses, responsibility for chemically related issues in California is distributed among numerous state, regional, and municipal agencies.

There is no single agency equipped to address chemical issues in an integrated, comprehensive manner.

***The effectiveness of state agencies is limited by a lack of data on the toxicity and distribution of chemicals.***

The Data Gap prevents California agencies from systematically identifying and prioritizing chemical hazards in the state. Agencies are able to gather chemical toxicity information only from publicly available databases and the scientific literature, neither of which is standardized or complete. Agencies are also unable to determine the identity and distribution of chemicals used in the state. A 2002 analysis conducted for the California Department of Health Services found that chemical *use* and *distribution* information from existing state and federal databases, or from voluntary submission by chemical producers, was inadequate for state agencies to characterize chemicals in commercial circulation (Table M).<sup>292</sup> As part of the analysis, only 17 of 96 chemical producers (18%) responded to a voluntary request for chemical distribution information; of these, six (6%) provided the requested information.

The lack of information on the toxicity and distribution of chemicals in California represents a significant barrier to state agencies. At present, agency staff are unable to determine the *identity* of chemicals used in processes and products in California, *where* those chemicals are used, in what *volume*, for what *purpose*, how people may be *exposed* to them, or how *toxic* and *ecotoxic* they might be. They are unable to identify the highest-volume chemicals used in California, for example, or what risks those chemicals might pose to public and environmental health. When new scientific information emerges on a particular chemical, it is not possible for agency scientists to efficiently assess what the information *means* for public health in California; it is therefore difficult for agencies to assess how quickly and to what degree the state should *respond* to the information.<sup>GG</sup>

***State agencies face procedural and legal barriers in acting to protect public health from known chemical hazards.***

While agencies are limited in their ability to *identify* and *assess* chemical hazards, they are also prevented from taking efficient and timely *action* to mitigate known hazards. With the exception of chemical emergencies, agencies are generally able to take regulatory steps to protect public and environmental health only after a chemical has been introduced into commerce and its adverse effects have become distinct and widely acknowledged. At public expense, this involves a protracted process of (1) gathering sufficient evidence to make a case for harm, (2) meeting scientific standards of proof of harm, (3) building the political will necessary to respond to the evidence of harm, (4) navigating the regulatory hearing process, and (5) responding to legal appeals.<sup>294</sup> To build a case, agencies face the same “logical paralysis” that constrains the U.S.

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<sup>GG</sup> Assembly Bill 816 (Lieber) was introduced in the 2005 legislative session as an initial step to address this issue. It would have allowed California’s Hazard Evaluation System and Information Service (HESIS) to respond to new chemical toxicity information by requesting client data from chemical product formulators for the purpose of alerting potentially affected businesses and workers in California.<sup>293</sup> The bill was opposed by the California Chamber of Commerce and vetoed by Governor Schwarzenegger in September 2005.<sup>294</sup>

Table M. State and federal chemical information databases and their key deficiencies.

	Title	Purpose	Key deficiencies
California data sources	California Accidental Release Prevention Program (19 CCR, Division 2, Chapter 4.5)	For local government agencies to obtain chemical information from industry to reduce risks associated with accidental chemical releases.	Data are collected at the local level in 125 different jurisdictions; only 415 chemicals are included in the program.
	Air Toxics Program (AB 2588)	For the state government to obtain emission data from industry on toxic air contaminants for identification of stationary emission sources.	Data are for emissions, not chemical use; database misses imports and chemicals in products; unable to identify facilities by chemical; only 189 chemicals included in the program.
	Site Mitigation and Brownfields Reuse Program Database (CalSites)	For the state government to collect information on areas where hazardous chemicals have been released or might be released.	Database is limited to hazardous waste sites; cannot be sorted by chemical.
	Certified Uniform Program Agencies (CUPAs) (SB 1082) (19 CCR, Division 2, Article 4)	For 82 regional government agencies to collect chemical information from businesses under six programs previously administered by about 1,300 local and state agencies.	With four exceptions, data are collected "on paper" at the regional level in 82 different jurisdictions; data are not uploaded to a statewide database.
	Unidocs Hazardous Materials Online Inventory Project	A voluntary effort of Certified Unified Program Agencies (CUPAs) to build an online database of hazardous materials inventories, risk management plans, and facility maps at industrial sites.	Effort by Counties of San Diego, Los Angeles and Orange, and the City of Palo Alto, to computerize CUPA data; lack of statewide participation.
	Waste Water Pretreatment and Pollution Prevention Plans (Water Code §13263.3)	For the state government to identify discharges of hazardous substances into publicly owned treatment works (POTW) from businesses and to encourage adoption of pollution prevention plans.	Data are collected at hundreds of local POTWs; a small number of chemicals is included in the program.
	Pesticide Use Reporting system (13 CCR 6 <i>et seq.</i> )	For the state government to accept pesticide registrations and to evaluate pesticides prior to marketing and application in California.	System is applicable to pesticides only.
Federal data sources	OSHA Integrated Management and Information System (IMIS)	For state and federal government to collect data on facility inspections by OSHA, including air sampling data.	Data are not comprehensive; OSHA inspects only a small fraction of firms in the U.S. and California.
	U.S. EPA Toxics Release Inventory (TRI) (42 U.S.C. 11023); also the Scorecard database of Environmental Defense	For interested parties to track and report the volume of chemical emissions released from some industrial facilities into air, water, and soil, and to waste transferred off-site.	Data are for chemical emissions, not use; misses imports and chemicals in products; covers largest manufacturers in SIC codes 20-39; only about 650 chemicals included in the program.
	CDC National Occupational Exposure Survey (NOES)	For interested parties to characterize the potential for hazardous workplace exposures to chemical, physical, and biological agents in selected U.S. industries.	The database has not been updated since 1983; chemical use data are applicable only to the two-digit SIC code level, covering thousands of facilities in California.

EPA under TSCA (Section 3): to demonstrate that a chemical represents a threat to public health, the agency needs toxicity and exposure data that industry is under no obligation to provide.

Despite these barriers, California has taken a number of steps to address public and environmental health problems related to chemicals (Section 3).

***The many agencies with chemical-related responsibilities in California are not well integrated.***

Numerous state and regional agencies and boards have responsibility for addressing issues related to chemicals in California (Table N). As previously noted, the responsibilities of these entities are not well integrated, and they do not routinely communicate among themselves, which can be frustrating for businesses that use chemicals.

*Table N. A sample of California agencies, districts, and boards responsible for addressing issues related to chemicals.*

Agency or Board
Office of Environmental Health Hazard Assessment
Department of Toxic Substances Control
Certified Unified Program Agencies
Environmental Health Investigations Branch
Air Resources Board
Regional Air Quality Management Districts
Integrated Waste Management Board
Water Resources Control Board
Regional Water Quality Control Boards
Occupational Safety and Health Standards Board
Division of Occupational Safety and Health
Occupational Health Branch
Department of Fish and Game
Office of Emergency Services

While the complexity of environmental and occupational health issues requires technical specialization, this *institutional* separation in California has led to a piecemeal approach to chemicals policy in the state. Chemical exposures and releases to the environment occur at numerous points in the life cycle of a chemical—from design, manufacture, and distribution to use, treatment, and disposal. These events, of course, do not recognize the jurisdictional boundaries of government agencies. When an endocrine-disrupting chemical enters commercial circulation, for example, humans can be exposed in the workplace, through the use of finished products, through industrial emissions into air and water, and through the generation of

hazardous waste. California's institutional arrangements for managing chemicals are not well suited to the fluid nature of chemical problems that arise throughout chemical life cycles.

#### 4.3.2 The Legislature

***In the absence of a chemicals policy, the Legislature will likely face a growing number of chemically related bills in the future.***

With TSCA and other environmental laws providing a limited federal role in chemicals management, and with the limited ability of state agencies to generate and gather chemical information and to act on it, the California Legislature has essentially become the "last stop" for public concerns regarding chemicals. About 35 bills pertaining to chemicals were introduced in 2005, most of which addressed a single, rather narrowly defined chemical issue (Figure 17).<sup>295</sup>

*Figure 17. Sample of 35 bills related to chemicals introduced in California in 2005.*

- AB 121 (Vargas) *Monitoring lead in candy imported or distributed in California.*
- AB 263 (Chan) *Amending law prohibiting sale of PBDEs (polybrominated diphenyl ethers) to include fines.*
- AB 289 (Chan) *Requiring producers to provide analytical test methods for biomarkers of exposure to chemicals.*
- AB 319 (Chan) *Prohibiting manufacture, sale, distribution of phthalates and bisphenol-A in children's products.*
- AB 342 (Baca) *Establishing a perchlorate fee.*
- AB 597 (Montanez) *Revising public participation procedures for cleanup projects.*
- AB 752 (Karnette) *Extending financial responsibility lower than \$300 for nontank vessels carrying below a certain threshold of oil.*
- AB 815 (Lieber) *Revising workplace exposure standards for which Office of Environmental Health Hazard Assessment (OEHHA) has published quantitative risk assessments when the existing permissible exposure limit (PEL) is not sufficiently protective.*
- AB 816 (Lieber) *Requiring producers to provide client information to state Hazard Evaluation System and Information Service (HESIS) on request.*
- AB 908 (Chu) *Prohibiting manufacture, sale, distribution of various phthalates.*
- AB 912 (Ridley-Thomas) *Providing tax exemption for loans offered to redevelop certain brown fields.*
- AB 966 (Saldana) *Regulating discharge of mercury from dental offices and requiring use of best available technology to remove mercury from dental wastewater.*
- AB 985 (Dunn) *Requiring DHS to perform testing and to regulate lead in candy.*
- AB 990 (Lieber) *Prohibiting sale of various halogenated solvents, requiring substitutes.*
- AB 1125 (Pavley) *Requiring retailers of household batteries to collect used batteries for recycling, reuse, or proper disposal at no cost to the consumer.*
- AB 1337 (Ruskin) *Providing certain exemptions for rail cars at hazardous waste transfer stations.*



- AB 1342 (Committee on Environmental Safety and Toxic Materials) *Expanding scope of immunity pursuant to California Superfund law.*
- AB 1344 (Committee on Environmental Safety and Toxic Materials) *Streamlining site mitigation procedures.*
- AB 1354 (Baca) *Establishing a primary drinking water standard for perchlorate of 6 parts per billion and establishing cleanup responsibilities.*
- AB 1415 (Pavley) *Prohibiting sale or distribution of mercury switches and relays*
- AB 1681 (Pavley) *Prohibiting lead in children's jewelry.*
- SB 419 (Simitian) *Prohibiting the transportation of ultra-hazardous materials on state highways and railroads.*
- SB 432 (Simitian) *Pertaining to toxic metals in electronic devices and the E.U. Directive 2002/95/EC.*
- SB 484 (Migden) *Requiring disclosure of carcinogenic chemicals in cosmetic products.*
- SB 490 (Lowenthal) *Cooperating with The Netherlands in compiling list of hazardous chemicals.*
- SB 600 (Ortiz) *Establishing a biomonitoring program to monitor the presence of certain chemicals in the population.*
- AB 623 (Aanistad) *Modifying minimum penalties for serious water quality violations.*
- AB 639 (Aghazarian) *Streamlining procedures for issuing ID numbers to hazardous waste generators.*
- SB 838 (Escutia) *Establishing a pollution control technology registry.*
- AB 848 (Berg) *Establishing an Ocean Ecosystem Resource Information System.*
- SB 849 (Escutia) *Supporting environmental health tracking program.*
- SB 982 (Environmental Quality Committee) *Establishing website for receiving reports of hazardous waste violations.*
- SB 989 (Environmental Quality Committee) *Expanding 2004 brownfields immunity legislation in AB 389 (Montanez) Stats.*
- SB 1067 (Kehoe) *Requiring adoption of public health goals regarding trihalomethanes and haloacetic acids in drinking water, and public notification at specific levels.*
- SB 1070 (Kehoe) *Establishing website to report water quality data.*

Most of these bills addressed a contemporary, legitimate chemical problem, but none were designed for the purpose of developing a comprehensive approach to chemicals policy in California. Without such a policy, and given the global expansion of chemical production, it is reasonable to expect that the number of bills devoted to chemical problems facing the California Legislature will continue to grow.

An effective chemicals policy will need to avoid both “paralysis by analysis” and the piecemeal approach that presently characterizes chemical legislative activity in California. By closing the Data, Safety, and Technology Gaps as a strategy to motivate industry investment in green chemistry, a comprehensive approach to chemicals policy will begin to address the underlying health and environmental concerns that are driving the majority of chemical legislative proposals today.

## **5. Initiatives to Correct the Data, Safety, and Technology Gaps**

In addition to the pressures facing the U.S. chemical industry described in Section 4, there are other developments in the chemicals policy arena that are of great relevance to California. As described in this section, these include sweeping new regulatory changes in the European Union, independent initiatives by U.S. and E.U. businesses to “clean” their supply chains of hazardous chemicals, and chemical policy initiatives by U.S. nongovernmental organizations. Though institutionally and strategically distinct, each of these developments is occurring in response to the recognition that regulatory approaches that have grown up with the chemical industry in the U.S. and Europe over the last 30 years are no longer adequately serving the needs of society. Collectively, these developments present California with a unique opportunity to consider a new, comprehensive approach to chemicals policy.<sup>HH</sup>

### **5.1 The European Union**

#### **5.1.1 The European Union is initiating sweeping new chemicals policy reforms.**

The position of global leadership in environmental policy that was once held by the U.S. has now shifted to the E.U. In the arena of chemicals and materials policy, the E.U.’s power to enforce its new directives comes not from its ability to levy fines, however, but from the size and wealth of its 25-nation market—and its capacity to restrict access to that market. Its ability to set standards and restrict access on the basis of those standards is affecting U.S. producers, including chemical producers, and it is doing so along the full length of the industrial supply chain.

The proposed REACH initiative (*Registration, Evaluation and Authorization of Chemicals*) is the most important initiative with respect to chemicals.<sup>297</sup> It represents one piece of a fundamental reorientation of chemicals and materials policy in the E.U. that includes directives on *Waste Electrical and Electronic Equipment* (WEEE) and on the *Restriction of Hazardous Substances in Electrical and Electronic Equipment* (RoHS), along with other initiatives pertaining to automobile recycling, cosmetics, and energy use.<sup>298, 299</sup>

The WEEE directive, effective August 2005, requires producers to recover and reuse electrical and electronic waste. It is intended to encourage the use of new materials in electronic products that are easier to handle during recycling and recovery.<sup>299</sup> In July 2006, the RoHS Directive will prohibit the use of certain toxic materials in new electronics products sold in the E.U., including

<sup>HH</sup> Other important developments we are not covering include the *Child, Worker and Consumer Safe Chemical Act*, introduced in 2005 by Senator Frank Lautenberg (D-NJ) and coauthored by Senator James Jeffords (I-VT); the development of a *Strategic Approach to International Chemicals Management* (SAICM) by the Governing Council of the United Nations Environment Programme; the development of a voluntary *Globally Harmonized System of Classification and Labeling of Chemicals* by the International Labor Organization, the Organization for Economic Cooperation and Development (OECD) and the United Nations Committee of Experts on the Transport of Dangerous Goods; and efforts by the OECD to coordinate more efficient screening methods for 4,100 high-production-volume chemicals.<sup>296</sup> Each of these initiatives is in various states of development and addresses an important aspect of chemicals policy; individually or collectively, however, they do not represent a comprehensive approach to chemicals policy that would correct the Data, Safety, and Technology Gaps.

lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and certain polybrominated diphenyl ethers (PBDEs).<sup>269, 270</sup>

Still undergoing adjustments, the proposed REACH initiative take effect in 2007. In a marked departure from current practice in both the E.U. and U.S., REACH will require chemical producers to *register* and supply basic health and environmental information to an E.U. Chemicals Agency for up to 30,000 chemicals that are already on the market.<sup>300</sup> Of these, 5,000 higher-volume chemicals will undergo more extensive *evaluation*.<sup>301</sup> About 1,400 “chemicals of very high concern” will be presumptively removed from commercial circulation in an *authorization* process in which producers will bear the burden of proof in seeking government approval to use such chemicals.<sup>302</sup> <sup>11</sup>

REACH represents the E.U.’s effort to address long-standing deficiencies in chemical information and regulatory authority that are nearly identical to those of the Data and Safety Gaps in the U.S. engendered by TSCA. For example, the European Commission justified the REACH proposal on the following grounds:<sup>305</sup>

- There is a lack of health, environmental, and other information on the great majority of chemicals in commerce; 99% of chemicals in commercial circulation in the E.U., by volume, lack adequate information on health and environmental effects.
- There is an implicit presumption that chemicals are safe unless proven otherwise by a public entity.
- The ability of public agencies to assess and demonstrate chemical risks has not kept pace with the rate of chemical production; only about 140 of 100,000 existing chemicals in the E.U. have been subject to risk assessments.

The total benefits of REACH are expected to outweigh the costs of implementation over a 30-year period in the form of health and environmental improvements.<sup>306</sup> A study published by the University of Sheffield, United Kingdom, estimated that the incidence of occupationally related asthma, chronic obstructive pulmonary disease (COPD) and dermatitis in the 25 nations of the E.U. per million persons per year is 400, 500 and 400 respectively, and that the proportion of those cases potentially preventable by REACH is 50%, 10%, and 50%, respectively.<sup>306</sup> Based on an E.U. population of 200 million, the number of future cases per year that would be avoided by REACH is 40,000 for asthma, 10,000 for COPD, and 40,000 for dermatitis. The European Commission estimated in 2003 that REACH would prevent about 4,300 occupational cancer cases per year and would save €50 billion (\$60 billion)<sup>307</sup> over a 30-year period in total occupational disease cases avoided.<sup>308</sup>

<sup>11</sup> Chemicals subject to *evaluation* are those produced or imported at 1,000 metric tons or more per year, per manufacturer. Chemicals subject to *authorization* (“chemicals of very high concern”) consist of chemicals that are carcinogenic (causing cancer), mutagenic (causing changes in the DNA of chromosomes), or toxic to reproduction; chemicals that are persistent, bioaccumulative, and toxic; chemicals that are “very persistent and very bioaccumulative,” irrespective of toxicity; and other chemicals considered to be particularly hazardous, such as endocrine-disrupting agents. Chemicals meeting these criteria will be presumptively removed from commerce unless chemical producers can demonstrate that the risks associated with their use are adequately controlled or that their risks are outweighed by their socioeconomic benefits.<sup>303</sup> *Authorization* can also be triggered on the basis of information that becomes apparent during *registration* and *evaluation*.<sup>304</sup>

The American Chemistry Council has opposed the REACH proposal. The ACC has expressed concern that the proposal relies on ambiguous standards of risk, and that it provides inadequate opportunities for producers to appeal decisions rendered by the European authorities on the basis of those standards.<sup>309, 310</sup> The ACC and others have also expressed concern that REACH does not contain adequate provisions for protecting confidential business information, that it could disfavor U.S. products in the E.U. market, and that it will be excessively costly for U.S. producers.<sup>311</sup>

Despite these and other concerns, the fact remains that REACH, like the RoHS and WEEE directives, will become law in the E.U. and will produce global changes in chemical production practices, including in the U.S.<sup>312-315</sup> China, for example, announced plans in 2005 to consider new regulations similar to those of RoHS, WEEE, and REACH.<sup>316, 317</sup>

**5.1.2 For California, the pending implementation of REACH raises four key issues.**

First, by improving accountability and regulatory oversight in the chemicals market, some observers expect that REACH will improve the commercial viability of cleaner technologies, including green chemistry.<sup>299</sup> Innovest Research Director Marc Brammer noted in 2005 that “There is significant potential for a sea-change in the market for chemicals as knowledge about toxicity expands under the new E.U. REACH directive and similar efforts elsewhere. There is little toxicity data available on many currently commercialized chemicals.”<sup>318</sup> The need for green chemistry science and technology innovation could improve in the near term, and California could take steps to attract investment in this sector of the chemical industry (Section 7). As a related case in point, General Electric’s CEO Jeffrey Immelt announced in 2005 that GE will devote \$1.5 billion annually to clean technology research and development, citing the potential for a U.S. competitive disadvantage with the E.U. in this arena.<sup>319</sup>

Second, REACH presents a unique challenge to California’s small and medium-sized chemical producers. To maintain access to the E.U. market, these producers will need to generate toxicity data and other data related to their products, and they will need to navigate the E.U. chain-of-commerce to understand and document how their products are used. California producers that fail to act early in meeting the requirements of REACH could face a loss of market share and profitability during the “catchup” phase, as some have suggested may be occurring with certain electronics companies in response to the RoHS directive.<sup>69, 269</sup> California firms that market products in the E.U. would benefit from information on the technical aspects of REACH. Manufacturers of chemical products would benefit from information on alternatives to riskier chemicals that are likely to fall under the REACH authorization process, for example. California could take steps now to assist its businesses in meeting REACH requirements.

Third, REACH represents an opportunity for a California state agency to gather information on the physical attributes and basic toxicological properties of many chemicals in commercial circulation. Some of this information on the set of 30,000 chemicals registered under REACH could become available to California as REACH is implemented. For this information to be most useful, however, California will need to gather data on the *distribution* of chemicals sold in

the state. California could take steps to communicate with the European Chemical Agency regarding the nature of chemical information that could become available under REACH.

Finally, while RoHS, WEEE, and REACH are expected to drive innovation in safer materials and chemicals, it is also conceivable that some producers will seek to market “non- E.U.-compliant” electronic products and chemicals in countries where regulatory oversight is weak, such as in the U.S., particularly during transition periods. The German chemical company BASF, for example, will continue to produce and sell monoester di[2-ethylhexyl] phthalate (DEHP) in the U.S. even though it will be permanently banned in the E.U. for use in toys in 2006.<sup>130</sup> BASF will discontinue production of DEHP and its raw material, 2-ethylhexanol, in the E.U., where it will introduce a substitute whose safety, according to the company, “is beyond all question.” California should take steps to ensure that producers do not shift sales of potentially hazardous “non-E.U. compliant” chemicals to California, particularly the 1,400 chemicals that could be presumptively removed from commercial circulation under the REACH authorization process. This will require a comprehensive chemicals policy in California.

## **5.2 U.S. and E.U. Businesses**

### **5.2.1 U.S. and E.U. businesses are seeking to “clean” hazardous chemicals and materials from their supply chains.**

As a result of the Data and Safety Gaps, U.S. businesses operate under conditions of considerable uncertainty regarding the chemicals they purchase and use (Section 4). The potential for liability resulting from these uncertainties, along with the costs of handling known hazardous chemicals and other concerns, is causing some large U.S. and E.U. companies to develop screening tools to remove hazardous chemicals and materials from their supply chains.

As previously noted, Kaiser Permanente, the largest private health-care provider in the U.S. and the largest private-sector employer in the San Francisco Bay Area, recently implemented a procurement policy for chemicals and materials for its 30 hospitals and 430 medical office buildings nationwide that calls for “avoiding the use of carcinogens, mutagens and reproductive toxins and persistent, bioaccumulative and toxic chemicals”(Figure 5).<sup>320</sup> The Consorta Group is the primary group purchasing agent for Kaiser and other health-care organizations in the U.S. and handles an annual purchase volume of \$4.1 billion. Consorta has adopted a purchasing policy to screen-out hazardous chemicals and materials by requiring manufacturers to produce data on the toxicity and ecotoxicity of their products.<sup>156</sup>

Firms with operations in California that are adopting chemical and material screening programs include Kaiser Permanente, Catholic Healthcare West,<sup>321</sup> Intel,<sup>322</sup> Hewlett-Packard,<sup>323</sup> Bentley Prince Street,<sup>324</sup> IBM,<sup>325</sup> and Apple.<sup>326</sup> In November 2005, for example, Catholic Healthcare West awarded a five-year, \$70 million contract to Braun Medical Inc. for the supply of polyvinyl chloride (PVC)/di-2-ethylhexyl phthalate (DEHP)-free intravenous (IV) bags, solutions, and tubing to the system's 40 hospitals in California, Arizona, and Nevada.<sup>321</sup> Other U.S. and E.U. companies working to “clean” their supply chains and produce safer products include Herman Miller, Shaw Carpets, Coastwide Labs, S.C. Johnson, Samsung, Sony, Fujitsu, Nike, Marks and Spencer, and Boots Group PLC.<sup>296, 327</sup>

These efforts signal a demand in the U.S. market for better chemical information and safer materials; they have been constrained, however, by the lack of robust, standardized chemical information in the market (the Data Gap). By improving chemical information flows (Section 7), California would enhance the ability of businesses to implement chemical and material screening strategies—along with more extensive green chemistry practices—and to market their products as such. Better information would “lower the threshold” for other business sectors in California to follow the efforts of Kaiser and other leaders noted above in conducting audits to clean their supply chains of hazardous chemicals and materials.

### **5.3 U.S. Nongovernmental Organizations**

#### **5.3.1 U.S. nongovernmental organizations are involved in campaigns to change chemical markets and policies.**

U.S. environmental and public-health groups have launched initiatives to encourage businesses to transition to safer chemicals, and they have developed recommendations to guide chemicals policy changes in the U.S. Health Care Without Harm (HCWH) has been one of the most successful organizations to date in motivating key players in a large business sector, the health-care industry, to identify hazardous products in their supply chain and replace them with products that are both efficacious and safer. HCWH now consists of over 400 organizations in 52 countries “working to protect health by reducing pollution in the health care industry.”<sup>328</sup> The coalition includes Kaiser Permanente, Catholic Health Care West, and the Consorta Group, among others. The campaign is particularly important because it affects an industry sector that accounted for 37% of all purchases of chemical products in the U.S. in 2002 (Table D).

In 2005, U.S. environmental and health groups drafted a set of guiding principles for chemical policy reform in the U.S. that has now been endorsed by over 60 organizations.<sup>329</sup> The principles, known as the *Louisville Charter*, include six key elements:

- Require safer chemical substitutes and solutions.
- Phase-out persistent, bioaccumulative, or highly toxic chemicals.
- Give the public and workers the full right to know and to participate in chemical policy decision-making.
- Act on early warnings of harm.
- Require comprehensive safety data for all chemicals.
- Take immediate action to protect communities and workers.

Meeting these goals in California will require a comprehensive chemicals policy that closes the Data, Safety, and Technology Gaps (Section 7).

In February 2006, a first-time gathering of 85 U.S. environmental and public-health advocates in Washington, D.C., focused on the concept of green chemistry as an essential element to addressing public and environmental health problems related to chemical design, use, and regulation in the U.S.<sup>330</sup> The meeting included representatives of HCWH, the Natural Resources Defense Council, the World Wildlife Fund, the Environmental Working Group, and Greenpeace, as well as numerous local and regional organizations.

## 6. Case Study: The Massachusetts Toxics Use Reduction Act of 1989

### 6.1 Background

We evaluated six state and four federal chemicals policies to determine whether and to what extent they represent models that address the Data, Safety, and Technology Gaps engendered by TSCA.

The state policies were:

- the California Safe Drinking Water and Toxic Enforcement Act (Proposition 65),
- the California Pollution Prevention Act (SB 14),
- the California Birth Defect Prevention Act (SB 950),
- the Massachusetts Toxics Use Reduction Act,
- the New Jersey Worker and Community Right-to-Know Act, and
- the New Jersey Pollution Prevention Act.

The federal policies were:

- the Federal Insecticide, Fungicide, Rodenticide Act,
- the Food Quality Protection Act,
- the Hazard Communication Standard of the Occupational Safety and Health Act, and
- the permissible exposure limits established under the Occupational Safety and Health Act.

We performed the evaluation using three questions:

- Does the policy address the Data Gap by ensuring that producers generate and distribute robust, standardized information on chemical toxicity, ecotoxicity, and other key data?
- Does the policy address the Safety Gap by improving the regulatory authority and flexibility of government to act to protect public and environmental health from known chemical hazards?
- Does the policy address the Technology Gap by directly or indirectly supporting green chemistry research and development?

Based on this analysis, we concluded that the Massachusetts Toxics Use Reduction Act (TURA) of 1989, though limited, is a model that is relevant to the development of a comprehensive chemicals policy in California. TURA is unique among U.S. environmental statutes in that it requires firms to report their *use* of hazardous chemicals, rather than their *releases* of chemical pollutants, and it requires firms to evaluate their operations and plan for process improvements. It is the only statute that includes an institute—funded with fees assessed against the use of a list of particularly hazardous chemicals—to provide ongoing technical assistance, training, and research for Massachusetts businesses in toxics use reduction strategies. Together, these approaches have motivated continual innovation by firms in strategies to reduce their use of hazardous chemicals. TURA takes a few steps toward correcting the Data, Safety, and Technology Gaps. We believe California can learn from (and build on) the 16 years of experience by government and industry in Massachusetts under TURA.

## **6.2 Gains Under TURA**

### **6.2.1 To reduce emissions of hazardous chemicals, TURA requires industry to carefully evaluate its chemical inputs and processes.**

TURA aims to “sustain, safeguard and promote the competitive advantage of Massachusetts businesses, large and small, while advancing innovation in toxics use reduction and management.” Toxics use reduction is defined under TURA as “in-plant changes in production processes or raw materials that reduce, avoid, or eliminate the use of toxic or hazardous substances or the generation of hazardous byproducts per unit of product, so as to reduce risks to the health of workers, consumers or the environment, without shifting risks between workers, consumers, or parts of the environment.”<sup>331</sup> TURA defines hazardous chemicals as those listed under Section 313 of the Emergency Planning and Community Right-to Know Act (EPCRA), commonly known as the Toxics Release Inventory (TRI), and those listed under Sections 104(14) and 102 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), known as the Superfund.

TURA established six toxics use reduction techniques: input substitution, product reformulation, production unit redesign or modification, production unit modernization, improved operations and maintenance, and in-process recycling, reuse, or extended use of production materials. Out-of-process recycling was not included as a toxics use reduction strategy. Green chemistry would play a role primarily in “input substitution” and “product reformulation.”

### **6.2.2 TURA takes steps to close the Data, Safety, and Technology Gaps.**

TURA has taken initial steps toward closing the chemical Data, Safety, and Technology Gaps.

To close the Data Gap, TURA requires firms to account for, evaluate, and disclose their use of listed hazardous chemicals. This has allowed Massachusetts to identify the most prevalent hazardous chemicals used by large producers in the state. Because the TRI and CERCLA chemicals are assumed to constitute a public and environmental health threat, additional toxicity data is not required under TURA.

To close the Safety Gap, TURA makes the assumption that chemicals listed under the TRI and CERCLA are inherently hazardous and their use in processes should be steadily reduced or eliminated; TURA does not rely on quantitative risk assessments for individual chemicals as the basis for decision-making and action. On the other hand, it does not *mandate* implementation of toxics use reduction plans by firms, nor does it enable government to prioritize chemical hazards and take action to reduce those of greatest concern.

To close the Technology Gap, TURA assigns fees and reporting requirements to the use of listed chemicals, thereby disadvantaging them in the market and encouraging the use of nominally safer substitutes. It encourages continual learning and innovation in industry by requiring regular evaluation of chemical inputs and processes and by providing technical assistance, training, education, and research in toxics use reduction strategies.



**6.2.3 TURA provides industry with technical assistance in developing and implementing toxics use reduction plans.**

To assist industry in meeting the requirements of TURA, the Act established the Toxics Use Reduction Institute (TURI) at the University of Massachusetts at Lowell to provide technical assistance, training, education, and research in toxics use reduction strategies. TURI trains toxics use reduction planners, who are then certified to practice in industry by the Massachusetts Department of Environmental Protection.

TURA also funds the state Office of Technical Assistance within the Department of Environmental Protection to provide technical assistance to industry. Between 1989 and 2004, the Office of Technical Assistance conducted over 1,400 site visits to about 600 firms in support of toxics use reduction activities.<sup>236</sup> During the same period, the Office of Technical Assistance sponsored over 200 toxics use reduction conferences, workshops, and other events for Massachusetts firms.

**6.2.4 TURA has produced marked improvements in environmental performance by Massachusetts firms.**

The initial objective of TURA was to reduce the use of listed hazardous chemicals in Massachusetts by 50% by 1997, with a baseline year of 1987. This goal was met in 1998 and then surpassed in 1999, adjusted for a 45% increase in production.<sup>332</sup>

A 2000 study based on 35 case studies and interviews with plant personnel found that between 1990 and 1997 Massachusetts companies decreased their volume of toxic chemical byproduct by 40%, indexed to production. In almost half the cases analyzed, improved worker health and safety was cited as a benefit of the toxics use reduction projects.<sup>333</sup> Solvents were eliminated or reduced in 63% of cases. About half of the companies profiled introduced water-based chemicals in the place of more volatile ones, and acids and caustics were reduced or eliminated in about 20% of the cases. Following implementation of TURA, Massachusetts firms outperformed virtually every other manufacturing state in the country on releases of substances under the TRI.<sup>236</sup>

An analysis of the effects of TURA showed that even though only one in 10 firms initially viewed TURA as positive, the mandatory planning, reporting, and continual learning process it requires of firms has led to an atmosphere of innovation in Massachusetts that has caused even reluctant firms to improve their environmental performance.<sup>236</sup> TURA has forced firms to better understand their chemical processes (and costs) and has pointed them to options for toxics use reduction through case studies, training, and examples from leading firms. A survey of Massachusetts firms showed significant improvements in involvement by firms in six measures of environmental performance before and after passage of TURA (Table O).<sup>236</sup>

Table O. Involvement of Massachusetts firms in six environmental performance areas before and after TURA.

Activity	Percentage of respondents 'very involved' in activity	
	Before TURA	After TURA
Tracking quantities of wastes generated	49%	89%
Tracking quantities of chemicals used	48%	90%
Establishing a corporate or facility environmental team	24%	68%
Setting goals for waste reduction	24%	73%
Reviewing changes in production processes for their environmental, health and safety impact	30%	76%
Allocating environmental costs to processes or products	21%	52%

### 6.3 TURA's Limitations

#### 6.3.1 TURA is limited in important ways.

Despite the improvements it has brought about in Massachusetts, TURA is limited in important ways. It does not apply to firms that manufacture or process less than 25,000 pounds of listed chemicals per year, or that use less than 10,000 pounds of listed chemicals per year, or that have fewer than 10 employees. In aggregate, however, small and medium-sized firms can generate significant chemical problems throughout the chemical lifecycle. Chemical exposures among workers may also be magnified among smaller firms that lack the resources to recognize, evaluate, and control exposures. Some chemicals may be hazardous even in small quantities. Importantly, the TURA list of hazardous chemicals reflects the state of knowledge prevailing in the 1980s and does not account for improved scientific understanding of chemical hazards. TURA is therefore constrained in the scope of exposures and health risks it targets.

Nor does TURA include regulatory tools to compel recalcitrant firms to implement their toxics use reduction plans. The lack of a regulatory "hammer" may be allowing some companies to gain a competitive advantage in Massachusetts through poor environmental performance. There has been little public participation in TURA activities and limited public disclosure of information on toxic use reduction performance by companies. The law does not link fiscal incentives such as grants or tax credits to industry research and development in toxics use reduction, and it employs only weak fiscal tools to discourage the use of listed hazardous chemicals. TURA has not resulted in the development of criteria for identifying and promoting green chemistry technologies.

Perhaps most importantly, TURA is intended primarily to address industrial *processes*. The law does not oblige manufacturers, retailers, or suppliers to evaluate the toxicity and ecotoxicity of chemicals used in intermediate or final consumer and commercial *products*, or to disclose this information to consumers, workers, businesses, and industry. It does not require business and industrial buyers of chemicals to evaluate the toxicity and ecotoxicity of the chemicals they use,

including those introduced into consumer and commercial products. It therefore does not support U.S. firms that are attempting to “clean” their supply chains (Section 5).

## **6.4 TURA and California Chemicals Policy**

### **6.4.1 TURA offers lessons for chemicals policy in California.**

Despite its weaknesses, TURA represents a chemicals policy approach that appears to motivate innovation by industry, as reported by O’Rourke and Lee in 2004:<sup>236</sup>

TURA makes clear that regulation can and should promote industry self-monitoring and exploration of process improvements. Regulatory implementation should be supported through new mechanisms of transparency, accountability and learning, rather than rigid technology-based standards. Perhaps most importantly, the history of TURA shows that regulations need to transform the attitudes of managers, and then support their efforts at change. Regulations can provide some “commands” to motivate action, and some assistance to guide explorations. TURA’s basic requirements of reporting and planning can motivate creative thinking, exploration, experimentation and “surprises.” TURA represents the potential for what could be termed a sort of “command-and-innovation” regulation.<sup>236</sup>

With modernizing and adaptation to California’s circumstances, TURA represents a potential model for some aspects of a comprehensive chemicals policy.

### **6.4.2 A TURA-like approach could be strengthened in California in a number of ways:**

- Establish a system for chemical reporting, screening, evaluation, and priority-setting as the basis for toxics use reduction planning in California, rather than relying on pre-existing lists of hazardous chemicals.
- Ensure that the scope of the regulation includes small and medium-sized firms.
- Require chemical producers, suppliers, and product manufacturers to review their products for chemical toxicity and ecotoxicity and distribute this information in standardized form to end users.
- Expand technical assistance and training programs to meet the needs of a larger set of businesses and industry, particularly for small and medium-sized firms.
- Incorporate green chemistry more explicitly into the technical assistance, research, education, and training aspects of the regulation.
- Structure the regulation so that it better motivates innovation and use of green chemistry processes and products.
- Establish mandatory toxics use reduction targets and schedules based on lowest-, low-, medium-, high-, and highest-priority chemicals.
- Improve public participation in decision-making regarding design, implementation, and updating of the regulation.
- Improve public disclosure of the performance of firms in meeting toxics use reduction targets.
- Ensure full integration of worker health and safety in toxics use reduction strategies.

- Include mechanisms for mandatory implementation of toxics use reduction strategies for priority chemicals, including product bans and phase-outs where appropriate.
- Efficiently update the regulation in response to new information that surfaces in the process of chemical reporting, screening, evaluation, and monitoring.
- Efficiently update lists of targeted hazardous chemicals based on developing environmental health knowledge.

## 7. Recommendations

*Problems cannot be solved at the same level of awareness that created them.*

—Albert Einstein<sup>334</sup>

Section 4 illustrates that many of the chemical problems facing public and environmental health, businesses and industry, government, and the chemical industry itself trace their roots to weaknesses in TSCA and other federal statutes that have produced the Data, Safety, and Technology Gaps. Addressing these weaknesses represents the logical framework for chemicals policy goals in California:

**Close the Data Gap.** Ensure that chemical producers generate, distribute, and communicate information on chemical toxicity, ecotoxicity, uses, and other key data.

**Close the Safety Gap.** Strengthen government tools for identifying, prioritizing, and mitigating chemical hazards.

**Close the Technology Gap.** Support research, development, technical assistance, entrepreneurial activity, and education in green chemistry science and technology.

A chemicals policy that makes steady progress toward meeting these goals would contribute to putting California on a developmental path that is socially, economically, and environmentally sustainable.

As described in this section, many policy mechanisms could be employed to achieve these three overarching goals; identifying those most appropriate for California will require resolution by a broad range of forward-looking stakeholders. We recommend that at this juncture the Legislature consider establishing a task force to explore various mechanisms and develop a legislative proposal based on the findings of this report. We recommend that the task force be charged with developing the proposal for the 2007 legislative session.

In reviewing the issues raised in this section, it should be kept in mind that the problems with chemicals policy in the U.S. have become apparent over many years and are deeply rooted. While the overarching objectives for correcting these problems are clear, the *details* of how best to do so are complex; they are not, however, insurmountable. In facing these complexities, it is reasonable for the Legislature to consider incremental measures that would lay the foundation for continued development toward a comprehensive chemicals policy. For example, it is reasonable to begin closing the Data, Safety, and Technology Gaps by focusing first on a subset of chemicals, such as those used in high volume in California. Identifying high-volume chemicals and their risks will require some form of chemical reporting in California that includes toxicity and basic exposure information, as noted below. There are numerous examples of steps such as this that would be both substantive and manageable.

**Goal 1: Close the Data Gap*****Ensure that chemical producers generate, distribute, and communicate information on chemical toxicity, ecotoxicity, uses, and other key data.***

Closing the Data Gap will require some form of chemical reporting in California. A mechanism will be needed that enables the state to require chemical producers to generate and disclose standardized, robust information on chemical toxicity, ecotoxicity, basic measures of exposure, and other key data. It will be necessary to require this information as a condition of placing or keeping a chemical or chemical product on the California market. A mechanism will also be needed to enable the state to efficiently obtain additional, more detailed information as needed for evaluating and prioritizing chemical hazards in the state.

A chemical reporting system in California will provide a state agency with the information necessary for setting chemicals policy priorities in the state, and it will arm businesses and industry with the information they need to reduce or eliminate their use of hazardous chemicals. It will also enable businesses and industry to identify (or demand) safer, green chemistry technologies. Dissemination of chemical information in a simple communication format will allow consumers to make purchasing choices for chemical products. These corrections in the chemicals market are essential to driving green chemistry innovation and commercialization in California.

It is important to recognize that the chemical information needs of recipients differ. Government agencies need standardized, robust information on chemical toxicity and ecotoxicity as well as information on the ways chemicals are used in the state, such as their volume in commerce, purposes, potential routes of exposure, and so forth. Businesses and industry, on the other hand, need toxicity and ecotoxicity data as well as good technical information on alternatives to hazardous chemicals. Chemical producers need information on the myriad ways their products are used in commerce. Consumers, small-business owners, and workers need standardized, simple chemical information schemes that allow for rapid decision-making.

***1.1 Who would produce chemical toxicity and ecotoxicity data?***

The experience in both the U.S. and the E.U. makes it clear that the responsibility for generating and distributing chemical toxicity and ecotoxicity data has to rest with chemical producers rather than with public agencies. As detailed in Section 4, comprehensive, easy-to-use information is essential for decision-making by businesses and industries that use chemicals, government, workers, consumers, and the public. It is also essential for the proper function of the market. Chemical producers are best equipped to meet this need, and they should be responsible for transmitting the information in standardized formats to government and the businesses, industries, consumers, and workers that use their chemicals or chemical products. Additional mechanisms to improve the information flow from industrial chemical *users* to chemical *producers*—“back up the supply chain”—will also be needed to address a persistent communication gap between the producers and users of chemicals in California.

Chemical producers that export products to the E.U. are already preparing toxicity and other data to meet the requirements of REACH (Section 5). Representatives of chemical companies reported to the U.S. Government Accountability Office (GAO) in 2005 that the industry would share these data with the U.S. EPA if requested.<sup>335</sup>

With a chemical reporting requirement in California, it can be expected that consumer and trade groups will serve as information intermediaries in preparing and transmitting chemical information to small and medium-sized firms, consumers, and workers in forms that are useful to them. Organic farmers in California, for example, established the California Certified Organic Farmers (CCOF) label to allow consumers to make efficient choices about purchasing organically produced foods.<sup>336</sup> The label is based on an agreed-upon technical definition of "organic." Chemical reporting and communication in California should be designed to be efficient while also motivating change on the part of producers by clearly differentiating the safety of chemicals and chemical products on the market.

### ***1.2 Who would produce information on the uses of chemicals in California?***

Sales information, combined with toxicity data, is needed from chemical producers for a state agency to characterize, prioritize, and mitigate chemical hazards in the state. More detailed chemical "use" information is best produced by the businesses and industries that use chemicals. Many businesses do not maintain careful chemical inventories, and they are often unaware of the nature of chemical "throughput" in their operations. Chemical use reporting, as required in Massachusetts under the Toxic Use Reduction Act (TURA), improves accountability in chemical management and often leads to strategies by firms to reduce chemical throughput and costs (Section 6).

### ***1.3 Who would pay for chemical reporting?***

Chemical reporting should include a fee paid by the producer that increases as a function of volume in commerce. A mechanism should also be considered that would enable California to assess fees on the basis of various measures of toxicity, ecotoxicity, and exposure potential. The fee would fund California chemical regulatory efforts and other activities, such as market incentives, research, and education.

In 1998, the U.S. EPA estimated that it would cost the chemical industry about \$427 million to provide a Standard Information Data Set (SIDS) I for the 2,800 chemicals produced or imported at more than one million pounds per year in the U.S., or about 0.2% of the total annual sales of \$231 billion for the top 100 U.S. chemical companies.<sup>30</sup> The costs and amount of animal testing needed for generation of this chemical information could be lowered by the development of alternative chemical testing methods.

### ***1.4 What chemicals would be reported?***

As outlined above, 81,600 chemicals are currently listed in the inventory of the TSCA inventory, about 62,000 of which were placed on the inventory in 1979. This represents a large backlog of chemicals for which the Data Gap must be closed. It is therefore impractical to consider

mechanisms in California that would close the Data Gap for all chemicals in commerce in a short period of time. Rather, a strategy is needed that allows for prioritizing the timing and nature of chemical reporting. For example, there are 8,282 chemicals in commercial circulation in the U.S. that are produced or imported at 10,000 pounds or more per year, and 2,943 HPV chemicals that are produced or imported at over one million pounds per year. The HPV chemicals constitute over 99% of chemicals in commercial circulation in the U.S., by volume. California could consider a reporting system that focuses initially on the HPV chemicals.

To support the need of industry for regulatory harmonization, California should consider reporting strategies similar to those of REACH. The October 29, 2003 draft of the REACH proposal requires registration over an 11-year period for about 30,000 chemicals produced or imported at over one ton per year per firm, and it sets out tiered data requirements in which more detailed toxicity information is required for higher-volume chemicals (Section 5).<sup>337</sup>

REACH also requires registration of chemicals that fall into a small number of hazard classes, regardless of their volume in commerce: persistent, bioaccumulative, and toxic substances (PBTs); carcinogens, mutagens, and reproductive toxicants (CMRs); very persistent and very bioaccumulative substances (vPvB); and endocrine disruptors. Establishing hazard classifications such as these would not be possible, however, without standardized, robust toxicity information and basic California exposure data. Existing lists of hazardous chemicals, such as California's Proposition 65 list, are based on very limited information and are therefore unreliable.

Unless a chemical screen for a particular chemical property is used for essentially *all* chemicals in commerce, it is likely that a "volume of sales" criterion, as proposed under REACH, would be the most feasible way to define a class of chemicals for reporting in California.

### **1.5 What information would be required as part of a reporting system?**

The Organization for Economic Cooperation and Development (OECD) has developed three chemical testing batteries, known as SIDS I, II, and III.<sup>338</sup> The U.S. EPA has recommended that the SIDS I battery represents a minimum screening-level dataset and that the SIDS II and III batteries would be necessary to "adequately assess the hazards of higher-exposure chemicals (e.g. chemicals in consumer products, chemicals to which children may be exposed, high-release TRI chemicals, chemicals with large numbers of exposed workers, etc.)."<sup>350</sup> Under the U.S. EPA's High Production Volume chemical program, U.S. chemical producers have voluntarily submitted screening-level data equivalent to the OECD SIDS I dataset for about 90% of HPV chemicals, and completion of this program is expected in 2006.<sup>36</sup><sup>31</sup> Because HPV chemicals account for over 99% of chemicals in commercial circulation in the U.S., this dataset will provide a useful foundation for chemicals policy in California, assuming it can be linked to basic measures of exposure.

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<sup>31</sup> Since the program's launch in 1997, about 700 additional chemicals have reached HPV status in the U.S. Chemical producers have voluntarily submitted information for about 100 of these, and the industry has announced an "Extended HPV Challenge" to address the remainder.



On the other hand, screening-level data are not sufficient for prioritizing chemical hazards, and the U.S. EPA presently has no efforts under way to obtain more extensive toxicity information on HPV chemicals or to gather screening-level data on the 5,000 chemicals produced or imported in the range of 10,000 to one million pounds per year.<sup>58</sup> To effectively support decision-making in chemicals policy, a reporting system in California will need to require the submission of a more extensive set of toxicity data than is currently being gathered under the HPV program, along with basic exposure data.

California could also consider adopting the battery of tests required under REACH, which requires more thorough data for higher-volume chemicals. Again, one advantage of this approach would be harmonization of requirements, which is important to companies that market products in both the E.U. and California.

Overall, a chemical reporting system in California should generate information sufficient to provide a reasonable evaluation of the toxicity and ecotoxicity of chemicals in, or proposed for, commercial circulation. Public disclosure and dissemination of this information will begin to direct the market toward favoring safer chemicals.

#### **1.6 Who would have access to the information, and in what form?**

The experience under TSCA suggests that producers will likely request that much of the information reported to the state be classified as confidential business information (CBI). Sixty-five percent of chemical information disclosures to the U.S. EPA under TSCA have been claimed as CBI (Section 3). CBI restrictions, of course, undermine the purpose of chemical reporting, which is to gather and disseminate information that is important for the users and regulators of chemicals. CBI restrictions also prevent public participation in government decision-making, which can lead to “capture” of the agency by the regulated industry.

On the other hand, producers have a legitimate interest in protecting their intellectual property. Small and medium-sized specialty chemical firms in particular face an ongoing threat from buyers who seek to vertically integrate their supply chains and terminate their dependence on small producers. A California chemical reporting system will have to balance the needs of chemical *producers* with those of chemical *users*, including businesses, industry, state agencies, workers, consumers, municipal governments and so forth.

#### **1.7 How would the validity of toxicity data generated by producers be assured?**

Data validation is an inherent challenge of a chemical reporting system that relies on submission of toxicity data by chemical producers who have a clear interest in preventing the release of information that could be damaging to their products. This conflict of interest, of course, is not unique to chemicals policy. In other arenas, the validity of data is assured through the use of third-party audits, legal sanctions, and other approaches. Independent laboratories such as Underwriters Laboratory (UL) routinely provide verifiable information on product safety in the U.S. Government laboratories funded by a reporting system could also be considered.

California can facilitate the generation of valid chemical information by assisting in the formation of consortia of producers that would pool resources for the purpose of developing toxicity data through an independent laboratory. Private laboratories that contract with the state to perform testing services would be subject to audit for adherence to internationally recognized standards of laboratory practice. California should support research into *in vitro* and other testing technologies that minimize or eliminate the use of animals in toxicity testing. The state should explore toxicity data-sharing arrangements with the European Chemicals Agency.

#### **1.8 In what ways can California motivate timely and thorough reporting?**

Chemical reporting would fail to achieve its purpose if the collection of data was continually challenged or delayed by producers or by businesses that use chemicals. California will therefore need to consider mechanisms to motivate timely and complete chemical reporting, such as by requiring reporting as a condition of marketing (or using) a chemical in California. For chemicals already on the market, fixed reporting deadlines will be needed. Incentives for early submission should be considered, along with escalating penalties for late submissions. For reporting data to stay current, automatic updating mechanisms will be needed, along with mechanisms that will enable California to efficiently gather additional information from producers and users of chemicals as needed.

#### **1.9 How would chemicals in consumer and commercial products be reported?**

Given the potential for “information overload” in chemical reporting, it is reasonable to require manufacturers of chemical consumer and commercial products to submit toxicity and other information on the *constituent* chemicals in their products but not on the chemical mixtures themselves. In addition, because some consumer products *unintentionally* release chemicals into indoor air that can pose a health threat, it is reasonable to expect that these products should be subject to reporting.

In general, information should be made available to the public in a platform that will allow trade associations and public-interest groups to access it and develop it into forms that are useful for consumers, workers, small-business owners, and so forth.

### **Goal 2: Close the Safety Gap**

#### **Strengthen government tools for identifying, prioritizing, and mitigating chemical hazards.**

To close the Safety Gap, it will be necessary to significantly improve the tools available to government in its efforts to identify, prioritize, and mitigate chemical hazards. *Identifying* chemical hazards begins with chemical reporting, as described above, which should allow California to gather standardized chemical information and to request additional information as needed. *Prioritizing* chemicals requires the use of screening and evaluation tools. *Mitigating* chemical hazards requires the use of various policy tools to support, motivate, and require action on the part of businesses and industry.

This subsection discusses issues related to the burden of proof, the use of chemical screening and evaluation tools, and the importance of new approaches to decision-making in the interpretation of screening and evaluation data.

### **2.1 In what ways can the burden of proof be altered to improve efficiency in chemicals policy?**

Altering the current burden of proof that is borne by government before it can take action on hazardous chemicals is the key element in closing the Safety Gap. A modern chemicals policy must make it easier for government to identify, prioritize, and mitigate chemical hazards. This represents a fundamental shift in the orientation of TSCA, in which producers that *lack* information on the safety of their products are free to market those products unless government is able to establish the existence of an unreasonable risk of harm, based on a very high burden of proof (Section 3). As the experience under TSCA has shown, this creates a structural, rational incentive for industry to resist generating and disclosing chemical safety information.

California should consider a range of options for altering the burden of proof. The proposed REACH initiative illustrates a useful model in this regard. Following implementation of REACH, the E.U. government will in most cases continue to carry the burden of proof in acting to restrict the use of a chemical; this burden, however, is significantly *lower* than that imposed on the U.S. EPA by TSCA. Under the REACH proposal, the E.U. government will be able to act if it concludes that there exists an “unacceptable risk to human health or the environment.”<sup>339</sup> As previously described, TSCA places a much higher burden of proof on the EPA, which is required to produce “substantial evidence” that (1) the chemical presents or will present an “unreasonable” risk to health and the environment, (2) the benefits of regulation outweigh both the costs to industry of the regulation and the lost economic and social value of the product, (3) the action is the least burdensome way to eliminate only the unreasonable risk, and (4) the agency has considered the environmental, economic, and social impact of any action it proposes to take (Section 3).

The ability of government to act is further facilitated under the REACH *authorization* process, wherein the burden of proof is fully switched from government to industry for select classes of chemicals.<sup>340</sup> Under the authorization process, about 1,400 “chemicals of very high concern” will be *presumptively* barred from all uses in the E.U. unless the producer can meet specified authorization requirements on a use-by-use basis (Section 5). This creates a compelling incentive for the producer to either generate chemical toxicity and exposure information for these chemicals or remove them from commercial circulation.

The E.U. approach of *lowering* the burden of proof on government for most chemicals and *switching* it to industry for selected classes of chemicals might be a reasonable strategy for closing the Safety Gap in California. This would require that the Data Gap be closed in tandem so that hazardous chemicals used in the state could be systematically identified and prioritized. It would also require that classes of chemicals of particular concern be chosen and that criteria be specified for their identification. Aside from certain forms of toxicity, such as carcinogenicity, mutagenicity, and reproductive toxicity, basic exposure data and physical criteria such as persistence and bioaccumulation will be important for prioritizing chemicals used in California.

## **2.2 What is chemical screening?**

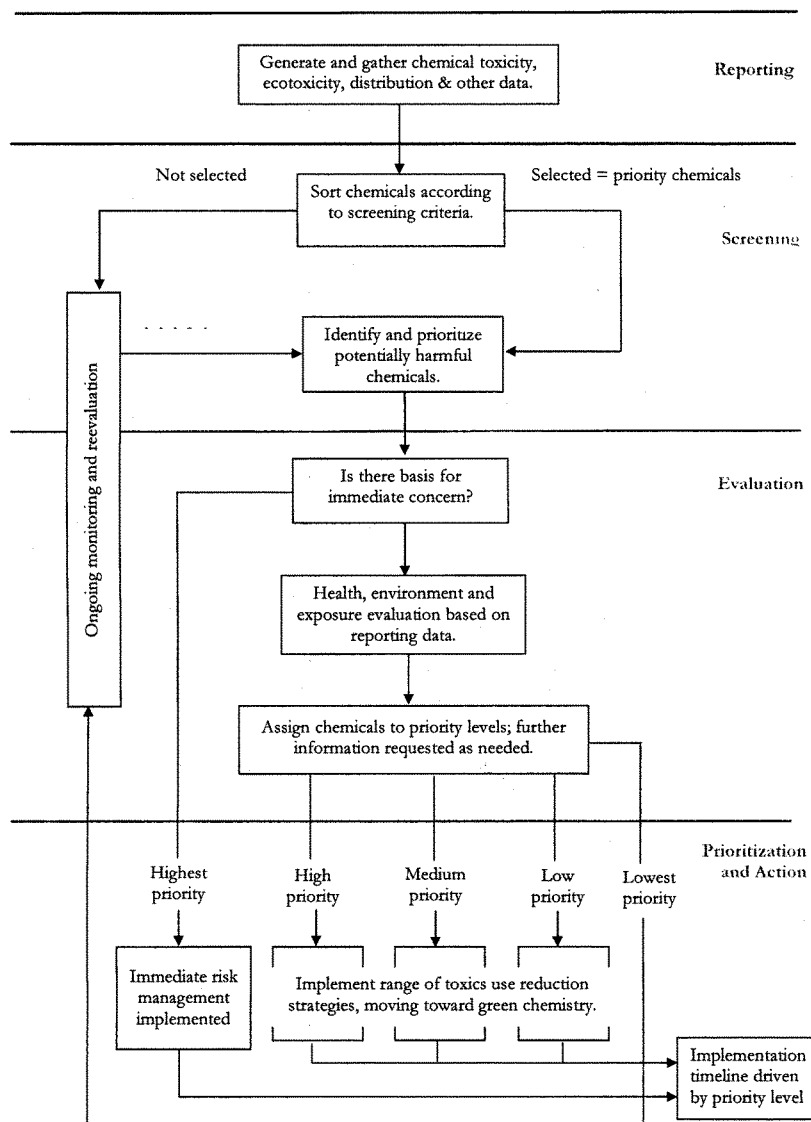
Chemical screening is the process of using inexpensive, relatively simple tools as a “first cut” to capture chemical attributes that do not necessarily require extensive toxicological testing but are important for public and environmental health. When combined with basic measures of exposure, screening tools are an important component of prioritizing chemicals. Chemicals used in closed industrial processes, for example, are generally of lower concern compared to those used in open processes and in consumer and commercial products. The U.S. EPA uses screening tools to evaluate chemicals submitted under the New Chemicals Program. California will need to identify screening tools such as these that are both efficient and scientifically robust.

## **2.3 How would chemical screening tools be used in California?**

In the chemical reporting process, the data to be submitted by producers to close the Data Gap should be designed to permit the use of a set of screening tools by the producer. Established criteria could then be used by California to classify chemicals into priority groups, such as chemicals that warrant immediate action, chemicals that require more data, and so forth. Standardized, effectively communicated screening-level data can also be useful for consumers, workers, and businesses and industries that use chemicals.

Figure 18 presents a theoretical flow chart in which chemical reporting, screening, and evaluation are illustrated as part of a process of sorting chemicals into lowest-, low-, medium-, high-, and highest-priority groups. This model, adapted from the U.K. *Royal Commission on Environment Pollution*, represents one of many possible schemes and is presented here not as an endorsement but simply for purposes of discussion.<sup>341</sup>

Figure 18. A flow chart showing chemical reporting, screening, evaluation, prioritization, and action.



## 2.4 What kinds of measures are included in chemical screening?

Chemical screening typically includes measures of environmental persistence, bioaccumulative potential, and basic measures of toxicity. Geiser has proposed a conceptual model for chemical screening that relies on the properties of environmental persistence and toxicity (Figure 19).<sup>342</sup> This model assumes that chemicals that are both persistent *and* toxic are especially problematic because they can give rise to toxic effects over a greater period of time and over greater distances compared to other chemicals. Many environmentally persistent chemicals also tend to be bioaccumulative. An agreed-upon technical definition of environmental persistence and toxicity is central to this and other screening models.

Figure 19. Geiser's model for classifying chemicals on the basis of toxicity and environmental persistence.

	← More Degradable	More Persistent →
Less Toxic ↑	<b>Group 1</b> <ul style="list-style-type: none"> <li>• Cellulose</li> <li>• Carbohydrates</li> <li>• Carboxylates (soaps)</li> <li>• Biopolymers</li> </ul>	<b>Group 2</b> <ul style="list-style-type: none"> <li>• Iron</li> <li>• Silicon</li> <li>• Aluminum</li> <li>• Copper</li> <li>• Polyolefins</li> </ul>
More Toxic ↓	<b>Group 3</b> <ul style="list-style-type: none"> <li>• Acids and bases               <ul style="list-style-type: none"> <li>• Ethers</li> </ul> </li> <li>• Alcohols and thiols</li> <li>• Aliphatic amines</li> <li>• Aromatic amines</li> <li>• Ethylene/propylene</li> <li>• Ethanol/methanol</li> <li>• Phenols</li> <li>• Aromatic hydrocarbons</li> </ul>	<b>Group 4</b> <ul style="list-style-type: none"> <li>• Halogenated aliphatic hydrocarbons               <ul style="list-style-type: none"> <li>• Lead</li> <li>• Mercury</li> <li>• Cobalt</li> <li>• Cadmium</li> </ul> </li> <li>• Halogenated aromatic hydrocarbons               <ul style="list-style-type: none"> <li>• Dioxins and furans</li> </ul> </li> </ul>

In Geiser's model, chemicals that appear in Group 4 would generally receive priority attention. Basic exposure data, however, is important to the application of this and similar models. For example, information on the way a chemical is *used* could affect its classification. A chemical in Group 4 that is used in small quantities in highly contained industrial processes would be of less concern than a chemical in Group 3 that is used in consumer products or with minimal controls in workplaces.

## 2.5 How is chemical screening used by businesses and industry?

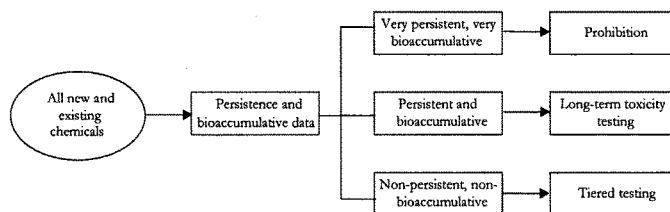
As noted in Section 5, a number of California companies have developed chemical and material screening programs as part of their procurement policies, including Kaiser Permanente, Catholic Healthcare West, Intel, Hewlett-Packard, Bentley Prince Street, IBM, and Apple. These

programs are based not on *clear evidence of cause-and-effect* but rather on a standard of evidence that could be characterized as *reasonable grounds for concern* (see below). The efforts of these leading businesses would be greatly facilitated by a California chemicals policy that closed the Data and Safety Gaps. This would also lower the threshold for a broader set of California businesses and industries to follow the example of leading firms in cleaning their supply chains.

## 2.6 How is chemical screening used in the European Union?

Concern with the properties of environmental persistence and bioaccumulation is reflected in chemicals policy developments in the E.U. The U.K. *Royal Commission on Environmental Pollution* has recommended that “where synthetic chemicals are found in elevated concentrations in biological fluids such as breast milk and tissues of humans, marine mammals or top predators, regulatory steps be taken to remove them from the market immediately.”<sup>343</sup> Under the proposed REACH initiative, chemicals that are found to be “very persistent and very bioaccumulative” (vPvB) (regardless of toxicity) based on the use of screening tools will be presumptively removed from commerce (Section 5). A screening tool proposed by Swedish researchers relies on the properties of environmental persistence and bioaccumulative potential (Figure 20).<sup>344</sup>

Figure 20. A proposed model for prioritizing chemicals on the basis of environmental persistence and bioaccumulation.



The Quick Scan method of The Netherlands' *Strategy on Management of Substances* is a useful model that prioritizes chemicals on the basis of environmental persistence and basic measures of toxicity and exposure.<sup>345</sup> Other chemical screening tools in the E.U. include the Evaluation Matrix of the German Federal Environment Agency, the PRIO model of the Swedish Chemicals Inspectorate and the Column Model of the German Institute for Occupational Safety. The University of Massachusetts Lowell has prepared a brief discussion of these and other screening tools.<sup>346</sup>

## 2.7 What is chemical evaluation?

In evaluation, chemicals are subject to more-intensive scrutiny than during screening. Evaluation requires additional toxicity and ecotoxicity data, such as the OECD SIDS II and III batteries, together with basic measures of exposure. As noted above, toxicity data and basic exposure data—such as the volume in commerce and intended uses—are best acquired from

chemical producers. More-detailed chemical accounting information for purposes of toxics use reduction planning has to be gathered from the businesses and industries that use chemicals.

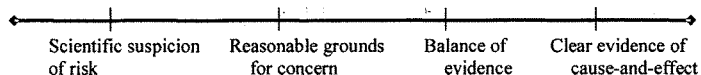
In designing and interpreting chemical evaluation tools, California will need to develop an alternative to quantitative risk assessment (QRA). It has become apparent from the experience in both the U.S. and E.U. that QRA is a poor tool for most chemicals policy decision-making, particularly given the present scope of the Data Gap. A new approach to interpreting chemical screening and evaluation data is needed in California.

### **2.8 What are the alternatives to quantitative risk assessment in interpreting chemical screening and evaluation data?**

Data gathered through chemical screening and evaluation are used to prioritize chemical hazards; this process, however, is driven fundamentally by the way in which screening and evaluation data are *interpreted*. The system by which chemical data are interpreted is thus critically important in chemicals policy. Quantitative risk assessment represents only one of a number of approaches to interpreting and using data.

Information on a chemical's toxicity and ecotoxicity can be illustrated using a continuum of theoretical standards of evidence, from *scientific suspicion of risk* to *clear evidence of cause-and-effect* (Figure 21).<sup>347</sup>

Figure 21. Various standards of evidence that could be used as the basis for decision-making in chemicals policy.



Each level could arguably be used as the basis for decision-making in chemicals policy. Government and industry could choose to act only on the basis of *clear evidence of cause-and-effect*, for example, arguing that in using this standard of evidence only genuine chemical hazards would be mitigated, which would allow resources to be used for other needs. On the other hand, this standard of evidence is expensive and time-consuming to achieve, and can produce highly uncertain results. Most importantly, it requires confirmation of harm to health or the environment before action can be taken. The evidentiary burden placed on the U.S. EPA under TSCA essentially requires this standard of evidence. As detailed in Section 3, this has prevented the agency from effectively assessing the hazards associated with the great majority of chemicals in commercial circulation or controlling those of greatest concern.

Acting strictly on the basis of *scientific suspicion of risk*, on the other hand, could preclude the use of chemicals that might have important social or industrial purposes, though it might also prevent the use of chemicals whose toxic effects might be partially evident now but which could become manifest later, at which point they could be irreversible and/or costly to ameliorate. The proposed \$140 billion federal asbestos legislation represents a case in point.



California will need to develop a system for interpreting chemical data that avoids dependence on data-intensive quantitative risk assessment and moves the decision-making point closer to the center of the continuum illustrated in Figure 21.<sup>348</sup> In developing a decision-making system for interpreting and acting on chemical screening and toxicity data, there are a few points to consider:

First, in evaluating whether or not a chemical might be hazardous to biological or ecological systems, scientists consider a range of scientific evidence, such as illustrated in Figure 21. Like the concepts of “health” and “disease,” scientific evidence related to the health and environmental effects of chemicals exists along a continuum; evidence is not simply “sound” or “unsound,” as some industry representatives have urged.<sup>349</sup> The challenge is to develop decision-making tools that are both efficient (recognizing that “perfect information” is unobtainable) and scientifically robust (utilizing standardized evidence of chemical toxicity, ecotoxicity, basic measures of exposure, and so forth).

Second, because “perfect information” is unobtainable (especially with regard to the health or environmental effects of chemicals), policy decisions must inevitably be made under conditions of uncertainty. In a 1994 consensus resolution, the American Public Health Association argued that the lack of “perfect information” should not be used as a reason for delaying policy decision-making.<sup>350</sup>

- Proof of cause-and-effect relationships is often difficult to establish because of nonspecificity of health effects, long latency periods, subtle changes in function that are difficult to detect without resource-intensive studies, and complex interactions of variables that contribute to adverse health effects.
- Public-health decisions must often be made in the absence of scientific certainty, or in the absence of perfect information.
- Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Given the reality of “imperfect information,” scientists will often disagree about the nature of uncertainty and ambiguity in a body of evidence. We agree, however, with the American Public Health Association that it is imprudent to await the appearance of *clear evidence of cause-and-effect* before acting to protect public and environmental health.<sup>344, 347, 351</sup> This approach is particularly relevant in chemicals policy, given the enormous backlog of information on toxicity and ecotoxicity. As noted above, businesses in California that have enacted policies to clean their supply chains have done so not on the basis of *clear evidence of cause-and-effect* but on the basis of *reasonable grounds for concern*. This approach is appropriate for chemicals policy in California as well.

The experience under TSCA makes it clear that California will not make progress in identifying, prioritizing, and mitigating chemical hazards if the threshold of evidence for doing so is too high. To efficiently prioritize chemicals into lowest-, low-, medium-, high-, and highest-hazard

classifications, California will need to develop a decision-making system that does not require waiting for the appearance of harm before steps can be taken to address potential risks. California can learn from the efforts of other governments around the world that face this same challenge in chemicals policy.

### **2.9 What policy mechanisms might California consider to close the Safety Gap?**

California will need to provide a state agency with greater authority and improved decision-making models to identify, prioritize, and mitigate chemical hazards. The agency will then be faced with identifying the mechanisms that would most effectively meet the proposed policy goals. In general, U.S. and California environmental statutes have relied on a finite set of mechanisms to limit hazards directly (Table P) or indirectly (Table Q).

*Table P. Policy mechanisms that directly limit hazards.*

<b>Policy mechanism</b>	<b>Description</b>
Health-based standards	Describes required end results, leaving regulated entities free to choose compliance methods.
Design standards	Describes required emissions limits based on what a model technology might achieve; regulated entities use the model technology or demonstrate that another approach achieves equivalent results.
Technology specifications	Specifies the technology or technique the regulated entity must use to control emissions.
Product bans and limitations	Bans or restricts manufacture, distribution, use or disposal of products that present certain kinds of risks.
Tradeable emissions	Allows regulated entities to trade emission control units among themselves, provided the aggregate regulatory cap on emissions is met in a specified geographic area.
Regulatory challenges	Gives the regulatory entities responsibility for designing and implementing a program to achieve a target goal, with a government-imposed program or sanction if the goal is unmet by a deadline.
Integrated permitting	Incorporates multiple requirements into a single emissions permit, rather than having a permit for individual emission sources at a facility.

Table Q. Policy mechanisms that do not directly limit hazards.

Policy mechanism	Description
Pollution charges	Requires regulated entities to pay a fixed dollar amount for each unit of material used, emitted or disposed of; no ceiling on emissions.
Information reporting	Requires regulated entities to report emissions, product information or materials used to a public agency and the public.
Technical assistance	Provides regulated entities additional knowledge regarding consequences of their activities (e.g., costs of managing hazardous chemicals) and what techniques or tools could reduce those consequences.
Subsidies	Provides financial incentives to encourage innovation or use of cleaner technologies.
Liability	Requires regulated entities causing emissions that adversely affect others to compensate those harmed to the extent of the damage.
Voluntary initiatives	Encourages participation of regulated entities in programs to reduce emissions in ways that generally exceed regulatory requirements.

The 16-year experience of the Massachusetts Toxics Use Reduction Act suggests that a combination of mechanisms is more likely to be effective compared to single mechanisms implemented alone (Section 6). Closing the Data, Safety, and Technology Gaps in California will require *information reporting* on chemical toxicity and ecotoxicity, *health-based standards* in establishing a technical definition of green chemistry products and processes, *pollution charges* for the use of certain hazardous chemicals, *subsidies* to encourage investment in green chemistry innovation and use, *technical assistance* for small and medium-sized businesses, *product bans and limitations* to reduce the use of highest- and high-priority hazardous chemicals, programs to award *voluntary initiatives* by industry, and so forth.

### 2.10 What are some aspects of an "ideal" policy mechanism?

We propose that the most effective mechanisms would strive to:

- meet the proposed objective in a measurable way,
- place the least demands on government,
- leverage market forces,
- leverage existing statutes and programs,

- be cost-effective and fair,
- consider impacts across the chemical life cycle (including the workplace),
- ensure public access and participation,
- integrate environmental and occupational health justice factors,
- emphasize prevention (including green chemistry) over mitigation,
- encourage continual learning by the regulated entity,
- motivate technology innovation and diffusion, and
- be adaptable to change.

### ***Goal 3: Close the Technology Gap***

#### ***Support research, development, technical assistance, entrepreneurial activity, and education in green chemistry science and technology.***

As described in Section 4, the broad adoption of green chemistry will require a technological transition by industry; this, however, introduces new costs and uncertainties that can be overcome only by market or regulatory drivers. The present lack of market and regulatory drivers represents a key barrier to the commercial success of green chemistry. Closing the Data and Safety Gaps is therefore essential to motivating investment by chemical producers in green chemistry research, development, and implementation. These measures represent the foundation for closing the Technology Gap.

To further close the Technology Gap, these measures should be augmented with incentives to encourage industry investment and entrepreneurial activity in green chemistry. These include market-based incentives and infrastructure-based incentives.

#### ***3.1 What kinds of market-based incentives would support green chemistry?***

- Offer tax credits to chemical producers and manufacturers of chemical products to support a technology transition to green chemistry.
- Offer low-interest loans and grants to green chemistry entrepreneurs.
- Provide information and technical assistance to firms in toxics use reduction technologies, including green chemistry.
- Facilitate development of technical criteria for green chemistry processes and products.
- Facilitate a green chemistry certification and labeling program for chemicals and chemical products.
- Establish a program to redirect certain compliance fees to investments in green chemistry technologies.
- Establish a state government procurement program for existing green chemistry products, based on an agreed-upon set of criteria.
- Establish a state government procurement program to serve as “first buyer” of new green chemistry products.
- Provide information and technical assistance to firms in meeting the requirements of the proposed E.U. REACH initiative.

Infrastructure-based incentives are less immediately applicable to businesses in operation, but they establish the scientific and technical foundation for new technologies, such as green chemistry, just as government-funded research underpins the biotechnology, pharmaceutical, and electronics industries in California. Government funding will be needed to train the next generation of chemists, scientists, policymakers, and others concerned with a sustainable future in California.

### **3.2 What kinds of infrastructure-based incentives would support green chemistry?**

- Fund research in the development and evaluation of chemical screening tools.
- Fund research into chemical evaluation tools that rely minimally or not at all on the use of animal testing.
- Fund research in basic green chemistry science.
- Fund research in green chemistry engineering, technology, law, and policy.
- Fund undergraduate and graduate education in green chemistry.
- Facilitate university-industry collaboration in green chemistry innovation initiatives.
- Establish collaborative relationships with institutions working to advance green chemistry in other U.S. states and around the world.

### **Administrative Arrangements**

Implementing a comprehensive chemicals policy in California would be most efficient if a single agency is assigned primary responsibility and authority for the great majority of chemicals policy matters. The scope of the agency should eventually encompass chemical issues related to public and environmental health as well as those pertaining to the state's involvement in green chemistry technology innovation, investment, education, research, and planning. To maintain credibility with the public, industry, and the scientific community, agency decision-making and priority-setting should be guided by a multidisciplinary board. The board should serve in a genuine leadership role, not simply as a vehicle for providing input to the agency.

To be most effective, the agency's scope should eventually encompass chemicals throughout their *life cycle* (design, manufacture, transportation, use, disposal, recycling); as they appear in various *media* (the workplace, indoor air, outdoor air, drinking water, ground water, surface water, soil, hazardous waste); as they are put to differing *uses* (industrial processes, commercial products, consumer products); and as they are experienced by various *stakeholders* (consumers, workers, children, small-business owners, industry, lower-income, and minority communities, residents of developing countries).

The agency should develop the capacity to provide comprehensive, integrated, and easy-to-use information on the full scope of regulatory requirements in California related to chemicals; it should develop the capacity to provide information and technical support to businesses and industry in best practices, chemical accounting systems, toxics use reduction strategies, and green chemistry technologies, as they emerge. The agency should serve as the primary technical resource for chemicals policy matters affecting other state agencies, municipal governments, and the Legislature.

## 8. Conclusion

We have analyzed chemicals policy issues in California in the context of a key question facing the state:

*How can California develop in ways that are environmentally, socially, and economically sustainable as its population grows from 36 to 55 million residents by 2050?*

A modern, comprehensive chemicals policy is a fundamental element in addressing this question. In an increasingly competitive global economy, and with global chemical production expected to double in the next 25 years, a new approach to chemicals policy is necessary for California to:

- reduce the burden of work-related disease attributable to chemical exposures;
- address concerns about chemical exposures that occur during fetal, infant, and child development;
- prevent the proliferation of hazardous waste and pollution of air, water, and land resources;
- meet the needs of business and industry for better information about chemical toxicity, ecotoxicity, and alternatives to hazardous chemicals;
- reduce or eliminate the use of the most hazardous chemicals;
- build productive capacity in ways that steadily improve public and environmental health and prevent continued growth in income inequality;
- proactively respond to sweeping chemicals policy changes occurring in the European Union;
- establish the scientific and technological basis for safer chemicals;
- motivate industry to invest in the design and use of safer chemicals;
- motivate the next generation of chemists to design and use safer chemicals; and
- position the state to become a global leader in green chemistry innovation.

Some of these issues have been previously broached in California in the form of individual legislative proposals; this report, however, illustrates that these issues are *all* relevant to a modern, comprehensive approach to chemicals policy. Developing a chemicals policy that addresses these issues is essential to a sustainable future in California.

We have proposed that problems associated with the present approach to chemical design, use, and management represent one of the major challenges of the 21<sup>st</sup> century, and that a deep technological transition within the chemical industry will be needed to correct these problems. This transition, which has partially begun, will require the design of new chemicals and chemical processes that are inherently safer for biological and ecological systems. This will provide long-term solutions to the many chemical problems currently facing public and environmental health, business, industry, and government in California. Motivating the chemical industry to invest *proactively* in this transition represents a key, underlying rationale for a comprehensive chemicals policy in California. In light of developments in the European Union and among some

large U.S. businesses, a chemicals policy that induces this transition in California could also position the state to become a global leader in green chemistry technology innovation.

Alternatively, in the absence of a comprehensive chemicals policy, a *reactive* transition could occur in the U.S. chemical industry in response to the many pressures described in this report. A reactive transition could have significant consequences for employment, public and environmental health, and productive activity in California, given the importance of chemicals in the California economy.

The analysis presented in the report is intended to support a proactive strategy in California by helping policymakers:

- understand the key weaknesses of federal statutes, particularly TSCA, that have given rise to the Data, Safety, and Technology Gaps;
- understand the problems the three Gaps have created in California for public and environmental health, business, industry, and government;
- recognize the need for a green chemistry technology transition in the chemical industry;
- understand the basis for resistance by chemical producers to policies that would induce this transition;
- recognize the significance of chemicals policy developments occurring in the European Union and among U.S. businesses and nongovernmental organizations;
- recognize the relevance of the Massachusetts Toxics Use Reduction Act to chemicals policy in California; and
- craft a chemicals policy that addresses health and environmental problems and motivates industry to invest in green chemistry technologies by closing the Data Gap, the Safety Gap, and the Technology Gap.

To close the Data Gap, we propose that a chemical reporting system will be needed in California. Closing the Safety Gap will require expanded regulatory authority and a new decision-making framework for a designated state agency. Closing the Technology Gap will require a range of market incentives and government support for green chemistry research, development, technical assistance, and education. A chemicals policy based on these goals is timely and necessary in California, given the state's expanding population, its health and environmental problems, and the pressures of an increasingly competitive global economy.

Because many policy mechanisms could be employed to reach these goals, the report recommends that as a first step the Legislature establish a chemicals policy task force to explore various mechanisms and develop a legislative proposal for a comprehensive policy based on the findings of this report. We recommend that the task force be charged with developing the proposal for the 2007 legislative session.

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### **Appendix A. Chemicals Policy Meetings Attended**

As part of the process of preparing this report, the primary author attended 35 meetings and conferences during 2003–2006 pertaining expressly or in part to chemicals policy:

<b>Title</b>	<b>Convener</b>	<b>Location</b>	<b>Date</b>	<b>Presentation by author</b>
Integrating Policy, not Transferring Risk	Center for Occupational and Environmental Health, University of California	Berkeley, California	April 2003	Yes
Implications of the Precautionary Principle in Environmental and Occupational Health	Division of Occupational and Environmental Disease Control, California Department of Health Services	Oakland, California	May 2003	No
Covering California: An All Hazards Approach to Managing Emergencies	California Emergency Medical Services Authority	Oakland, California	September 2003	No
California Chemicals Policy Workshop	University of Massachusetts, Lowell, Center for Sustainable Production	Oakland, California	October 2003	No
Innovations in the European Union to Develop Integrated Chemical Policies: Lessons and Opportunities for California.	Office of the President, University of California; the University of Massachusetts; the European Environment Commission.	Berkeley, California	October 2003	No
Making it Real: Reforming Chemicals Policy in the U.S.	World Wildlife Fund	Washington, D.C.	February 2004	No
Moving Forward Together	California Integrated Waste Management Board, California EPA	Sacramento, California	March 2004	Yes
National Environmental Assistance Summit	U.S. EPA	Baltimore, Maryland	April 2004	Yes
U.S. – E.U. Transatlantic Environment Conference on Chemicals	Office of Pollution Prevention and Toxics, U.S. EPA	Charlottesville, Virginia	April 2004	No
Alternatives Assessment Strategies	Coming Clean, Kaiser Permanente	Oakland, California	May 2004	No

Promoting Primary Prevention in the California Workers' Compensation System	Northern California Center for Occupational and Environmental Health, University of California	Berkeley, California	October 2004	No
Public Health and the Environment	American Public Health Association	Washington, D.C.	November 2004	Yes
National Workshop on Chemical Reform	Coming Clean	Seattle, Washington	December 2004	No
Critical Building Blocks and Tools for Sustainability in the Chemical Industry: Identifying an Agenda for National Research	The Board of Chemical Sciences and Technology, National Academy of Sciences	Washington, D.C.	February 2005	No
REACH and U.S. Chemicals Policy	The Committee for the Environment, Public Health and Food Safety, the European Parliament	Sacramento, California	March 2005	No
Green Chemistry Retreat	Commonweal	Bolinas, California	April 2005	No
Framing a Future Chemicals Policy: A Working Forum for Stakeholders	University of Massachusetts, Lowell, Center for Sustainable Production	Boston, Massachusetts	April 2005	No
California Chemicals Policy Update (teleconf.)	The Phylmar Regulatory Roundtable	Berkeley, California	May 2005	Yes
National Environment, Health and Safety Conference	Kaiser Permanente	Walnut Creek, California	June 2005	Yes
Sensitizing Substances in the Cal/OSHA Permissible Exposure Limits	Division of Occupational Safety and Health, California Department of Industrial Relations	Oakland, California	June 2005	No
California Regulatory Update	ORC Worldwide, Inc.	Palm Springs, California	June 2005	Yes
California Regulatory Update	The American Chemistry Council	Sacramento, California	June 2005	Yes
Annual Conference	Western Regional Pollution Prevention Network	Tahoe City, California	September 2005	Yes

Annual Regulatory Update	The Pacific Industrial and Business Association	Vishay Siliconix, Santa Clara, California	October 2005	Yes
Green Chemistry in California	Women's Voices for the Earth	San Raphael, California	October 2005	No
Chemicals Policy in the European Union	Berkeley Roundtable on the International Economy	Berkeley, California	October 2005	No
Strategies for Chemicals Policy in California	Occupational Health Branch, California Department of Health Services	Richmond, California	October 2005	Yes
Occupational Medicine Grand Rounds	University of California, San Francisco	San Francisco, California	October 2005	Yes
Occupational and Environmental Health in the Developing World: Making a Difference	Center for Occupational and Environmental Health, University of California	Berkeley, California	October 2005	No
Green Chemistry and Engineering Education Roundtable	The Board of Chemical Sciences and Technology, National Academy of Sciences	Washington, D.C.	November 2005	No
California Issues Forum	Chemical Industry Council of California (CICC)	Lafayette, California	November 2005	Yes
Strategies for Chemicals Policy in California	Office of Environmental Health Hazard Assessment, (OEHHA) California EPA	Oakland, California	November 2005	Yes
Bridging the Gap: Science to Policy	California Industrial Hygiene Council & American Society of Safety Engineers	San Francisco, California	December 2005	Yes
Leading Change: Toward a Sustainable Future	California Manufacturers and Technology Association & Industrial Environmental Association	San Diego, California	December 2005	Yes
Environment Committee Meeting	Silicon Valley Leadership Group	Sony, San Jose, California	February 2006	Yes

### Appendix B. Sales Data on Consumer and Commercial Chemical Products Sold in California

These data present daily sales in short tons and pounds per day of chemical consumer and commercial products in California.<sup>153</sup> These data are based on the most recently available (1997) sales information as reported by the California Air Resources Board on March 21, 2000. These data do not include chemicals sold for use in industrial processes.

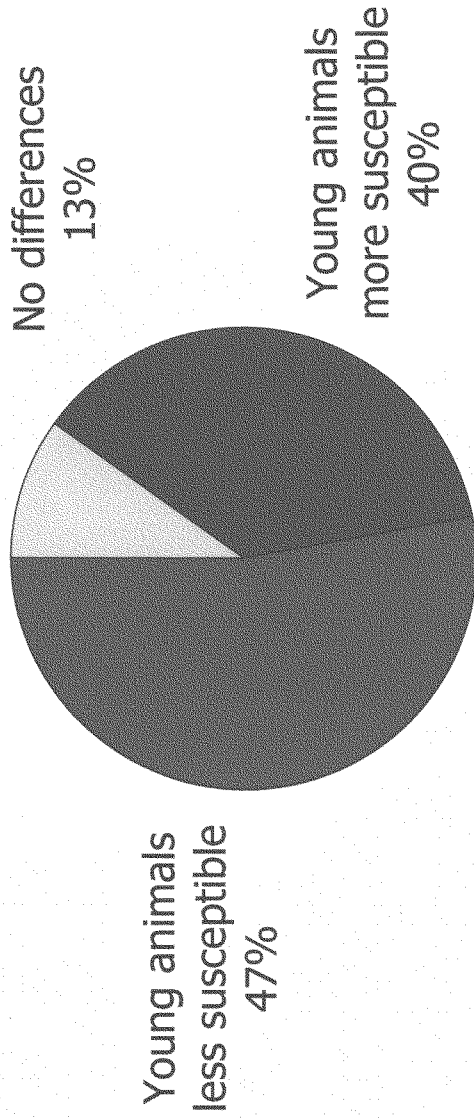
ID #	Tons	Pounds	Category name	ID #	Tons	Pounds	Category name
1	73637.09	147,274,180	General purpose cleaners	51	8.39	16,780	Hair mousses
2	2966.33	5,932,660	Non-selective herbicides/defoliants	52	6.65	13,300	Flying insect insecticide
3	1358.65	2,717,300	Carpet and upholstery cleaners	53	5.25	10,500	Underarm deodorants
4	1325.01	2,650,020	Disinfectants	54	4.85	9,700	Wheel cleaners
5	530.33	1,060,660	Sanitizers	55	4.84	9,680	Metal polishes & cleaners
6	315.22	630,440	Lawn and garden insecticides	56	4.60	9,200	Automotive rubbing and polishing compounds
7	230.73	461,460	General purpose degreasers	57	4.34	8,680	Tire sealants and inflators
8	180.43	360,860	Floor wax strippers	58	4.19	8,380	Construction and panel adhesives
9	165.61	331,220	Selective herbicides/defoliants	59	4.06	8,120	Nail polish removers
10	108.84	217,680	Toilet bowl cleaners	60	3.72	7,440	Solvent parts cleaner
11	101.92	203,840	Glass cleaners	61	3.48	6,960	Aerosol cooking sprays
12	82.25	164,500	Crawling bug insecticides	62	3.39	6,780	Tire cleaners
13	64.46	128,920	Automotive waxes/polishes/sealants	63	3.20	6,400	Insect repellants
14	63.18	126,360	Fungicides and nematocides	64	3.12	6,240	Woodworking glues
15	56.72	113,440	Tub, tile & sink cleaners	65	2.86	5,720	Aerosol adhesive
16	53.91	107,820	Caulking compounds	66	2.58	5,160	Wood fillers
17	51.87	103,740	Hair spray	67	2.55	5,100	Bug and tar removers
18	51.44	102,880	Hand and body lotions	68	2.47	4,940	Wasp and hornet insecticide
19	51.21	102,420	Automotive windshield washer fluids	69	2.42	4,840	Insecticide foggers
20	50.17	100,340	Flexible floor wax/polish	70	2.40	4,800	Undercoatings
21	45.51	91,020	Liquid/pump spray air fresheners	71	2.23	4,460	Shoe care products
22	41.68	83,360	Laundry pre-wash	72	2.14	4,280	Stenilants (not including ethylene oxide)
23	38.88	77,760	Spot removers	73	1.77	3,540	Fllea and tick insecticides
24	33.01	66,020	Cold process roof cements	74	1.76	3,520	Pipe cements and primers
25	29.73	59,460	Laundry starches, sizings etc	75	1.74	3,480	Fabric protectants
26	28.44	56,880	Paint thinners	76	1.74	3,480	Penetrant
27	27.37	54,740	Dusting aids	77	1.67	3,340	Non-resilient floor wax/polish
28	24.69	49,380	Carpet and upholstery cleaners	78	1.61	3,220	Automotive instant detailers
29	23.51	47,020	Hair styling gels	79	1.41	2,820	Automotive hard paste waxes
30	22.91	45,820	Underarm antiperspirants	80	1.30	2,600	Graffiti removers
31	21.38	42,760	Astringents/toners	81	1.29	2,580	Wood floor wax/polish
32	21.09	42,180	Multipurpose solvents	82	1.13	2,260	Nail polish
33	18.97	37,940	Rubber and vinyl protectants	83	1.02	2,040	Silicone based multi-purpose lubricant
34	18.23	36,460	Solid/gel air fresheners	84	0.91	1,820	Automotive adhesives
35	17.25	34,500	Paint removers and strippers	85	0.86	1,720	Electronic cleaner
36	17.02	34,040	Rubbing alcohol	86	0.75	1,500	Single phase aerosol air fresheners
37	15.30	30,600	Chacoal lighter materials	87	0.74	1,480	Carpet and tile adhesives
38	15.14	30,280	Dual phase aerosol air fresheners	88	0.73	1,460	Brush cleaners
39	14.59	29,180	Multi-purpose lubricant	89	0.68	1,320	Adhesive remover
40	14.43	28,860	Furniture waxes and polishes	90	0.60	1,200	Personal hygiene sprays
41	13.40	26,800	Specialty lubricant	91	0.46	920	Foot powders
42	12.86	25,720	Automotive brake cleaners	92	0.45	900	Hair shines
43	12.76	25,520	Oven cleaners	93	0.44	880	Contact adhesive
44	11.85	23,700	Engine degreasers	94	0.43	860	Personal fragrance products (>20% fragr)
45	11.64	23,280	Personal fragrance products (<20% f	95	0.37	740	Vinyl and leather cleaners
46	9.76	19,520	Carburetor, choke cleaners	96	0.17	340	Dual purpose air fresheners, disinfectants
47	9.73	19,460	Shaving creams	97	0.16	320	Base coats, undercoats
48	9.54	19,080	General purpose adhesive	98	0.11	220	Arts and crafts adhesives
49	8.99	17,980	Shaving gels	99	0.11	220	Battery cleaners
50	8.39	16,780	Carpet deodorizers				
				<b>Total</b>	<b>82,043</b>	<b>164,086,840</b>	
					<b>short tons</b>	<b>pounds</b>	

**Exhibit 1**  
**Age and Drug Clearance Rates**

<u>Compound</u>	<u>Age</u>	<u>Clearance Rate</u>
• Morphine	children	20 - 25 ml/min/kg
	adults	6 - 15 ml/min/kg
• Methotrexate	children	0.6 l/kg/hr
	adults	0.1 l/kg/hr
• Thorazine	children	3.1 l/hr/kg
	adults	0.6 l/hr/kg
• Lidocaine	newborns	0.3-1.1 l/hr/kg
	adults	0.3-1.1 l/hr/kg

Source: ECETOC (2005)

## Exhibit 2 Effects of Age on Laboratory Animal Carcinogenesis



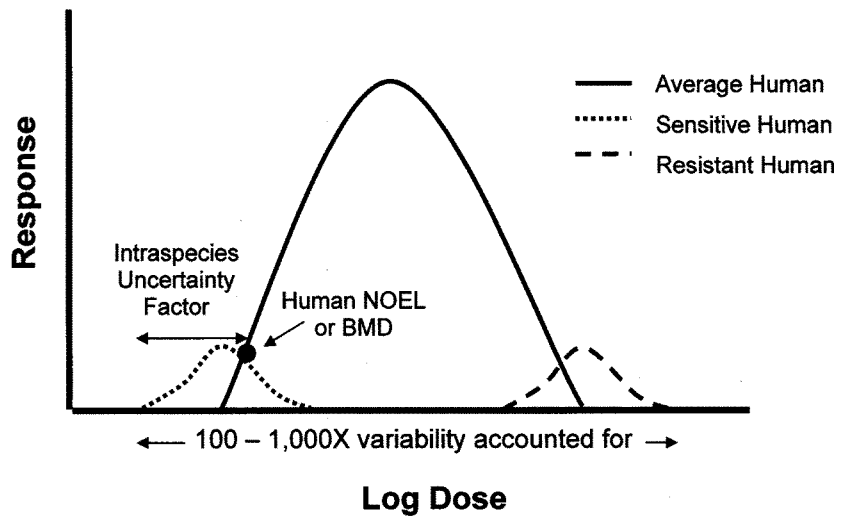
**Exhibit 3**  
**Example of Influence of Age:**  
**DDT Toxicity in Rats**

<b><u>Age</u></b>	<b><u>LD50 (mg/kg)</u></b>
Newborn	>4000
10 days	730
2 weeks	440
1 month	360
2 months	250
4 months	190
Adult	220



# Exhibit 4

## Response as a function of dose for humans of different sensitivities



270

