H.R.———, THE "U.S. AGRICULTURAL SECTOR RELIEF ACT OF 2012," AND H.R.———, THE "ASTHMA INHALERS RELIEF ACT OF 2012"

HEARING

BEFORE THE

SUBCOMMITTEE ON ENERGY AND POWER

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

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C O N T E N T S

WITNESSES

SUBMITTED MATERIAL

H.R.———, THE U.S. AGRICULTURAL SECTOR RELIEF ACT OF 2012, AND H.R.———, THE ASTHMA INHALERS RELIEF ACT OF 2012

WEDNESDAY, JULY 18, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY AND POWER,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:20 a.m., in room 2123 of the Rayburn House Office Building, Hon. Ed Whitfield (chairman of the subcommittee) presiding.

Members present: Representatives Whitfield, Shimkus, Walden, Terry, Burgess, Bilbray, Scalise, Olson, McKinley, Gardner, Griffith, Barton, Upton (ex officio), Rush, Sarbanes, Dingell, Engel, Green, Capps, and Waxman (ex officio).

Staff present: Anita Bradley, Senior Policy Advisor to Chairman Emeritus; Allison Busbee, Legislative Clerk; Cory Hicks, Policy Coordinator, Energy and Power; Heidi King, Chief Economist; Ben Lieberman, Counsel, Energy and Power; Mary Neumayr, Senior Energy Counsel; Jeff Baran, Democratic Senior Counsel; Phil Barnett, Democratic Staff Director; and Caitlin Haberman, Democratic Policy Analyst.

Mr. WHITFIELD. I would like to call this hearing to order this morning. This morning, we will be focused on two pieces of legislation: the U.S. Agricultural Sector Relief Act of 2012 and the Asthma Inhalers Relief Act of 2012. Our friends on the other side of the aisle are not here yet. They have been delayed except for Mrs. Capps of California, so the way we will proceed is that I will give my 5-minute opening statement. Then, I will call on the chairman of the full committee, Mr. Upton, to give his 5 minutes. And by then, we believe Mr. Waxman will be here and then if Mr. Rush is not here, I think Mrs. Capps is going to give an opening statement. So you all have to listen to the Republicans for about 10 minutes first before we hear the other side.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

As I said, we are holding a legislative hearing on the U.S. Agricultural Sector Relief Act of 2012 and the Asthma Inhalers Relief Act of 2012. Both bills relate to Title VI of the Clean Air Act, specifically, the Montreal Protocol. This international environmental treaty seeks to phase out the use of ozone-depleting substances.

One of the substances to be phased out is the fumigant methyl bromide. And basically, it has been phased out except for certain critical use exemptions.

Now, this substance is used by many agricultural groups around the country, those who grow eggplant, flowers, peppers, strawberries, used in milling companies and so forth. And while many of these farmers have been able to switch to substitutes for certain purposes—for example, sulfuryl fluoride—we now discover that EPA wants to ban sulfuryl fluoride, the substitute. So we think that that does provide a problem.

And I might also add that this methyl bromide is very important—I think I indicated this earlier—in milling operations. So it is also critical uses that the U.S. Agricultural Sector Relief Act sets out a process to allow limited but continued availability of methyl bromide. And we want to set that out clearly in the statute.

I would also like to just say a brief word about the Asthma Inhalers Relief Act. This bill simply allows the CFC inhalers already manufactured before the ban to be sold or distributed providing a temporary supply for those asthmatics who would like the option to purchase this. So it is a limited amount. It has already been manufactured. It is just sitting on the shelves and there are many people out there who have requested the ability to continue to use this over-the-counter medicine for their asthma condition. So that is the purpose of this legislation.

At this time I would like recognize the gentleman from Texas, Mr. Burgess, for 2 minutes and 35 seconds.

[The prepared statement of Mr. Whitfield follows:]

Opening Statement of the Honorable Ed Whitfield
Subcommittee on Energy and Power
Hearing on the "U.S. Agricultural Sector Relief Act," and the "Asthma Inhalers Relief Act"
July 18, 2012
(As Prepared for Delivery)

Today we will be holding a legislative hearing on the "U.S. Agricultural Sector Relief Act of 2012," and the "Asthma Inhalers Relief Act of 2012."

Both bills relate to aspects of implementing the Montreal Protocol. This international environmental treaty seeks to phase-out the use of ozone depleting substances, such as the CFCs that were once used in refrigerators, car air-conditioners, and other products.

One of the substances to be phased out is also the fumigant methyl bromide. While many farmers that once used methyl bromide have been able to switch to substitutes for certain purposes, for some specific uses – such as preparing the soil for growing strawberries, tomatoes or other crops – it is still needed.

I might add that another application where methyl bromide is important is in milling operations. My congressional district is the home of the Hopkinsville Milling Company who supports this legislation because they say it helps them ensure that they are able to meet clean food regulations. As we will hear from today's witnesses, it is still needed because there are no adequate substitutes available.

And it is for those critical uses that the U.S. Agricultural Sector Relief Act sets out a process to allow limited but continued availability of methyl bromide.

The amounts of methyl bromide at issue won't make even a dent in the continued declines of ozone depleting compounds in the atmosphere, but they will make a major difference for thousands of struggling farmers who don't see a future without it.

I would also like to say a word about the Asthma Inhalers Relief Act. As I mentioned, CFCs have been phased out, and a ban now also applies to the very small amounts of CFCs used in medical devices, including over-the-counter asthma inhalers. While these inhalers represent only a fraction of one percent of global CFC emissions, there is a ban on them that became effective at the end of last year. This bill simply allows the CFC inhalers already manufactured before the ban to be sold or distributed, providing a temporary supply for those asthmatics who would like the option to have them.

I look forward to the witnesses' testimony today on these pieces of legislation.

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OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for the recognition.

You know, this past January 1, a common over-the-counter emergency asthma inhaler was taken off the pharmacy shelves due to an international treaty agreement known as the Montreal Protocol. Now, asthma sufferers who find themselves awakened at 2:00 a.m. with an unexpected attack and who don't have other medicines in the home don't have immediate access to an inhaler and they are forced to undergo a time-consuming and expensive emergency room visit, or worse yet, stay up the rest of the night using the accessory muscles of breathing, wondering if they are going to live through the experience.

A replacement inhaler has been before the Food and Drug Administration's approval board for some time, but the FDA has taken no action to allow for another over-the-counter inhaler to be available for consumers. When the January 1, 2012, ban went into effect, people expected that its replacement would be available. They did not expect disruption to health services for asthma patients. But this is not the case. Because of the Food and Drug Administration's intransigence, asthmatics currently do not have an over-the-counter remedy when they have an unexpected attack, especially if that attack happens when they are traveling and they don't have access to their regular medicines.

However, there is a fairly simple solution. The Environmental Protection Agency has within its authority to ability to waive the ban on the over-the-counter epinephrine meter-dosed inhaler to allow the existing stock to be sold, at least until a replacement can be approved. Yet, despite multiple letters to the EPA and in fact to the President of the United States and questions during committee hearings, the EPA remains unresponsive to the plight of millions of asthmatics.

Why does EPA refuse to grant a waiver? I simply cannot tell you because they will not tell me. It is because of their refusal, EPA's refusal to account for the health and safety of asthma patients that we are in the predicament that we are in today. We have got a straightforward piece of legislation—require the EPA to grant a waiver to allow for the sale of remaining stock, which otherwise would be wasted on the shelves of storage facilities where it sits, allowing perfectly good inhalers to sit unused when patients need them really cries out for remedy. The miniscule amount, I mean miniscule amount, of chlorofluorocarbons that exist in the over-the-counter inhalers will have a negligible effect on the hole in the ozone, especially considering the limited supply left.

The Environmental Protection Agency should be on the side of patients and consumers. In this case, it is not. Administrator Lisa Jackson and President Obama need to stop this senseless war on asthmatics.

And I will yield back my time.

Oh, Mr. Chairman, I would ask for unanimous consent to provide for the record a copy of the letter I sent to the President of the United States on February 29 of this year asking for this waiver.

[The information follows:]

MICHAEL C. BURGESS, M.D.
26TH DISTRICT, TEXAS

ENERGY AND COMMERCE
SUBCOMMITTEES
HEALTH
VICE CHAIRMAN
OVERSIGHT AND INVESTIGATIONS
ENERGY AND POWER

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February 29, 2012

President Barack Obama
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

President Obama:

As a lifetime asthma sufferer, I would like to bring to your attention an issue that has been of critical importance to me as well as to millions of asthma sufferers across the country. On January 1, 2012, a common over-the-counter (OTC) emergency asthma inhaler, Primatene® Mist, was forced off pharmacy shelves due to an international treaty agreement known as the Montreal Protocol which bans the use of chlorofluorocarbon (CFC) propellant, an ingredient in Primatene® Mist. Primatene® Mist is the only OTC approved inhaler for asthma symptoms with epinephrine as the active ingredient.

Currently, the Food and Drug Administration (FDA) has under its review a replacement OTC inhaler for Primatene® Mist. While I am concerned over the undue delay in the review of this medication by the FDA, my more immediate concern is over the current lack of any available OTC emergency asthma inhaler. I myself have used Primatene® Mist on numerous occasions where I have found myself in need of an emergency inhaler, and I know other asthma sufferers who have found themselves in the same situation. At present, asthma sufferers who find themselves awake at 2am with an unexpected asthma attack, and who do not have immediate access to an inhaler, are faced with the costly and time-consuming task of rushing to the emergency room for a prescription inhaler, increasing healthcare costs and doing a disservice to asthma sufferers who have long found comfort in knowing that relief could be had with just a short trip to the local drug store.

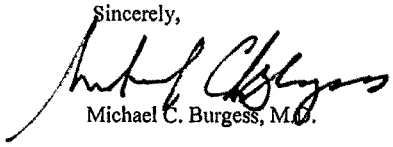
What is all the more frustrating with this situation is that the OTC version of Primatene® Mist is still available in large stocks, sitting in warehouses, unable to be sold in the U.S. Further, the Environmental Protection Agency (EPA), which has repeatedly espoused its concern over asthma sufferers nationwide, has the ability to grant a waiver to the Montreal Protocol and allow the existing stock of Primatene® Mist to be sold. I have repeatedly approached representatives of the EPA, including Administrator Lisa Jackson and Assistant Administrator Gina McCarthy and asked them to grant such a waiver. While simultaneously pointing their fingers at claiming

the problem lies at the feet of the FDA, they have been unresponsive in answering why the EPA has thus far refused to grant a waiver to allow the existing stock of Primatene® Mist to be sold.

If assisting asthma sufferers and lowering healthcare costs are truly a priority for your administration, allowing the existing stock of Primatene® Mist to be sold to asthma sufferers should be an easy decision. The small amount of CFC propellant used in the remaining stock of Primatene® Mist will hardly have a negative impact on the global environment, especially when weighed against the health benefits of assisting asthmatics suffering from emergency attacks. Indeed, even if not used, the existing stock of this life-saving drug will simply be discarded, allowing the propellant to be emitted into the atmosphere without providing its known benefit to asthma patients. Moreover, this is a finite number of Primatene® Mist inhalers which are at issue, as the company responsible for their manufacture has already switched over to a Montreal Protocol-compliant propellant currently under FDA review.

Because of your stated commitment to helping asthma sufferers and lowering healthcare costs generally, and EPA's refusal to respond to calls to allow the existing stock of Primatene® Mist to be sold, including letters from the Energy & Commerce Committee which have gone unanswered by the EPA, I am writing to you to ask that you direct Administrator Jackson to review this issue and allow Primatene® Mist to be sold until the existing stock is depleted and FDA is able to fully review and approve its replacement. The health and lives of millions of Americans are at risk until this issue can be resolved.

Sincerely,



Michael C. Burgess, M.D.

Mr. WHITFIELD. At this time, I would recognize the gentleman from California, Mr. Waxman, for his 5-minute opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

In the 1970s, scientists warned that manmade chemicals were depleting the stratospheric ozone, which protects our planet from harmful ultraviolet rays from the sun. In response, governments around the world acted to address the threat. At first, we acted unilaterally taking steps such as banning CFCs from hairspray. Then, we entered into the Montreal Protocol to ensure that all the nations of the world were working together to solve the problem. The Montreal Protocol is widely recognized as a tremendously successful international environmental agreement. As a result of the protocol, global emissions of the gases are a small fraction of their 1990 levels. And if we continue to comply with the protocol and enforce the Clean Air Act, the ozone layer is expected to recover later this century.

But this progress cannot be taken for granted. Legislation like we are considering today would undermine the effectiveness of the Montreal Protocol. The first bill we are considering would increase the use of methyl bromide, a pesticide that is a powerful ozone-depleting chemical. Methyl bromide has been banned since 2005, but there is a mechanism in the law for critical use exemptions.

Each year, growers apply for exemptions. EPA analyzes those applications with the help of USDA and the U.S. Government requests critical use exemptions under the Montreal Protocol. This process is working. Since 2005, the level of critical use exemptions requested by the United States and granted through the Montreal Protocol has decreased dramatically. That is exactly what is supposed to happen.

California's strawberry growers are the largest remaining user of methyl bromide. They have been predicting for years that these reductions in methyl bromide would ruin their crops, but according to a recent study, "the years of declining methyl bromide use have been years of rising yields, acreage, exports, revenues, and market share for California growers."

This bill reverses the progress that has been made on methyl bromide. Instead of requiring growers to justify continued use of methyl bromide, the bill reverses the presumption. It would require EPA to accept growers' requests unless EPA can prove they are unnecessary. The bill also freezes into law an outdated list of approved critical uses. As a result, sectors that have completely phased out the use of methyl bromide during the last 7 years would be permitted to use methyl bromide again. Incredibly, even golf courses would once again be allowed to seek critical use exemptions. And the bill creates a gaping emergency event loophole.

I also have concerns about the Primatene Mist bill. Primatene Mist is an over-the-counter epinephrine inhaler from the 1960s. It was phased out at the end of 2011 and has been off the shelves for over 6 months. The bill would put Primatene Mist back on the shelves to its manufacturer could sell off its remaining inventory.

A long list of physician, patient, public health, and industry groups strongly oppose the bill. Medical and public health organizations don't want Primatene Mist back on the market because they say it is not safe or recommend it for treating asthma. Physician groups are concerned that the bill will result in patient confusion and companies that made the necessary investments to develop CFC-free inhalers argue that the bill would unfairly provide special treatments to a single company.

Mr. Chairman, we should be looking at these issues very carefully. We should be celebrating and strengthening the Montreal Protocol, not considering legislation to weaken it. And I hope we will reject the methyl bromide bill and rethink the Primatene Mist bill as well.

In the last 30 seconds I just want to point out some history. I was here in 1977 when the first time the issue was raised. We were considering Clean Air Act amendments. One of my colleagues was able to dissuade the committee from doing anything on CFCs because he said it had not been proved beyond a reasonable doubt that CFCs were harmful, and therefore, Congress didn't act. We finally did act and we acted first and then went to complete and international agreement. It is exactly the kind of thing we ought to do with carbon emissions. We ought to be looking at that issue and dealing with it, not denying the science, which is where we are now today in the Congress of the United States.

I thank the chairman for allowing me to exceed my time by 22 seconds.

Mr. WHITFIELD. Thank you.

At this time, I recognize the chairman of the full committee, Mr. Upton, for 5 minutes.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman.

Over the last several decades, environmental quality has improved significantly, and our goal is to maintain that progress without imposing unnecessary burdens on our economy or the American people. And that is why we have consistently advocated for regulatory common sense and balance. And that is what we are going to talk about today—two sensible proposals, I believe, that ensure environmental rules do not impose unnecessary hardships.

Congress examined and addressed ozone depletion through the 1990 Clean Air Act amendments, which provide the framework of the U.S. participation in the Montreal Protocol treaty. As a result, the use of CFCs as refrigerants in air-conditioners and refrigerators has been sharply curtailed. And other ozone-depleting substances have also been restricted.

For the most part, the transition to the substitutes has gone well, but there are two exceptions that we hope to address through targeted legislation. One deals with the crop fumigant methyl bromide, which was widely used in agricultural applications until it was included on the list of ozone-depleting compounds. For many crops and uses there are adequate substitutes, and as a result, methyl bromide use is down by 90 percent. But for some crops,

methyl bromide is still needed because viable alternatives are not yet available.

And to address that issue, I am pleased that Michigan farmer Russ Costanza has joined us today. Russ grows peppers, eggplant, squash, tomatoes, cucumbers back on his farm in Sodus, Michigan, and he employs 125 folks. And we need to hear him out because his message is that of many farmers throughout the country who doubt whether they can remain in business without continued access to methyl bromide. The U.S. Agricultural Sector Relief Act would allow farmers like Russ to keep using methyl bromide on a limited basis.

While one bill provides relief to farmers, the other provides relief to patients with asthma. The over-the-counter asthma inhalers containing CFCs, most commonly marketed as Primatene Mist, have been banned because they use very small amounts of CFCs as propellants. But no non-CFC over-the-counter inhalers are available at this time, leaving asthmatics without an over-the-counter option. The Asthma Inhalers Relief Act would allow for the remaining inventories of this inhaler, which were available in the U.S. for more than 40 years, to be temporarily sold or distributed without penalty.

So on behalf of the American people, we are working to ensure reasonable environmental protections and we are doing so while avoiding unnecessary harm. The two bills at issue today satisfy those obligations.

And I yield to the chairman emeritus, Mr. Barton, the balance of my time.

[The prepared statement of Mr. Upton follows:]

Opening Statement of the Honorable Fred Upton
Subcommittee on Energy and Power
Hearing on the "U.S. Agricultural Sector Relief Act," and the "Asthma Inhalers Relief Act"
July 18, 2012
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Over the last several decades, environmental quality has improved significantly. Our goal is to maintain that progress without imposing unnecessary burdens on our economy or the American people. That's why we have consistently advocated for regulatory common sense. And that's what we're here to talk about today - two sensible proposals that ensure environmental rules do not impose unnecessary hardships.

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As a result, the use of CFCs as refrigerants in air-conditioners and refrigerators has been sharply curtailed. And other ozone depleting substances have also been restricted.

For the most part, the transition to substitutes has gone well. But there are two exceptions that we hope to address through targeted legislation.

One deals with the crop fumigant methyl bromide, which was widely used in agricultural applications until it was included on the list of ozone depleting compounds. For many crops and uses there are adequate substitutes, and as a result, methyl bromide usage is down by over 90 percent. But for some crops, methyl bromide is still needed because viable alternatives are not yet available.

To address that issue, I am pleased that Michigan farmer Russ Costanza has joined us today. Russ grows peppers, eggplant, squash, tomatoes, and cucumbers back on his farm in Sodus, Michigan, and he employs 125 workers. We need to hear him out, because his message is that of many farmers throughout this country who doubt whether they can remain in business without continued access to methyl bromide. The Agricultural Sector Relief Act would allow farmers like Russ to keep using methyl bromide on a limited basis.

While one bill provides relief to farmers, the other provides relief to patients with asthma. The over-the-counter asthma inhalers containing CFCs, most commonly marketed as Primatene Mist, have been banned because they use small amounts of CFCs as propellants. But no non-CFC over-the-counter inhalers are available at this time, leaving asthmatics without an over-the-counter option. The Asthma Inhalers Relief Act would allow for the remaining inventories of this inhaler, which was available in the U.S. for more than four decades, to be temporarily sold or distributed without penalty.

On behalf of the American people, we are working to ensure reasonable environmental protections. And we are doing so while avoiding unnecessary harm. The two bills at issue today satisfy both these obligations.

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OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Chairman Upton. And thank you, Chairman Whitfield and Mr. Rush, for holding this hearing. We may have already done it, but I would like to welcome back former Congressman Bart Stupak, who is in the audience and a distinguished former member of the committee. We are glad to have you, Bart.

I support the U.S. Agricultural Sector Relief Act of 2012 and I tend to support the Asthma Inhaler Relief Act of 2012 also, although I have got some concerns about that piece of legislation.

Methyl bromide is essential as an agricultural fumigant. There are some alternatives for agricultural uses, but methyl bromide is still needed for others where there doesn't appear to be a viable alternative. Under the Montreal Protocol, we have seen a considerable decrease in the critical use exemptions since 2005. This bill is important not only for American jobs but as a matter of national security as well.

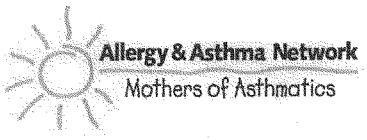
In terms of the Asthma Inhaler Relief Act, Dr. Burgess has got a well intended piece of legislation. I am going to put into the record, Mr. Chairman, by unanimous consent, a letter from the Allergy and Asthma Caucus and the Mothers of Asthmatics. Their president and founding member is in the audience today, Nancy Sander, and we are glad to have you, too, Nancy, here.

Their group has got very legitimate concerns about Dr. Burgess' bill, and I have worked with them and put them in touch with Dr. Burgess to try to alleviate some of those concerns. I think it is important that Americans have an over-the-counter alternative to a prescription inhaler. And that is basically what Dr. Burgess's bill intends to do. The letter that I will ask unanimous consent to put in the record at the end of my statement, Mr. Chairman, does say that there is an alternative. There is a handheld bulb nebulizer that is available over-the-counter, and that is one reason I have some concerns about Dr. Burgess' bill.

With that, I would ask unanimous consent to put a letter dated July 17, 2012, from the Allergy and Asthma Network Mothers of Asthmatics, into the record and then yield back the balance of my time.

Mr. WHITFIELD. Without objection, it will be entered.

[The information follows:]



July 17, 2012

The Honorable Ed Whitfield
Chair, Subcommittee on Energy & Power
2368 Rayburn House Office Building
Washington, DC

Dear Chairman Whitfield:

Allergy & Asthma Network Mothers of Asthmatics serves families with allergies and asthma. Founded in 1985 by families for families, we've enjoyed a long history of bipartisan support from Congress to change laws and policies affecting school children with asthma and anaphylaxis, and worked with federal agencies such as FDA, EPA, CDC, NHLBI and NIAID to ensure evidence-based, cost effective and patient-centered care. This collaborative effort means that today, it is possible to improve patient quality of life, prevent asthma and anaphylaxis deaths and suffering while reducing healthcare costs. Thank you for consideration of our views opposing the Asthma Inhaler Relief Act.

- The Act gives unprecedented preferential and exclusive exceptions and financial benefits to Armstrong Pharmaceuticals, an Amphastar Company, for the sale of one product, Primatene Mist (PM) under the guise of serving otherwise unmet needs of poor and uninsured patients with asthma.
- However, PM is not recommended for the treatment of asthma in NIH/NHLBI Asthma Guidelines, the accepted standard for care in the U.S. (Attachment) Therefore, no Act of Congress should cause the poor be subject to outdated and substandard modes of treatment.
- Primatene Mist contains a CFC propellant banned through the Montreal Protocol, an international treaty signed by 191 countries since 1987 and the Clean Air Act of 1990 and upheld by every Congress and President since.
- This same Montreal Protocol and Clean Air Act required all pharmaceutical manufacturers to cease production, distribution and sale of albuterol inhalers containing CFCs on December 31, 2008.
- At that time, Armstrong/Amphastar was a leading manufacturer of generic albuterol and as such was required to cease production, distribution and sale of generic albuterol inhalers in 2008. Therefore, Armstrong/Amphastar is no stranger to the Montreal Protocol, Clean Air Act or the FDA process for ANDA and NDA submissions.
- Armstrong/Amphastar plans to manufacture generic albuterol HFA inhalers as soon as patents expire and PM HFA inhalers upon approval which the company continues to promise is any day now. The

company hopes to dominate both the generic albuterol and OTC asthma market according to public securities documents.

- By December 31, 2008, 40 million patients with asthma and chronic obstructive pulmonary disease transitioned to one or more of the non-CFC asthma and COPD inhalers shown on AANMA's Asthma Inhalers Posters. [Attachments]

- Armstrong/Amphastar does not meet established U.S. and International criteria to determine essential use status or to qualify for the exemptions outlined in the Act. There is no unmet need. There is no evidence-based data suggesting otherwise.

- Those consumers who desire to purchase and use aerosol epinephrine can continue to do so inexpensively and without a prescription. Contact Nephron Pharmaceuticals. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=26023

Epinephrine

Hand-held Bulb Nebulizer

- In August 2011, Armstrong/Amphastar continued to manufacture Primatine Mist knowing that sales would cease on December 31, 2011. FDA required the manufacturer to post this warning on the front of all packaging and on their website.

- Armstrong/Amphastar's numerous and extensive media and Internet marketing campaigns garnered significant and sympathetic press coverage. Yet, Armstrong/Amphastar was unable to unload 1 million excess PM canisters that now languish in a warehouse one year later. Was this poor planning or strategic planning? It was one or the other and in either case, purposeful.

- In the last quarter of 2011, the PM prices climbed upwards of $250 a canister. On this PM Facebook page, recent posting show where to buy the device for $250 a canister. Similar activities occurred when generic CFC albuterol was discontinued as well. https://www.facebook.com/permalink.php?story_fbid=344976305571968&id=256149177788015&comment_id=3033671&offset=0&total_comments=7

- The "Bring Back Primatene Mist" Facebook page was started 7 months ago by an unnamed source with no identity yet he/she/they coach 185 "friends" on how to badger members of Congress and FDA. Identity of most "friends" on most Facebook and other types of social media sites is masked suggesting that such campaigns may be little more more than "blog for hire". https://www.facebook.com/pages/Bring-Back-Primatene-Mist/256149177788015?sk=wall&filter=12

- All but two CFC metered dose inhaler products and nasal sprays have completed the CFC transition. Both are in compliance with US law. Combivent will soon be available as an aerosol inhaler that requires no propellant. MaxAir's market share was so small that the manufacturer will discontinue the product.

- Most new metered dose inhalers have or will soon have dose counters, the only way the patient knows when medication runs out and all that remains is propellant.

- Recently, Armstrong/Amphastar posted a warning to patients that there have been reports of PM canisters breaking or exploding if dropped since January 2012.

- The transition was not voluntary for patients or manufacturers. No federal funds were allocated for patient awareness and education programs. That responsibility fell to manufacturers and nonprofit organizations. Manufacturers making the transition provided free drug to patients in need and some offered coupons to help offset the cost of higher co-pays charged by health insurance companies. Patients absorbed have absorbed the bulk of costs with average $10 co-pay rose to $20, $50 and $60 per HFA inhaler.

The Act should not be seen not an act of charity. The manufacturer will not give the drugs away and has no way to ensure that only poor or uninsured patients receive product. If they could, how many canisters would each patient be allowed to purchase? Who will tell the poor when 1 million canisters are available in stores or when supplies will be running low?

What if patients don't like the HFA taste or force of spray and perceive it to be inferior to the CFC? Will packaging warn consumers of the potential for glass canisters to break and cause injury?

The Act brings confusion. Why is PM given preferential treatment while 40 million insured and uninsured children and adults are not?

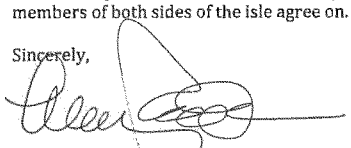
Asthma is a disease that is always present but not always noticed. When severe attacks occur, patients do not have time or luxury to think about where they stashed their inhaler last or if medication vs. propellant is all that remains in the canister.

Asthma is the master deceiver. You don't wake up one day and say this will be the day I die or my two year old dies of asthma. It happens slowly, but the lungs fill with fluid and plug with mucus until the brain perceives a dangerous situation.

Death by asthma doesn't look so scary. Just ask the father whose two year old daughter died in his arms as he gave her a routine nebulizer treatment. She didn't struggle. She just whispered, "I love you" and stared with empty eyes.

AANMA remains ready to help patients find the care and relief they seek. We need your support to ensure existing cost productive protocols provide patients with patient-centered, evidenced based care that saves lives, puts kids back to school and parents back to work. It's no mystery and it's something that members of both sides of the isle agree on. Thank you for your consideration.

Sincerely,



Nancy Sander
President and Founder

8201 Greensboro Rd., Suite 300, McLean, VA 22102 800.878.4403 www.aanma.org

Mr. WHITFIELD. At this time, I would like to recognize the gentleman from Illinois, ranking member of the subcommittee, Mr. Rush, for a 5-minute opening statement.

OPENING STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. RUSH. Well, thank you, Mr. Chairman.

Mr. Chairman, in keeping in line with the majority party's overall agenda of bypassing, overriding, and curtailing the Clean Air Act, as well as any and all regulations that may hamper industry profits regardless of the health or environmental benefits that those rules were designed to protect, we are here yet again holding this hearing on the Agricultural Sector Relief Act and the Asthma Inhalers Relief Act of 2012.

My Republican colleagues, Mr. Chairman, continue to ignore the fact that the U.S. has set more than 40,000 high temperature records this year and that the last 12 months have been the hottest ever recorded in U.S. history. And the fact that more than 113 million Americans are living under extreme health advisories, while the USDA has declared a Federal disaster area in more than 1,000 countries covering 26 States also does not seem to concern the majority party.

Mr. Chairman, while the country literally burns around us, I can't believe that we are here today holding yet another hearing on two issues of far less importance to most Americans other than a few industry lobbyists.

Today, fully 2/3 of the country is experiencing extreme drought and 30 percent of the Nation's corn crop is in poor or very poor condition. While at the same time, water levels of four of the five Great Lakes have plummeted due to high evaporation rates and insufficient rainfall. We are still here having hearings on two not very important bills to the majority of the American people.

Mr. Chairman, I ask this committee to not to deal with these two bills but to deal with a different kind of drought, the drought of laws that come from the inaction of this subcommittee. While even all the heat-related and fire-related and the atrocities that are occurring to farmers of our Nation, to the consumers of our Nation, the two bills before us would only serve the interests of select industries by rolling back gain we have made under the Montreal Protocol.

The Montreal Protocol is widely recognized as a tremendously successful international environmental agreement, and in 2009 became the first of its kind to achieve universal ratification by every country in the world. Mr. Chairman, let us get on to some real business.

And with that, I yield a minute, the balance of my time, to Mrs. Capps of California.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. I thank my colleague for yielding to me. And I want to focus a few comments on the methyl bromide bill, a very important issue to my constituents.

I represent some of the very best strawberry and cut flower growers in the country, and just a couple of weeks ago, I was invited by the Strawberry Commission of California to meet with them in Santa Maria to discuss this exact issue. We met in the midst of the strawberry fields. While I have seen firsthand the tremendous progress in finding alternatives to methyl bromide, I have also seen firsthand why methyl bromide is still a necessity to many if not most strawberry growers.

I am proud to say that many of the flower farmers in my district like June and Rene Van Wingerden of Ocean Breeze Farms and Lane Devries of Sun Valley Floral no longer use methyl bromide because they have pioneered innovative new methods that are effective. But let us be clear. These alternatives don't work for everyone and they don't work in every situation. And the cost of the disease our growers face are very real, very threatening. During my recent visit, I saw firsthand the impacts of charcoal rot in some fields in Santa Maria, as well as other diseases. They can literally shut down an operation hurting not only the growers but also their workers and the local economy.

I must add that agriculture is a growing force of my congressional district, strawberries are the number one crop, and these local economies stretch far and wide in central and southern California, including the local economies of my colleague, Mr. Bilbray, I know.

So it is very important that this issue be addressed but I am, I must say, Mr. Chairman, disappointed that we are going to be back here in just a very few hours to mark up this legislation without hearing from the administration or really adequate time to fully consider the testimony of our witnesses. I am pleased to say that one is from the Strawberry Commission in California. It is a very important issue that should not be rushed through the legislative process.

That being said, I do look forward to hearing the witness testimony and working toward a solution on this matter. And I yield back. Thank you, Mr. Rush.

Mr. WHITFIELD. Thank you, Mrs. Capps.

And I will say that while we did invite EPA to testify, they were unable to be here, but they have submitted a pretty detailed statement for the record relating to these two bills. And this will be part of the record, so thank you.

We have two panels of witnesses this morning and I would like at this time to call up the first panel of witnesses. And on that panel we have five people. First, we have Mr. Russell Costanza, who is the owner of Russell Costanza Farms. Number two, we have Mr. Scott DiMare, who is vice president and director of farm operations, DiMare Ruskin, Inc. We have Mr. David Doniger, who is no stranger to our committee, and he is the policy director of Climate & Clean Air Program at the Natural Resources Defense Council. And I would like to call on Mr. Bilbray to introduce our next witness, please.

Mr. BILBRAY. Thank you, Mr. Chairman.

Chairman Whitfield, thank you for holding this hearing on this very important issue, especially to certain segments of our society and economy.

Methyl bromide is a critical application, as my colleague from California said, in certain situations, limited but critical in those limited. And I wish to ask for unanimous consent to enter into the record a letter supporting the U.S. Agricultural Sector Relief Act.

Mr. WHITFIELD. Without objection.

[The information follows:]

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July 17, 2012

The Honorable Ed Whitfield
Chairman
House Committee on Energy and Commerce and Subcommittee on Energy and Power
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Whitfield,

The San Diego County Farm Bureau supports the U.S. Agricultural Sector Regulatory Relief Act of 2012. The State of California and San Diego County in particular, is a leading producer of flower crops and strawberries in the United States. Strawberries and flowers are high value crops with significant impact on the agricultural economy. These two crops are also dependent on soil sterilization for consistent production. Recognizing the phase out of methyl bromide, growers are looking forward to the establishment of viable alternatives for reliable soil sterilization. However, no alternative has yet been found. Until such alternatives are discovered, the need is critical for growers to have access to methyl bromide as a crop production tool. We thank you for addressing this important issue.

Sincerely,

E Larson

Eric Larson
Executive Director

Mr. BILBRAY. It is my honor to introduce Michelle Keeler. She is one of our panelists today. Ms. Keeler, I apologize for the un-San Diego weather that you have to endure at this time. I hope you understand what a sacrifice those of us in California who serve in Congress do every day, OK, at least during the summer.

Mr. Chairman, Ms. Keeler is vice president of Mellano & Company. It is a prestigious family-owned business that specializes in cut flower growing in the sunny San Diego/Carlsbad area and right along the coast. As you are driving up Highway 5, you can see the hillsides filled with her products and the beauty that has been appreciated by the community.

The company prides itself in progressive ideas of cut flowers. Many of them have been developed as an industry-wide standard as improved logistics in growing techniques. These achievements have utilized pre-cooling allowing flowers to be shipped with optimum freshness.

Mr. Chairman, let me point out that when Mrs. Keeler speaks, she is not just speaking about her endeavor to keep a family business alive, to keep American jobs in America, but as a former California Coastal Commissioner, I want to remind everybody, too, that the California Coastal Commission has determined that Mrs. Keeler's operation is a cultural heritage that needs to be preserved. It is actually mandated in the Coastal Act's enforcement that she keep her production of flowers in this area.

And Ms. Keeler, I want to welcome you to California and welcome your ability to enlighten those of us in Washington of the challenges you face on the West Coast.

Mr. WHITFIELD. Thank you. And welcome, Ms. Keeler.

And the final witness in the first panel will be Mr. Mark Murai, who is the president of the California Strawberry Commission. And we appreciate your being here.

I will be calling on each one of you to give a 5-minute opening statement and on the table there are a couple of little small boxes that have colors red, yellow, and green. And when you get to red, we hope you will be finished, but if not, we will let you go over for a brief period of time.

So Mr. Costanza, we will recognize you first and you are recognized for 5 minutes to give an opening statement. And make sure your microphone is turned on as well. Thank you.

STATEMENTS OF RUSS COSTANZA, OWNER, RUSSELL COSTANZA FARMS; SCOTT M. DIMARE, VICE PRESIDENT AND DIRECTOR OF FARM OPERATIONS, DIMARE RUSKIN, INC.; DAVID D. DONIGER, POLICY DIRECTOR, CLIMATE AND CLEAN AIR PROGRAM, NATURAL RESOURCES DEFENSE COUNCIL; MICHELLE CASTELLANO KEELER, VICE PRESIDENT, MELLANO & COMPANY; AND MARK MURAI, PRESIDENT, CALIFORNIA STRAWBERRY COMMISSION

STATEMENT OF RUSS COSTANZA

Mr. COSTANZA. Well, thank you. And thank you for the warning because it takes me about 6–1/2 minutes to read this and I am going to skip over some of this keeping this in mind. OK.

First of all, I want to thank each and every one of the members for allowing me this opportunity to speak before you today and represent my farm, my workers in the State of Michigan.

My name is Russ Costanza. I grew up on our family farm. I am the owner of Russell Costanza Farms. My wife and I established our farm in 1976 with 10 acres. Today, we have grown that farm with our two kids and their families to over 500 acres of peppers, eggplant, squash, tomatoes, and cucumbers. Our farm is labor-intensive. Over the years, we have grown from my wife and I doing all the work on the farm to 125 farm workers. Sadly, the inability to use methyl bromide and the lack of a truly viable alternative is threatening our family and our remaining workers' livelihood.

Mr. WHITFIELD. Would you mind just moving the microphone a little closer?

Mr. COSTANZA. I am usually a little loud anyway.

Methyl bromide is a fumigant that controls insects, nematodes, pathogens, and weeds, and we use the fumigant on our farm to treat the soil prior to planting. Fumigation with methyl bromide allows us to grow a higher quality crop with increased yields and provides more onetime effective pest control than any other alternative product.

Methyl bromide has allowed us to treat our fields and cultivate abundant, high quality, high demand produce. This year, however, we were not granted any critical use exemptions for methyl bromide. Without any CUEs, the only way to use methyl bromide is to purchase dwindling stocks of the chemical that were produced prior to 2005. Such stocks are not readily available and are cost prohibitive. I currently have enough methyl bromide to last through one or perhaps two growing seasons for eggplant only, but after that, I do not know how I will be able to continue to produce adequate crops.

I used to be able to purchase methyl bromide for about $1 a pound. Today, the cost averages $9 a pound. It costs over $800 an acre to use methyl bromide. Between the scarcity and high cost, it is impossible to compete with inexpensive, quality produce from other countries whose growers are able to legally use methyl bromide. Further, the quality of our produce will deteriorate due to the lack of methyl bromide use, further eroding our ability to compete with foreign growers in our own markets.

While we have a limited supply of methyl bromide available for eggplant, we cannot use methyl bromide for our other crops. Due to the loss of quality and yields associated with these crops, we have experienced decreased profits for our remaining workers and our farm. Our dwindling profits also mean a loss of tax revenue for local, State, and Federal governments.

Our family and our workers pride ourselves on providing high quality and affordable food to U.S. consumers and to making a meaningful contribution to our country's economy. Unfortunately, our ability to do this is diminishing due to the lack of methyl bromide and an effective, affordable alternative.

Our farm has spent a great deal of money and effort seeking viable alternatives to methyl bromide. In 2005, staff from the EPA Chicago office was invited to tour our farm. They came, observed our operation, how we worked, and how methyl bromide was used.

We demonstrated how methyl bromide increased our yield of our eggplant and pepper crops. These increased yields and lack of effective alternatives were documented through the research conducted on our farm with Michigan State University on all methyl bromide alternatives. We donated the land, the manpower, and the resources to research the efficiency of alternatives on eggplant. Sadly, we did not find any affordable, usable replacement.

Due to the weather in Michigan, we have a narrow window of time before planting in which we can apply a fumigant. We cannot wait an additional 2 or 3 weeks to reenter the field prior to planting, as was required by iodomethane, Midas, and some other alternatives, or we would lose our market window. Further, Midas is no longer being sold in the United States.

For my Michigan operation, methyl bromide is truly the only treatment option available. And then we will go on with a study from Michigan State University. Our circumstances are dire, which I am very appreciative of the committee. I and other Michigan growers are facing an emergency situation on our farms, and for that reason, I am grateful that the legislation includes the provisions related to the emergency use of methyl bromide under certain circumstances.

The law must allow for flexibility when a planned, affordable alternative is no longer an option or another unanticipated event occurs. While I understand that EPA is the lead organization in making CUE recommendations to the parties, I appreciate that the legislation includes consultation with the U.S. Department of Agriculture. Because of its close working relationship with growers, the USDA and extension agents are best equipped to determine when an emergency situation exists. The Department's role in this process is critical.

I cannot overstate the importance of access to methyl bromide for my farm operation and my fellow Michigan growers. We are facing a crisis and need relief. I am hopeful that Congress will pass the Act of 2012 and the EPA and USDA will quickly implement a process to allow for limited emergency exemptions when circumstances exist.

Thank you very much for your leadership in addressing this critical issue for myself and other Michigan growers.

[The prepared statement of Mr. Costanza follows:]

Summary of Testimony of Russ Costanza on the "Agricultural Sector Relief Act of 2012"
July 18, 2012

- I am the owner of Russell Costanza Farms in Sodus, Michigan. Our farm grows about 500 acres of peppers, eggplant, squash, and cucumbers. The inability to use methyl bromide and the lack of any truly viable alternatives, is threatening our family and our remaining workers' livelihood.
- Methyl bromide has allowed us to treat our fields and cultivate abundant and high quality, high demand produce. This year, however, we were not granted any critical use exemptions (CUEs) for methyl bromide. Without any CUEs, the only way to use methyl bromide is to purchase dwindling stocks of the chemical that were produced prior to 2005. Such stocks are not readily available and are cost prohibitive. Between the scarcity and high cost, it is impossible to compete with inexpensive, quality produce from other countries whose growers are able to legally use methyl bromide.
- While we have a limited supply of methyl bromide available for eggplant, we cannot use methyl bromide for our other crops. Due to the lost quality and yields associated with these crops, we have experienced decreased profits for our remaining workers and our farm.
- Our farm has spent a great deal of money and effort seeking viable alternatives to methyl bromide. Research conducted on our farm with Michigan State University found that without methyl bromide, growers can expect yield losses of 70% or more. It also concluded that other fumigants are not suitable for use in cool spring soils and do not allow growers in Michigan to participate in the early vegetable markets that are the most profitable.
- I support the provisions of "Agricultural Sector Relief Act of 2012" that would extend the CUE process beyond 2013. This provision is very important and helpful to growers that currently hold CUEs. Sadly, my operation would not benefit from such a provision because we have not been granted CUEs for this year or next.
- The Environmental Protection Agency and the U.S. Department of State should pursue expanded CUEs for growers whose allocations were reduced due to the availability of iodomethane or other alternatives that are no longer options and consider new CUE requests for growers who may be facing new or re-emergent pest pressures.
- I strongly support the legislation's provisions related to the emergency use of methyl bromide under certain circumstances. The law must allow for flexibility when a planned affordable alternative is no longer an option or another unanticipated event occurs. We are facing an emergency situation on our farm and need relief.
- While I understand that EPA is the lead organization in making CUE recommendations to the Parties to the Montreal Protocol, I appreciate that the legislation includes consultation with the U.S. Department of Agriculture (USDA). Because of its close working relationship with growers, USDA and extension agents are best equipped to determine when an emergency situation exists. The Department's role in this process is critical.
- Please pass the "Agricultural Sector Review Act of 2012."

Testimony of Russ Costanza
Before the
House Energy and Commerce Subcommittee on Energy and Power
on the
"Agricultural Sector Relief Act of 2012"
July 18, 2012

Thank you very much Chairman Whitfield, Ranking Member Rush, and members of the subcommittee for the opportunity to testify before you today. I would also like to thank full committee Chairman Upton and Ranking Member Waxman for this opportunity.

My name is Russ Costanza. I grew up on our family farm. I am the owner of Russell Costanza Farms in Sodus, Michigan. My wife and I established our farm in 1976 with 10 acres. Today we've grown that farm with our two kids and their families to over 500 acres of peppers, eggplant, squash, tomatoes and cucumbers. Our farm is labor intensive. Over the years we have grown from my wife and I doing all the work to over 125 farm workers. Sadly, the inability to use methyl bromide and the lack and any truly viable alternatives, is threatening our family and our remaining workers' livelihood.

Methyl bromide is a fumigant that controls insects, nematodes, pathogens, and weeds. We use the fumigant on our farm to treat the soil prior to planting. Fumigation with methyl bromide allows us to grow a higher quality crop with increased yields and provides more one-time effective pest control than any other alternative product.

Methyl bromide is subject to phaseout under an international treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer and the federal Clean Air Act. All production and imports of methyl bromide were banned in the U.S. as of January 1, 2005, except for the following limited uses: 1) "critical" uses subject to annual exemptions granted by the Parties and U.S. EPA; 2) quarantine and pre-shipment uses; and 3) "emergency" uses.

Methyl bromide has allowed us to treat our fields and cultivate abundant and high quality, high demand produce. This year, however, we were not granted any critical use exemptions (CUEs) for methyl bromide. Without any CUEs, the only way to use methyl bromide is to purchase dwindling stocks of the chemical that were produced prior to 2005. Such stocks are not readily available and are cost prohibitive. I currently have enough methyl bromide to last through one, or perhaps two growing seasons for eggplant only; but after that, I do not know how I will be able to continue to produce adequate crops. I used to be able to purchase methyl bromide for about $1 per pound. Today, the cost averages $9 per pound. It costs over $800 per acre to use methyl bromide. Between the scarcity and high cost, it is impossible to compete with inexpensive, quality produce from other countries whose growers are able to legally use methyl bromide. Further, the quality of our produce will deteriorate due to the lack of methyl bromide use, further eroding our ability to compete with foreign growers in our own markets.

While we have a limited supply of methyl bromide available for eggplant, we cannot use methyl bromide for our other crops. Due to the lost quality and yields associated with these crops, we have experienced decreased profits for our remaining workers and our farm. Our dwindling profits also mean a loss of tax revenue to the local, state and federal governments. My family, our workers, and I pride ourselves on providing high quality and affordable food to U.S.

consumers and to making a meaningful contribution to our country's economy. Unfortunately, our ability to do so is vanishing due to the lack of methyl bromide or an effective, affordable alternative.

Our farm has spent a great deal of money and effort seeking viable alternatives to methyl bromide. In 2005, staff from the EPA Chicago office was invited to take a tour of our farm. They came and observed our operation, how we worked and how methyl bromide was used. We demonstrated how methyl bromide increased the yield of our eggplant and pepper crops.

The increased yields and the lack of effective alternatives were documented through research on our farm conducted with Michigan State University on all methyl bromide alternatives. We donated the land, manpower and other resources to research the efficacy of alternatives on eggplant. Sadly, we did not find any affordable, usable replacement. Due to the weather in Michigan; we have a very narrow window of time before planting in which we can apply a fumigant. We cannot wait an additional two to three weeks to re-enter the field prior to planting, as was required by iodomethane and some other alternatives, or we would lose our market window. Futher, iodomethane is no longer being sold in the United States. For my Michigan operation, methyl bromide is truly the only treatment option available. According to the study:

- Without methyl bromide, growers can expect yield losses of 70% or more.
- Other fumigants are not suitable for use in cool spring soils and do not allow growers in Michigan to participate in the early vegetable markets that are the most profitable.
- Methyl bromide reduces the amount of soil microbes that infect vegetable roots and fruits and cause root rot, wilting, and plant death.
- These damaging microbes include *Verticillium*, *Fusarium*, and *Phytophthora*. Eggplant, melons, peppers, and tomatoes are most susceptible to these damaging soil microbes.

- Two of these microbes do not respond to any fungicide. The third microbe has developed resistance to the most effective fungicide that is available.
- The soil microbes that harm vegetable crops do not naturally decrease to a safe level even when growers use long crop rotations.
- Harsh winters do not kill these vegetable pests.
- Currently, soil tests that can alert growers to the presence of damaging soil microbes prior to planting do not exist.
- Vegetables that are adequately resistant to the damaging soil microbes have not been developed. Only vegetables that are susceptible to these soil microbes are available to growers.

Our circumstances are dire, which is why I am very appreciative of Chairman Whitfield, Chairman Upton and members of the subcommittee for your leadership in drafting methyl bromide legislation and in holding this hearing. I support the provisions of "Agricultural Sector Relief Act of 2012" that would extend the CUE process beyond 2013. This provision is very important and helpful to growers that currently hold CUEs. Sadly, my operation would not benefit from such a provision because we have not been granted CUEs for this year or next. I hope that moving forward, EPA and the U.S. Department of State will pursue expanded CUEs for growers whose allocations were reduced due to the availability of iodomethane or other alternatives that are no longer options and consider new CUE requests for growers who may be facing new or re-emergent pest pressures.

I and other Michigan growers are facing an emergency situation on our farms and for that reason, I am grateful that the legislation includes provisions related to the emergency use of methyl bromide under certain circumstances. The law must allow for flexibility when a planned affordable alternative is no longer an option or another unanticipated event occurs. While I understand that EPA is the lead organization in making CUE recommendations to the Parties to the Montreal Protocol, I appreciate that the legislation includes consultation with the U.S. Department of Agriculture (USDA). Because of its close working relationship with growers,

USDA and extension agents are best equipped to determine when an emergency situation exists. The Department's role in this process is critical.

I cannot overstate the importance of access to methyl bromide for my farm operation and my fellow Michigan growers. We are facing a crisis and need relief. I am hopeful that Congress will pass the "Agricultural Sector Review Act of 2012" and that EPA and USDA will quickly implement a process to allow for limited emergency exemptions when circumstances merit.

Thank you very much for your leadership in addressing this critical issue for myself and other Michigan growers.

Mr. WHITFIELD. Well, thank you, Mr. Costanza.
And Mr. DiMare, you are recognized for 5 minutes.

STATEMENT OF SCOTT M. DIMARE

Mr. DIMARE. Thank you, Mr. Chairman.
Mr. WHITFIELD. Be sure and turn your microphone on and move it up close.
Mr. DIMARE. Thank you, Mr. Chairman. Ranking Member, the rest of the committee, I want to thank you for having me here today. My name is Scott DiMare. I am a director of farm operations for a family business that is over 80 years old. I am a third-generation farmer. We are based in Ruskin, Florida. We farm tomatoes. I employ about five to six hundred people. And we are here to talk about methyl bromide for emergency use.

With rising costs, we have a cost of about $2,500 to $3,000 an acre to lay our plastic mulch and do our fumigation process before we ever put a plant in the ground. Methyl bromide is the foundation for our operation. It allows for uniformity and consistency, which is key in our industry. It kills soil-borne diseases, pests, and weeds. The idea is to sterilize the ground before you plant it. We used to call methyl bromide idiot-proof. And basically, it is not a reckless term; it is how we view under all conditions—and the key being all conditions, OK, because the rest of the alternatives that we will talk about are very sensitive to soil, moisture, temperature, and so forth, whereas methyl bromide worked uniformly across the board under all conditions.

Furthermore, with the tools that we have available today, I feel pretty confident that we have reduced any if not all emissions. And among those tools we use are a Raven computer, which is on the tractor, which precisely turned on and off the system, allows for no leakage. We are also using the VIF or high barrier films, which reduce the emissions down to virtually nothing.

And let us just talk about the alternatives for a minute. We have made numerous capital investments over the years. We have known the phase-out was coming. For many years, we have tried to be ahead of the curve by being proactive in trying the number of different alternatives that are available. As Mr. Costanza mentioned earlier, one of the tools that we had has been taken away—Midas—which I felt was one of the most comparable or efficacious products out there but still had its limitations.

But be that as it may, we have the alternatives that are there, and among them, we cannot use them in certain areas because of groundwater issues. In the other areas we can use them, we still have many unresolved issues and most of them are attributed to weather. Soil conditions, soil temperature mainly being wet or cold, does not allow for the dispersion of the product, which again brings us to the point where we have an unpredictable situation. As a farmer, we can control only so many things. And what we do before we lay our plastic mulch is crucial. And once we do that, we are at the hands of Mother Nature. And we can't control the weather. In Florida we live in a subtropical climate. With these alternatives, the plant-back periods are up to 2 months that I have to have this plastic sitting out there with nothing being grown because of the fact that it is damaging to the crop because we don't know what

the result is going to be, whereas methyl bromide in the past we had a maximum of a 2-week leeway time. That is a huge risk that we have created.

OK, we have got, as I told you, $3,000 in the ground before we ever put a plant in the ground. You got leeching of fertilizer, you got more weed control issues, herbicides, weeding by hand, which is very labor-intensive for that extra month-and-a-half period. We got tropic storms. We have laid hundreds of acres before and been wiped out by storms. The longer time you have between your planting periods, the more risk you have, the higher your cost is going to be. And with methyl bromide we didn't have that.

I guess, you know, when all is said and done, you know, this comes down to a need of a product that we I feel need, must have, in order to clean up some of these situations that we have. Since the phase-out of methyl bromide, we have an increasing incidence of soil-borne diseases. You can see it getting worse every year behind methyl bromide and it is going to continue to get worse. We have, you know, Fusarium, Fusarium crown rot, southern blight, which we never had. Fusarium I have in fields this year that I have never had before ever. Weeds, nutsedge is getting out of control and, you know, again these are things that we never had issues with when we had methyl bromide.

I just again appeal to you to use some good foresight and—it is a tool that we need. Thank you.

[The prepared statement of Mr. DiMare follows:]

Testimony of Scott M. DiMare
Vice President and Director of Farm Operations, DiMare Ruskin Inc.

Before the U.S. House of Representatives

Committee on Energy and Commerce

Subcommittee on Energy and Power

July 18, 2012

Chairman Whitfield, Ranking Minority Member, Mr. Waxman, and members of the subcommittee, my name is Scott DiMare. I am the Vice President and Director of Farm Operations for DiMare, Ruskin, Inc. a family farm headquartered in Florida. We have been in continuous operation for over three generations with our production focused on fresh market tomatoes. We are part of the industry that provides a majority of the fresh tomatoes available to the U.S. population during the fall, winter and spring months. This industry has averaged 400 to 600 million dollars of farm gate revenue each production season. The farms I oversee are located in the Ruskin/Palmetto growing region southeast of Tampa in central Florida. Our primary production seasons include a spring crop that is transplanted in January and February and a fall crop that is transplanted in late August. The success of this cropping system is highly dependent on the ability to control weeds, plant pathogens and nematodes through a pre-plant fumigation that takes place when the plastic mulch is placed in the field. Historically this was accomplished through the use of methyl bromide – the subject of today's hearings.

It is important to note that this crop production activity is done at the onset of the crop and serves as the foundation for all aspects of successful crop management during the subsequent growing season. Prior to the regulatory phase-down on production and availability of methyl bromide under the Montreal Protocol, the preferred fumigation treatment comprised an in-bed shanked application of either methyl bromide 98:2 or methyl bromide 67:33. The different formulation of methyl bromide in combination with chloropicrin, were used dependent on the history of the farm and the prevalence of soil borne pathogens. These treatments were highly efficacious and did not require the additional application of other crop protectant materials to

ensure efficacy. The availability of methyl bromide under the current regulatory process has resulted in the loss of access to these formulations.

The distribution and application of methyl bromide is highly specialized and varies by the region of the country. In Florida, the farm-level application of the materials is done by the grower rather than by custom applicators as is generally the situation in other areas of the country. We as a grower community have not had access to any formulation other than 50:50 methyl bromide (50 % methyl bromide, 50 % chloropicrin) for the past three control periods under the US Clean Air Act and this was limited to rates that are only marginally effective. While the regulatory process has identified quantities of methyl bromide as "available stocks" these reserves of the active ingredient are not accessible by our industry. The "available stocks" are in the channels of trade and it is believed that those stocks are being held by various third parties including chemical distributors and applicators for other non-agricultural uses.

As an active participant in the Florida Fruit and Vegetable Association and the Florida Tomato Exchange, we have been heavily engaged in the USDA Agricultural Research Service, University of Florida – Institute for Food and Agricultural Sciences and commercial research for all of the proposed methyl bromide alternatives that have been identified over the past fifteen years.

We have made major commitments and capital expenditures to test the "Three Way" system, that includes 1,3-dichloroporpene and chloropicrin co-applied with metam sodium; the "Yeutter Rig" broadcast application of 1,3-dichloropropene followed by in-bed shanked applications of

chloropicrin; in-bed shanked and drip applied iodomethane; and shanked in-bed applications of dimethyl disulfide (DMDS). The current fumigation program at the farms I manage is centered on the use of Pic-Chlor® 60, a combination of 1,3-dichloropropene and chloropicrin.

In our multiyear experience this alternative program to methyl bromide is highly variable and has proven to be much more inconsistent in efficacy even when conditions appear to be nearly identical to those that result in acceptable levels of control. More problematic is the resurgence of pest populations and the overall continuous increase from year to year in specific troublesome pests. The primary increases are being seen in weeds as evidenced by both yellow and purple nutsedge, and also in the soil borne pathogen fusarium crown rot. Just as important, we are also seeing increase in population and corresponding impacts of rootknot nematodes during the production season, especially during periods of weather related stress. Attached are photographs from a recent tour that illustrate the level of some of the impacts during the past growing season.

One of the problems confronting plastic mulched production systems in Florida is the overall decline in tomato plant health and vigor as production practices have shifted to the alternatives. It has been observed that the general ability of the crops to withstand historical stresses, including weather related phenomena and low levels of pest pressure, have resulted in larger than anticipated impacts from both yield and quality perspectives.

Each potential methyl bromide alternative has its own set of characteristics, generating its own particular impacts on the treated crop. In short, the alternatives are not uniform regarding their timing, rates of application and their comparative efficacy across the total pest spectrum

commonly encountered that require the fumigation treatment. Methyl bromide is consistently reliable when used at the appropriate rates. Our experience shows us that at a certain rate, we are confident that application can be made relatively close (e.g., with two weeks) of the transplanting date without crop injury, and we know it will be efficacious. However, the potential alternatives requires that they be applied with a much longer pre-planting interval. As a result the grower is at greater risk of some event adversely impacting the efficacy of the alternative treatment from the time the soil is treated until the crop is planted.

The uncertainty alternatives have created over established tomato cropping patterns has led to wholesale changes in the risks associated with each tomato crop. We currently face unknowns surrounding the required plant back-period associated with the alternatives under the different conditions dictated by the seasonal aspects of our production window – continuous production over the fall, winter and spring months. This uncertainty has led to initiation of the fumigation season as much as one and a half to two months earlier than that required when methyl bromide was available. This then leads to tremendously increased risk to the production system due to the highly variable weather conditions that occur in Florida. For the summer fumigations this increases the risk from tropical weather systems. During the December, January and February fumigation period for the spring crop, the erratic nature of cold temperatures and periodic rainfall disrupts the subsequent planting schedules. This is due to the inability of the alternatives to disperse properly within the bed leaving phytotoxic residues for much longer periods of time. This inability to maintain ideal conditions soil and bed conditions associated with efficacy for the alternatives also leads to highly variable pest control in the subsequent or second crop.

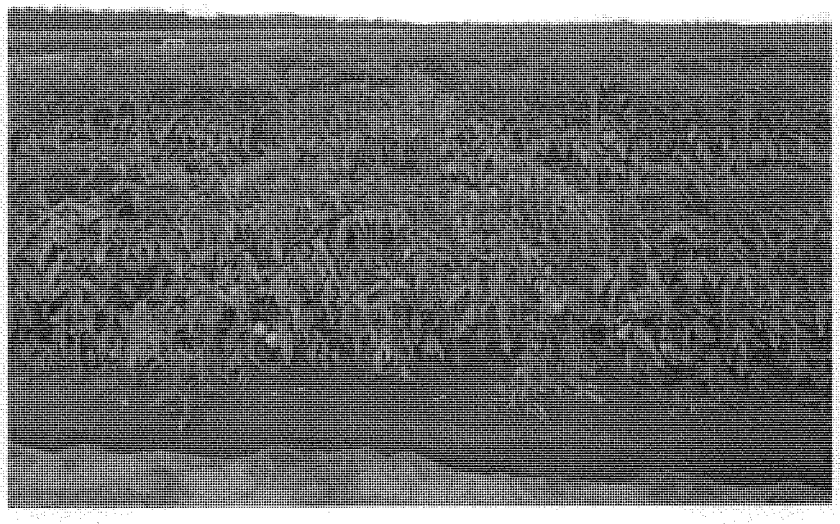
As an industry that is struggling to remain competitive in the globally expanding sourcing of fresh vegetables, we have seen our fumigation costs triple since the mainstay of our production system, methyl bromide, has come under regulatory restrictions dictated by the Montreal Protocol on Substances that Deplete the Ozone Layer and its implementation under the US Clean Air Act. We are encouraged by the legislation being discussed before this subcommittee today. While we support the goals of both the Montreal Protocol and the Clean Air Act, we feel that the currently highly restrictive view of the U.S. obligations under the Treaty have resulted in unnecessary and extremely costly impacts to our industry.

We have made significant advancements through technology and management changes to minimize the emissions that result from our use of the regulated substance. It is hoped that as we face the pressures created by the shifting pest populations on the land we farm that this invaluable tool will indeed be available to growers to utilize where the situation warrants.

Thank you for your attention and I look forward to your deliberations today, I will be happy to answer any questions you may have.

Photographs from Tomato Production Areas, April 2012

Purple Nutsedge in Tomato Production Field – Approximately 21 Days Post Transplant
(Ruskin Palmetto Production Area)
April 2012
Third Season of Pic-Chlor 60 Use This Farm



Fusarium Crown rot, at first Harvest
(Ruskin Palmetto Production Area)
April 2012
Third Season of Pic-Chlor 60 Use On This Farm

Mr. WHITFIELD. Thank you very much.

And Mr. Doniger, you are recognized for a 5-minute opening statement.

STATEMENT OF DAVID D. DONIGER

Mr. DONIGER. Thank you very much, Mr. Chairman and Mr. Rush.

Protecting the ozone layer is a huge bipartisan public health success story. The treaty was signed under Ronald Reagan and it has had the support of four Presidents since then. The phase-out of ozone-destroying chemicals, including methyl bromide, is saving literally millions of Americans and tens of millions of people around the world from death and disease, from skin cancer, cataracts, and immune diseases. And it is also savings farmers billions of dollars in avoided ultraviolet light, ultraviolet radiation crop damage.

Now isn't the time to tamper with the Protocol or the Clean Air Act. I won't mince words. By slowing or actually reversing the transition from methyl bromide, this bill will lead to more skin cancers, more cataracts, more immunological disease. It will benefit a number of growers who have profited by abusing the critical use exemption for more than a decade. Some of the people now seeking relief now haven't even asked for critical use exemptions for years. Thousands of other farmers growing other crops will suffer more crop losses as a result.

Now, the treaty and the Clean Air Act already allow for well supported exemptions and no one is suggesting that the pursuit of exemptions under existing law isn't possible. This has been done for 7 years and well supported exemptions have been forwarded by the U.S. and granted by the parties. But this industry has dragged its feet on replacing this dangerous compound. No other industry has had more time or more leeway to transition away from dangerous ozone-destroying chemicals.

The U.S. is responsible for more than 90 percent of all methyl bromide exemptions. Every other strawberry- and tomato-growing country with California-like growing conditions or Florida-like growing conditions—including Italy, Spain, Greece, and Australia—has ended use of methyl bromide. There is a lot of concern expressed over the years about competition from Mexico. Mexican growers use less methyl bromide per acre than their California counterparts, and Mexico will end the use of methyl bromide entirely this year.

California strawberry growers have done very well during this whole experience. Strawberry acreage is up despite ground rules that countries would not use methyl bromide on expanded acreage. Yields are up, grower prices are up, crop values are up.

U.S. critical use exemptions have been coming down. California strawberries are now the only field use for which the U.S. still seeks exemptions. And there are several other structural and commodity uses. Together they amount to about a little more than 400 tons. That is significantly down from 10,000 tons 7 years ago. And as I said, there is an opportunity to keep asking for well supported exemptions. There is also a stockpile of 1,200 tons, three times the requests now being made.

This bill would do reckless damage in three ways. First, it would permanently define as critical uses all of the uses that were deemed critical in 2005 even though the vast majority of those uses don't use methyl bromide anymore. Why would we make golf course turf grass a critical use again? It makes no sense to freeze into law the utterly out-of-date list from 2005.

Second, the bill relieves the applicants of the need to show why they need exemptions. Doesn't it make sense that if you are asking for an exemption for a banned product, you should explain why and you should produce the data that shows that you need it? Some people do that and some people make the case. Some people's case is convincing and the U.S. makes the application and the other parties agree to it. Other people don't even ask. Some people make exemption requests that can't even get past first base.

So EPA under this bill would bear the burden of saying why any wish list shouldn't be forwarded to the parties. And this is actually going to backfire for the applicants because it actually helps the U.S. to win approval for the exemptions to show that it has exercised judgment and discipline in framing its requests and hasn't mechanically asked for everything that domestic applicants may have wanted.

Lastly, the bill would blast an enormous loophole into the Clean Air Act and our pesticide safety laws by allowing any individual user to write his own ticket for up to 20 tons of methyl bromide per farm simply by asserting the existence of an "emergency." There could be hundreds of emergency exemptions per year, totaling up to 2,000 tons, the 2011 critical use amount.

The testimony today illustrates the abuse that this emergency exemption would provide where some witnesses are saying, well, we just needed to go in and "clean up" problems for which we didn't get critical use exemptions. So it is just an alternate route to write your own critical use exemption.

This is a bad bill. It is an unneeded bill. It would harm public health, harm other farmers, and indeed it would even harm the farmers it is intended to help because it would make it even more difficult to get critical use exemptions through the current process. The current process is working and this committee should leave well enough alone. Thank you.

[The prepared statement of Mr. Doniger follows:]

NATURAL RESOURCES DEFENSE COUNCIL

Testimony of David D. Doniger
Policy Director and Senior Attorney, Climate and Clean Air Program
Natural Resources Defense Council

Hearing on the U.S. Agricultural Sector Relief Act of 2012

Subcommittee on Energy and Power
Committee on Energy and Commerce
House of Representatives
July 18, 2012

Summary

- Protection of the ozone layer is a huge bi-partisan public health success story. The phase-out of ozone-destroying chemicals, including methyl bromide, is saving literally millions of Americans, and tens of millions of people around the world, from death and disease, from skin cancer, cataracts, and immune diseases. It is also saving farmers billions of dollars in UV-related crop losses.

- Now is not the time to tamper with the Montreal Protocol and the Clean Air Act. By slowing or even reversing the transition away from methyl bromide, "The U.S. Agricultural Sector Relief Act" will lead to more skin cancers, more cataracts, more immunological disease. It will benefit strawberry growers and others who have profited by abusing the "critical use exemption" for almost a decade. Thousands of other farmers growing other crops will suffer more UV-related crop losses as a result.

- Methyl bromide suppliers and users have dragged their feet on replacing this dangerous compound for two decades. No other industry has had more time and more leeway to transition from dangerous ozone-destroying chemicals.

- The United States is responsible for more than 90 percent of all methyl bromide exemptions. Every other strawberry- and tomato-growing country with California-like growing conditions – including Italy, Spain, Greece, and Australia – has ended use of methyl bromide. Mexican growers use less methyl bromide per acre than their California counterparts, and Mexico will end methyl bromide use entirely this year.

- California strawberry growers have done very well during the whole experience, according to a recent peer-reviewed economic study. Strawberry acreage is up 16% and yields are up 14% since 2004 despite significant reductions in methyl bromide allocations. So are U.S. grower prices and total crop values.

- U.S. critical use exemptions have been coming down. California strawberries are now the only field use for which the U.S. is still seeking critical use exemptions. Together with several structural and commodity uses, the total U.S. exemption request for 2014 is down to slightly more than 400 tons.

- The bill would do reckless damage in three major ways: First, it would permanently define as "critical uses" all of the uses that were labeled critical in 2005, even though the vast majority no longer even use methyl bromide. Absurdly, the bill would make even golf course turf grass a "critical use." It makes no sense to freeze into law an utterly out-dated list of "critical uses."

- Second, the bill relieves applicants of the need to show why they need exemptions. They could just submit their exemption wish lists without any supporting data. EPA then would bear the burden of gathering the data to support any reduction. Absent resources and data, EPA would have little choice but to forward the applicants' unsupported wish lists to the parties. This would be foolish even from the growers' perspective. It actually helps the U.S. government win approval for exemptions to have shown that it has exercised judgment and discipline in framing its requests, and has is not mechanically asked for everything its domestic applicants may have wanted.

- Third, the bill would blast an enormous new loophole into the Clean Air Act and our pesticide safety laws, by allowing any individual user to write his own ticket for up to 20 tons of methyl bromide

simply by asserting the existence of an "emergency." There could be a hundreds of emergency exemptions per year, totaling up to 2,000 tons per year (the 2011 critical use amount).

- This is a bad and unneeded bill. It would harm public health, harm other farmers, and indeed even harm the farmers it is intended to help. The process is working. This Committee should let well enough alone.

Thank you Chairman Whitfield and Ranking Member Rush for the opportunity to testify on behalf of the Natural Resources Defense Council on the proposed "U.S. Agricultural Sector Relief Act of 2012." Founded in 1970, NRDC is a national nonprofit environmental organization of scientist, lawyers, and environmental specialists with more than 1.3 million members and online activists, served from offices in New York, Washington, Chicago, San Francisco, Los Angeles, and Beijing. I am policy director of NRDC's Climate and Clean Air Program. I have been with NRDC twice, from 1978 through 1992 and from 2001 to the present. In the 1990's I served as director of climate change policy in the EPA Office of Air and Radiation. Relevant to the topic of today's hearing, I have worked on the phase-out of ozone-destroying chemicals for more than a quarter century.

There are few greater success stories than the global effort to phase out the ozone-damaging chemicals. Every American, and every citizen on this Earth, relies on the ozone layer to block dangerous ultraviolet radiation that causes skin cancer, cataracts, immune disorders and other diseases. The treaty to protect the ozone layer, known as the Montreal Protocol, has enjoyed bipartisan support from five presidents beginning with Ronald Reagan. So have the ozone layer protection provisions of the Clean Air Act. They are saving literally millions of Americans, and tens of millions of people around the world, from death and disease. They are also preventing billions of dollars in UV-related crop losses and other economic damages.

Yet the ozone shield is still being weakened by ozone-depleting chemicals that increase our exposure to dangerous UV radiation. Millions of Americans – including farmers – must work everyday in the sun. Millions more – from school children to seniors – spend hours of their days out of doors. Millions of concerned parents check the UV Index and cover their kids with sunscreen before letting them go out in the sun.

That brings us to methyl bromide. Methyl bromide is the most powerful ozone-depleter still in widespread use. All of the other more potent ozone-destroying chemicals have been successfully

eliminated – worldwide. Methyl bromide is also highly toxic, with inhalation or dermal exposure causing a wide range of acute and chronic effects, including death.

Mr. Chairman, I will not mince words. You are considering a bill to further slow the snail-like pace of the transition from this dangerous chemical – a bill that will lead to more skin cancers, more cataracts, more immunological disease, and more crop losses due to ozone-destruction and UV radiation, as well as more illness from direct exposure. Contrary to the bill's grandiose title, this bill will not broadly benefit "the U.S. agricultural sector." Indeed, thousands of farmers growing other crops will suffer more UV-related crop losses as a result. Instead, this bill will benefit only a small sliver of strawberry growers and few others who have profited handsomely by abusing the "critical use exemption" for the better part of a decade.

No industry has had more time and more leeway to transition from dangerous ozone-destroying chemicals than this one. The auto industry replaced CFCs in car air conditioners in less than four years. The electronics industry replaced ozone-depleting solvents in circuit board manufacture in less time than that. The air conditioning and refrigeration industry and the fire protection industry got rid of their potent ozone-depleters in well under a decade. Indeed, some of these industries have gone through two rounds of transitions to safer chemicals in the last 20 years. And all of these industries have been able to produce better, more energy-efficient, and more profitable products.

But methyl bromide stands apart. The producer and the users of this chemical have dragged their feet on replacing this dangerous compound for two decades. Let's review:

The phase-out of methyl bromide was supposed to be completed by 2001 pursuant to the 1990 Clean Air Act Amendments. With a decade of lead-time, growers and other users should have invested in developing and field testing other agents and other agricultural practices, like every other industry did. Their effort was minimal. And their minimal effort was rewarded by pushing the deadline back to 2005, in conjunction with amendments to the Montreal Protocol to phase out methyl bromide world-

wide. An post-2005 exemption was allowed for so-called "critical uses," but all observers then thought this would be just a small percentage of historical ("baseline") methyl bromide use, just as the "essential use" exemptions for other ozone-destroying chemicals had been only a small fraction of their baselines.

Indeed, other countries with comparable agricultural conditions played by those rules, submitting critical use exemption requests, if any at all, that reflected small fractions of their historical methyl bromide use levels. Only the U.S. took a different tack. In 2003, U.S. growers and others sought exemptions totaling some 15,000 tons, more than 60 percent of country's baseline use in the early 1990s. The U.S. government requested more than 10,000 tons of exemptions, and nearly broke the back of the Montreal Protocol. For the first time in its history, the parties were unable to come to a consensus decision. For the first time, there was an impasse that could not be resolved without calling an extraordinary meeting of the parties.

For eight years running, the United States alone has requested more than 90 percent of all exemptions. Over this period, nearly every other developed nation has eliminated its need for methyl bromide. Specifically, every other strawberry- and tomato-growing country with Mediterranean-like growing conditions – including Italy, Spain, Greece, and Australia – has moved beyond use of methyl bromide. Even Mexico – the California strawberry growers' only competitor – is committed to end its use of methyl bromide this year.[1]

Throughout this period, and here again today, the California strawberry growers have led the pack in coming to Congress playing the hardship violin. In fact, however, California strawberry growers have done very well during the whole experience, according to a recent peer-reviewed economic study by Erin N. Mayfield and Catherine Shelley Norman, published in the *Journal of Environmental*

[1] "The Government of Mexico has committed to achieve the complete phase-out of MB by the end of 2012." United Nations Environment Programme, Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol, Sixty-sixth Meeting, Montreal, 16-20 April 2012, "Project Proposal: Mexico, National methyl bromide phase-out plan (third tranche), ¶9, http://www.multilateralfund.org/66/English/1/6641.pdf.

Management.[2] They have expanded their strawberry acreage and increased their yields dramatically despite significant reductions in methyl bromide allocations: California strawberry acreage in 2010 had increased 83 percent over 1991 levels and 16 percent over 2004. Yields per acre in 2010 increased 29 percent over 1991 levels and 14 percent over 2004. California's share of U.S. production also increased during this period, from about 80 percent in 1991 to more than 90 percent in 2010. U.S. grower prices and total crop values adjusted for inflation also increased during the exemption years.

The expansion of the strawberry acreage treated with methyl bromide is extremely troubling because it breaks a commitment made by the U.S. government not to allow such expansion. For instance, the "National Management Strategy for Methyl Bromide, United States of America, December 2005" states: "An important way that the United States addresses the issue of avoiding increases in MeBr use is our policy to disallow any increases in acreage or throughput that CUE applicants might include in their CUE request."[3] This turns out to have been a hollow promise.

The growers' complaints often center on the claim of unfair competition from Mexico. Throughout this period, however, Mexican growers used less methyl bromide per acre than their California counterparts, and Mexico, as I mentioned, has committed to stop using methyl bromide this year. Mayfield and Norman note that although strawberry imports from Mexico increased as the overall U.S. strawberry market grew, Mexico's share of total U.S. consumption did not increase significantly, and U.S. growers' strawberry exports to Canada rose by almost as much as imports from Mexico.

Mayfield and Norman also note that the economic analysis supporting the critical use nomination for 2014 – an analysis prepared by the strawberry growers – indicates that a range of alternatives to methyl bromide are effective and available at comparable cost and without yield losses.

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[2] E. Mayfield & C. Norman, *Moving away from methyl bromide: Political economy of pesticide transition for California strawberries since 2004*, Journal of Environmental Management, Vol. 106, Pp. 93-101 (2012), available at http://www.sciencedirect.com/science/article/pii/S0301479712001909, and attached to this testimony.
[3] http://www.epa.gov/ozone/mbr/downloads/MeBrNatMgmtStrat.pdf, p. 4.

Notably, these results do not depend on methyl iodide, which was withdrawn from the market by its manufacturer earlier this year.

As it turns out, the industry is still sitting on a stockpile of methyl bromide made before 2005 and stored in railroad cars in various communities around the country. Believe me, tank cars of highly toxic methyl bromide baking in the sun on rail sidings are not something I'd want in my community, or rolling through my Congressional district, yet few people know if they enjoy that privilege. As of today, the stockpile still exceeds 1,200 tons – three time the U.S. critical use nomination for 2014.

Why is the stockpile important? Because the rules of the road under the treaty are that a country may request permission to manufacture new methyl bromide to serve critical use needs only if it has exhausted its stockpiles. The industry attempted to conceal that stockpile from both the public and the government, and this led to the U.S. government's initially misrepresenting to the other Montreal Protocol parties in 2003 that there would be no stockpile left in 2005. But the true stockpile, divulged only later in response to an NRDC lawsuit, was nearly 13,000 tons – more than the entire amount the U.S. claimed to need for 2005. The methyl bromide stockpile has been used – illegally, in our view – for crops that no longer qualify as critical uses, such as golf course turf grass, and to exceed the critical use limits on crops such as strawberries. Each year since 2004, the stockpile has been larger than the next year's total critical use request. That is true for 2013 and 2014. The deception over the stockpile, once revealed, almost caused the breakdown of the treaty process, and the existence of a continuing stockpile is still a major irritant between the parties today.

NRDC acknowledges that the amounts of U.S. critical use exemptions have been coming down, however belatedly. Many growers and other users have finally taken up alternative chemicals and alternative pest management practices, so that we have now come to the point where the only field use for which a critical use nomination is still being made in 2014 is California strawberries. Together with several structural and commodity uses, the total U.S. exemption request is down to slightly more than

400 tons, as compared to nearly 10,000 tons in 2005. This progress, though long delayed, is noteworthy and must continue. Further progress is possible even in the short run, through practices such as greater use of impermeable films (something other countries have already adopted) and by continued adoption of alternatives.

In short, the process is working. Now is not the time to tamper with the methyl bromide phase-out requirements under Montreal Protocol and the Clean Air Act. Mr. Chairman, the bill before you would pointlessly weaken curbs on this dangerous ozone-destroying chemical, threaten the recovery of the ozone layer, and further strain our relations with other countries that are already experienced with U.S. abuse of critical use exemptions. The bill does reckless damage in at least three major ways:

First, the bill would permanently define as "critical uses" all of the uses that were labeled critical in 2005, regardless of the fact that the vast majority of those crops and applications have successfully transitioned to alternatives and no longer even use methyl bromide. Absurdly, the bill would make golf course turf grass a "critical use," even though the Bush administration's agriculture department dropped it from the list in 2006. Why in the world does it make sense to revive and freeze into law an utterly out-dated list of "critical uses"?

Second, since growers and other applicants are seeking exemptions for a chemical that is otherwise already banned under both domestic and international law, and since they are in the best position to innovate and test alternatives, they quite properly now bear the burden of showing the need for methyl bromide and the absence of economically practical alternatives. But the bill would turn that burden around. It would allow applicants to submit their wish lists for exemptions without providing any data in support. Even though this chemical is already supposed to be banned, the bill would then require EPA to shoulder the burden of developing the data to support any reduction from the growers' or other applicants' requests. As the growers would be quick to point out, EPA does not run farms, and EPA does not run alternatives testing programs.

Absent the resources and access to data, EPA would have little choice but to forward the applicants' wish lists to the parties for consideration. Even from the growers' perspective, this would be a fool's errand. It is difficult enough for the U.S. to gain approval for its out-sized exemption requests when it can bring a reasonably robust case forward for technical scrutiny by the other parties. It actually helps the U.S. win approval for exemptions to have shown that the government has exercised some judgment and discipline in framing its requests, and that the U.S. is not asking for everything its domestic applicants may have wanted.

Third, the bill would blast an enormous new loophole into the Clean Air Act and our pesticide safety laws, by allowing any individual user to write his own ticket for up to 20 tons of methyl bromide simply by asserting the existence of an emergency. "Emergency" is conveniently defined to mean any situation where someone wants to use more methyl bromide than is available under a critical use exemption, and where he declares that there is no alternative. The bill would allow a hundred 20-ton emergency exemptions per year, up to a total of 2,000 tons per year (the amount of critical use exemptions in 2011). This would be a massive abuse of the emergency exemption provision under the Montreal Protocol, which has been invoked only twice so far (once by Australia and once by Canada) in genuine emergencies.

Imagine, Mr. Chairman, how cool it would be to be able to withdraw more cash from the bank than you have in your account, just by calling it an emergency. There's another name for that: bank robbery.

This is a bad bill, and an unneeded bill. It would harm public health, harm other farmers, and indeed even harm the farmers it is intended to help. The process is working. This Committee should let well enough alone.

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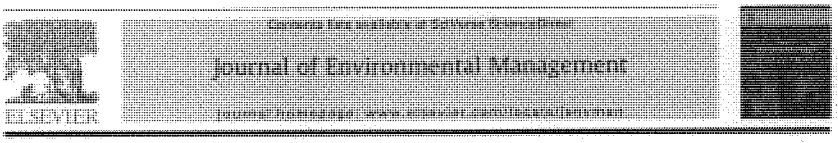

Moving away from methyl bromide: Political economy of pesticide transition for California strawberries since 2004

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Iodomethane

ABSTRACT

We examine the progress of the phaseout of the use of the pesticide methyl bromide in the production of California field strawberries. This phaseout is required under the Montreal Protocol and has been contentious in this sector, which receives exemptions from the schedule initially agreed under the treaty, and in international negotiations over the future of the Protocol. We examine the various ex-ante predictions of the impacts on growers, consumers and trade patterns in light of several years of declining allocations under the Critical Use provisions of the Protocol and the 2010 approval of iodomethane for use in California and subsequent 2012 withdrawal of this alternative from the US market. We find that, contrary to ex-ante industry claims, the years of declining methyl bromide use have been years of rising yields, acreage, exports, revenues and market share for California growers, even when faced with a global recession and increased imports from Mexican growers who retain the right to use the chemical under the Protocol. This has implications for the Protocol as a whole and for the remainder of the US phaseout of this chemical in particular.

1. Introduction and background

US fruit and vegetable growers using the fumigant methyl bromide (MeBr), scheduled for phaseout under the Montreal Protocol on Substances that Deplete the Ozone Layer, faced uncertainty about the cost and effectiveness of alternative chemicals and practices, and many of them applied for exemptions allowing continued use after the planned elimination of MeBr. This process was controversial – so much so that the United States suggested that they might withdraw from the Montreal Protocol, up to that point considered a model of successful international environmental policy, if their nominations for exemptions were not granted (Gareau and DuPuis, 2009). In the exemption process, which allowed exceptions to the scheduled 2005 complete phaseout date, one of the most contested uses was for strawberry farming, especially in California where many alternatives are strictly regulated or disallowed. Growers argued that none of the alternatives met the 'economic and technical feasibility' conditions of the Critical Use Exemption (CUE) rules. DeCanio and Norman (2005) discuss possible interpretations of the feasibility criteria at length, emphasizing that it cannot mean that no changes in costs or agricultural practices are required of methyl bromide users, but there is not a consensus definition of precisely what standard must be met.

Currently, the majority of CUEs for methyl bromide are allocated to the United States.[1] The share of field (rather than nursery) strawberries in total exemption requests has also grown; the 2014 US field strawberries nomination was for over 93% of the total US allocation, and was exclusively for use in California, which produces 90% of US strawberries (ERS, 2011c). In 2007 the same share was only 13% and more geographically dispersed, including uses in the southeastern US as well as California (USDoS, 2010, 2005, ozone.unep.org). Substitutes have been slower to develop in California,

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[1] For the last seven years reported, 2007–2013, approved US CUEs have been more than 75% of non-Article 5 exemptions approved globally, so US strawberry uses are a significant amount of remaining global use of MeBr. In the first year of the exemption process, US allowances were a bit over 40% of total non-Article 5 allocations. For 2013, the United States has received over 90% of approved CUE allowances. Article 5 parties, which are, roughly speaking, less developed countries, do not have to complete phaseout until 2015, but their total use peaked in 1998, and by 2010 total consumption in Article 5 and non-Article 5 countries were approximately equal (exclusive of quarantine and pre-shipment uses, which are regulated separately and excluded from the discussion throughout this paper) (ozone.unep.org).

due to different farming practices and a relatively stringent regulatory climate that has slowed the approval of some MeBr alternatives. The California strawberry crop is worth more than $2 billion annually and is the 6th highest-valued fruit crop in the state, so while the industry is small at the national level it is economically significant in the region.[2]

California growers and those negotiating the CUE process on their behalf were deeply concerned that the main source of US imports of fresh strawberries, Mexico, would not be required to eliminate the use of MeBr at the same time that California growers were scheduled to. The Montreal Protocol allows delays in the elimination of ozone depleting substances for less developed countries, and growers feared that lowered trade barriers under NAFTA would combine with a technological advantage to Mexican growers using the fumigant, leading to dramatically increased imports of fresh strawberries and reduced sales of and/or prices for domestic berries.

This work investigates how the process of phaseout has affected the California field strawberry industry and finds that management and regulatory decisions at the international, national, and state levels have allowed California growers to maintain and enhance their dominance in the domestic and North American market as the phaseout has progressed. The period between the beginning of the methyl bromide phaseout and the availability of iodomethane, the closest thing to a 'drop-in' substitute yet developed, for use in the state has been characterized by slow elimination of MeBr, rising acreage, yields and consumption, improved balance of trade, increasing domestic market share, and rising or relatively stable prices. Iodomethane itself has recently been voluntarily withdrawn from the US market, and we consider how this might affect our assessment of the phaseout process to date.

2. Ex-ante analyses of economic effects and political factors influencing phaseout

Economic analyses earlier in the process did not reach a consensus regarding the likely impacts of phaseout. Norman (2005) relied heavily on data from nominations for CUEs and found that trends in demand growth for fresh strawberries[3] and significant pass-through of cost increases to consumers were expected to outweigh the stated negative effects of production cost increases associated with use of alternative fumigants, even in the absence of direct government support, under fairly conservative assumptions, and that increased consumer costs per household would be minimal, even if they were substantial in aggregate.

Carpenter et al. (2000) simulated production, consumption, and crop prices for methyl bromide users (e.g., California) and direct competitors (e.g., Mexico) – prior to and after the 2005 MeBr ban using a spatial partial-equilibrium model. To simulate post-ban conditions, shifts in production technology and corresponding changes in production costs and monthly yields were assumed.[4] Model results suggested that following a ban, US consumers would pay higher prices for strawberries and consume fewer of them. The increased price of strawberries would outweigh increases in CA production costs for growers and, when coupled with increased acreage devoted to CA strawberry production, CA strawberry growers' gross and net revenues would increase and remain stable, respectively.

Goodhue et al. (2005) and Carter et al. (2005), on the other hand, suggested that MeBr phaseout could cause significant problems for US or California growers. The former included field trials to estimate weed control costs using MeBr and various available alternatives but were unable to estimate yield losses from the use of MeBr alternatives directly, and concluded that acreage and thus supply would have to decline significantly to raise market prices enough to eliminate the net losses to remaining growers. The latter note that a single annual demand elasticity parameterization obscures important variation in seasonal demand and supply functions and can bias estimates of losses downward, with the most significant losses accruing between mid-May and early July. Their simulation results suggest full-season losses of between 4 and 20% of revenue, with a point estimate of around 12%, excluding revenue realized from lower valued crops as acreage in strawberries decline. Neither study considered longer-term trends in the fresh strawberry market.

The design of these studies reflected concerns that Mexico, which provided (and continues to provide) more than 99% of imported fresh strawberries to the US (ERS, 2010, Table 14), was an Article 5 country under the Montreal Protocol and thus not required to eliminate MeBr until 2015, at which point their MeBr use would also have to comply with CUE standards to be permitted. NAFTA rules would make it hard to shield US growers from Mexican competition. Rising costs to US producers forced to transition away from their preferred fumigant could make Mexican imports more competitive over more of the year, reducing market share and revenues to domestic growers. Carpenter, Gianessi, and Lynch (2000) projected that after the 2005 ban – exemptions notwithstanding – increased acreage in Mexico devoted to strawberry production would be observed, and in the absence of land and water constraints, Mexico would continue to increase acreage and displace acreage in California.

On the regulators side, there was concern that significant exemptions would slow the phaseout and increase lobbying efforts at the expense of efforts to develop and implement alternate fumigation strategies. Using even the lowest estimate of the cost burden of the elimination of MeBr for California strawberries growers from Norman (2005) of $51[5] ha/year suggests that diversion of funds to directly unproductive rent seeking around CUE rights could be significant; the 2011 industry survey indicates that 15,145 ha are planted in strawberries in California, and less than 5% of that land is devoted to organic production (CSC, 2011). This implies that delays in phaseout for conventionally grown berries could be worth more than $700,000 annually (15,145 × .95 × $51 = $733,775), and any successful efforts to secure delays that cost less than this amount are profit maximizing for the industry as a whole.

The California Strawberry Commission (CSC), the most active industry group, doubled (nominal) federal lobbying expenditures from $40,000 in each of 2001–2007 to $80,000 in 2008, and expenditures have remained at that level through 2010 (Center for Responsive Politics, 2011). State nominal lobbying expenditures were about $30,000 for the 2001–2002 legislative session, as decisions about initial CUE applications were being made, and then dropped to around $3000 for the next session, rising for each subsequent legislature to a level of about $20,000 in 2009–2010 (CalAccess, 2011). It is likely, of course, that only some of these

[2] http://www.californiastrawberries.com.

[3] We focus on fresh berries throughout; in the US, frozen berries are largely a residual crop (ERS, 2011c), and as they are not perishable this market operates quite differently. Large increases in the share of production going for frozen or otherwise processed berries might suggest quality issues associated with various changes to fumigation processes, but we do not observe this in the data.

[4] The model assumes that the best alternative technology – which is assumed to be the technology resulting in the highest yield per acre for the lowest cost per acre – is selected. Given that the study was completed in 2000, the best technologies projected at the time do not entirely correspond to the alternatives actually employed during the phaseout.

[5] All figures converted to 2010 dollars using the CPI unless otherwise noted.

efforts were focused on preserving MeBr phaseout exemptions for growers. We were not able to find evidence of significant lobbying expenditures for strawberry growers in other regions. While lobbying expenditures are one indicator of lobbying efforts, the rapidity of regulatory movement – in this case, the reduction timeline – may also be suggestive. The reduction timeline in California has been much less aggressive than in other US regions, which no longer use MeBr for field strawberries, and more broadly, the reduction timeline in the US has been much less aggressive than other non-Article 5 parties. Taken together, the lobbying expenditures and reduction timeline suggest that if lobbying has slowed the phaseout of methyl bromide for strawberries in CA, it has been a rational investment for the industry, even if the costs of using alternative pesticides are a relatively small fraction of revenues and profits.

The Critical Use Exemption process involves stakeholders who use the regulated chemical, national nominations, and recommendations or analysis by the Technology and Economic Assessment Panel (TEAP) of the Montreal Protocol, leading to final amounts which must be approved by the Parties to the Protocol at their annual meeting. In the US, the Environmental Protection Agency (EPA) solicits yearly applications with supporting information on use patterns and economic impacts from growers, and then the Department of State submits these as Critical Use Nominations (CUNs). For the last year for which data are available – the nominations and final decisions for 2012 exemptions – the CSC requested permits to treat 4454 ha, which were passed on to the Parties to the Montreal Protocol, who approved 4421 of those hectares, albeit at a lower application rate than was originally requested.[6] If this smaller amount receives the low estimate of value from continued use of MeBr, CA growers have gained about $225,000 in 2012 by securing the 2012 exemptions, as well as slowing further phaseout and broader price impacts until their chief competitor in the North American fresh strawberry industry completes their phaseout. At this point Mexican growers presumably lose any price advantage gained by ongoing MeBr use, and alternative pest control practices will be more established in California.

Interestingly, this approved MeBr fumigation allowance for about 30% of California acreage annually could mean use over the majority of the growing region on an intermittent basis. The CSC notes that "[m]ethyl bromide is often being used in rotation with alternative fumigants. Many growers will use alternative fumigants for 2–3 years then rotate back to methyl bromide to clean up emerging weed and disease problems" (California Strawberry Commission, 2008, *Request for a critical use exemption for methyl bromide on strawberries for the 2011 use season*. Cited in 2013 US Field Strawberries CUN). While a move towards using MeBr every 2–3 years rather than annually is certainly a substantial reduction in MeBr applications, it is not a reduction in the geographic area reliant on MeBr as part of strawberry production, and thus reflects less progress towards achieving a permanent phaseout than the reported reductions in acreage needing treatment would suggest. Unobserved cooperation within the industry to produce this outcome would undermine the intent of the Parties to the Protocol, particularly as it could allow the use of MeBr on fields put into production after the beginning of phaseout. In California, 2009 acreage represented an increase of 89%, or 7600 ha, over the 1991 'baseline' year established for MeBr under the Protocol (ERS, 2010, Table 4). It is not possible to determine if new acreage is using MeBr on the basis of allocations currently in use, as these are not broken out by sector or sub-state geographic regions by the US EPA once exemptions are granted (Federal Register, 2011). While the United States did articulate a policy of not allowing growth in CUNs due to new acreage (UNEP, 2005), they did not specify that new acreage reliant on MeBr was not allowed even if it did not drive increasing total amounts of requested MeBr, and so the continued decline in CUNs for this sector seems to satisfy this domestic policy.

While lobbying efforts are ongoing, the CSC and other industry groups also work closely with farmers and researchers developing and testing MeBr-free growing methods. CSC reports research expenditures of over ten million dollars to date toward this end, presumably beginning in the early to mid-1990s, which suggests that research expenditures are a substantial part of the CSC budget (calstrawberry.com). Additionally, within regional nomination applications, research expenditures and funding resources have historically been reported and used to substantiate nominations.[7] Sufficient data to elicit trends in those expenditures is not available. Overall, it seems reasonable to deduce that investment in new technology hedged by investment in lobbying for continued exemptions represents an effective risk management strategy for growers and has been an influential driver of industry and regulator decision-making.

The political-economic and sociological issues around agricultural exemptions to the MeBr phaseout have been studied extensively. Clark (2001) offers an early analysis of the relationship between growers, the state of California, and the Federal EPA. Badulescu and Baylis (2006) consider the harmonization of pesticide rules under NAFTA and the possibility that that process has favored US strawberry producers. Kent-Monning (2007) raises concerns about the environmental justice implications of the use of the CUE process in California.

More recently, DuPuis and Gareau (2008); Gareau (2008, 2010, 2012) and Gareau and DuPuis (2009) argue in a series of papers that increasing pressure to provide market solutions rather than command and control ones – as evinced partly by the economic justification for exemptions to agreed phaseout schedules, which was not allowed for the previously established 'Essential Use Exemptions' granted for other ozone depleting substances in earlier stages of the Protocol – undermined the later stages of the Montreal Protocol. They further suggest that an emphasis on the credibility of estimates of private costs over estimates of public benefits will drive decision-making about exemptions in the future, while in the past a precautionary principle approach to the human and environmental risks associated with ozone depleting substances was more important. Stakeholder processes have been 'captured' to a significant degree by industry groups rather than involving a broader group more focused on the welfare of civil society as a whole. That this mode of discourse is so dominant in US policymaking is thus offered as an explanation for the ongoing use of significant amounts of MeBr in the US when other countries granted early exemptions have completed phaseout.

[6] The 2013 nominations proved very contentious in 2011; additional bilateral (including with the CSC as well as with representatives of affected nations) and TEAP meetings were added to the schedule and multiple submissions were revised and new research offered during the process (UNEP, 2011a). The decision in the advance draft report of the 23rd Meeting of the Parties reflects the MBTOC (the Methyl Bromide Technical Options Committee, part of the TEAP) recommendation (a 2013 exemption of 461.186 metric tons for field strawberries) but not that of the minority report offered by several members of the MBTOC (UNEP, 2011a,b), which recommended granting the full nomination amount (531.737 metric tons). Application rates used to calculate CUNs and CUEs and the availability of alternative pesticides in specific California growing regions were disputed within the TEAP and among governmental and nongovernmental stakeholders.

[7] Publically reported research expenditure information is incomplete – CSC has reported research expenditures as Confidential Business Information, and detailed expenditure data are not typically reported in regional nominations.

3. Progress and barriers in eliminating MeBr under the Montreal Protocol

For the first year of CUNs, 2005, 28 countries nominated critical uses. This number has declined steadily and most recently, four nominating parties (the US, Japan, Australia, and Canada) requested CUEs for 2013 (UNEP, 2011). Global CUEs for non-Article 5 countries have decreased by 94% since 2005. Use in Article 5 countries has also declined, falling below total non-Article 5 use for the first time in 2007. This decline is partly due to the support of phaseout programs paid for by the Protocol's Multilateral Fund, which is not available to non-Article 5 countries. 2010 MeBr use in Article 5 countries was 5.2% of the 1991 baseline.

Nominations by the US and requests for nominations from the California Strawberry Commission between 2005 and 2014 are shown in Fig. 1. The US, which has had the slowest average annual rate of decrease in MeBr usage of non-Article 5 countries using the CUE process, had nonetheless reduced CUN amounts by 78% from 2003 to 2013. Although the US has been accelerating the MeBr phaseout in recent years, with a large drop in the 2014 nomination, a complete phaseout has not been planned and it remains unclear when complete phaseout will be achieved.

Within the US, California is now the only state still requesting critical use exemptions for field strawberries. Porter et al. (2006) conducted a global meta-analysis of strawberry yields based on hundreds of studies and found that many alternatives produce "statistically equivalent yields" to MeBr, and thus worked to undermine arguments for exemptions related to technical feasibility. The resistance to phaseout of MeBr in California has centered on technical issues but also on economic feasibility and uncertainties associated with the availability of alternative fumigants – namely iodomethane. Approval of iodomethane for use in California was predicted for 2003, and then 2005 (Carter et al., 2005), but it was not actually available for use until December 2010. The failure of California to permit the use of iodomethane was a key rationale for the ongoing exemption request in that state (UNEP, 2011); this is consistent with the US not decreasing its CUN request between the nominating years 2010 and 2011. Since the registration of iodomethane in the 2011 growing season, however, only one California strawberry grower has used it, and that usage was small in scale (Wozniacka et al., 2012).

The registration of iodomethane by the US Environmental Protection Agency and the California Department of Pesticide Regulation was controversial due to potential public and occupational health hazards resulting from its use in pre-plant soil applications. After first denying registration of iodomethane in April 2006, the US EPA granted a one-year registration in October 2007 and, by 2008, licensed iodomethane for sale and use in the US with some restrictions on its application. Most states – with California the most notable exception – quickly followed suit by registering the fumigant. California eventually did approve the sale and use of iodomethane, but with restrictions more stringent than those imposed by the US EPA and other states. Legal challenges to the approval of this fumigant are ongoing, and an ongoing dialogue with respect to concerns about the registration of iodomethane persists between the general public, the US EPA, the California state legislature, and the risk assessment community, including government scientists involved in assessing the risk of iodomethane, a neurotoxin and possible carcinogen (Urevich, 2011). In early 2012, while no legal ruling against the use of iodomethane was made, the manufacturer announced that, based on an internal review of the fumigant and its economic viability in the U.S. marketplace, they would no longer sell this alternative fumigant in the United States and withdrew its registration in California (Chawkins and Marcum, 2012; ALC, 2012).

4. California strawberries today

US strawberries had record production levels in 2009; production, real value per unit and the total real value of the fresh strawberry crop have risen every year since 2004 according to the USDA (ERS, 2010, Table 1). Real US cash receipts have risen in every year from 2005 to 2010, the last year reported (ERS, 2011a, Table A-8). As noted above, acreage in California has also increased according to each of several data series (California Agricultural Resource Directory, 2010-2011, CSC, 2011; ERS, 2010), contrary to the predictions of declining acreage in the Carter et al. (2005) work and consistent with Carpenter et al. (2000). The ERS data go back the farthest and show that harvested acres of California strawberries have increased steadily since 1970. An OLS linear regression of acreage on time for 2001–2009 data fits well and yields an estimated increase of 650 ha/year; regressions including the earlier decades also show positive and significant trends but do not fit the data as well, suggesting that the time trend alone is not as explanatory over longer periods. These data show acreage increases in every year since 1997, with the exception of 2007, when they declined by less than 1%. Additionally, the ERS data show that the share of California acres in US strawberry acreage has grown steadily over time, from less than a third of the total in the early eighties, to more than half by the mid-90s and rising over two-thirds in 2006, where it remains.

Productivity of planted acres has also risen during this time period. ERS data on California yields from 1970 to 2009 show steadily increasing output per acre (ERS, 2010 Table 4). This trend continues for years subsequent to the onset of efforts to eliminate MeBr, though yields are, predictably, subject to weather and other conditions and thus more volatile than acreage. The share of California production in total domestic production has also grown over the time period covered, and has hovered around record highs of 88–89% since 2003. More recently, the Fruit and Tree Nuts report notes of 2010 that "last year, the increase in average yields per acre

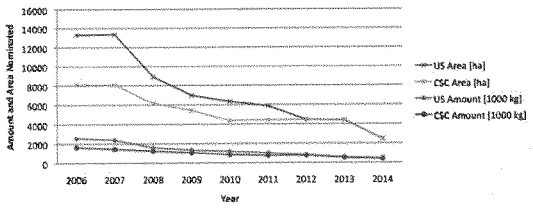

Fig. 1. US and California Critical Use Nominations, with MeBr requests and acreage.

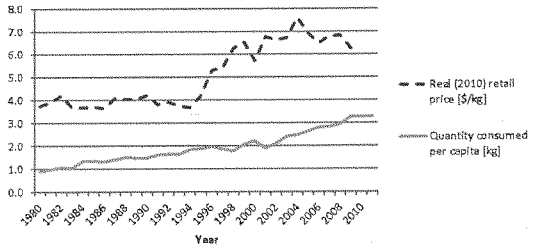

Fig. 2. US fresh strawberry prices and consumption.

in California (up 7 percent from 2009) more than made up for the decline in harvested acres (down 3 percent), resulting in a larger crop" (ERS, 2011c).

On the consumption side, we see that per capita consumption and total consumption of fresh and frozen strawberries continues to rise. In fact, per capita annual consumption of fresh strawberries has broken record levels in each year from 2003 to 2009 (ERS, 2011c; ERS, 2010, Table 12) even as real retail prices have stayed relatively stable or declined slightly. The most recent figures suggest an increase of 48% in per capita consumption of fresh berries since 2002, the last year covered in Norman (2005); with population growth that has amounted to a 67% increase in total US consumption over the same period. The continuing increase in per capita consumption as well as trends in real retail prices can be seen in Fig. 2.

We examine seasonal patterns in retail prices to evaluate hypotheses about patterns of trade raised in some of the ex-ante studies discussed above. Real retail prices in June, the period identified by Carter et al. (2005) as most vulnerable to losses in a MeBr phaseout, rose in 5 of the 10 most recent years for which data are available (2000–2009). The average of real June retail prices from 2005 to 2009 was 1% higher than for 2000–2004, suggesting no significant change in the trend over time as a driver of this observation. Looking more closely, however, and in contrast with all but 3 of the preceding 24 years of available data, we note that for 2004–2008 May retail prices were higher than April prices, reversing again in 2009. Grower prices confirm this trend; for 2005–2011, May prices to growers for fresh berries were higher than April prices in 5 years and lower in two years (http://quickstats.nass.usda.gov).

While farming is subject to significant variability from year to year, both in the various growing regions domestically and abroad, this is suggestive of an increasingly competitive market in North America. Norman (2005) predicted that the pre-2005 gap between higher April prices and lower May prices was likely to decrease in size in the absence of methyl bromide. Ex-post, we see that the gap has not just diminished but has reversed, while significant MeBr use continues. In the past, imports from Mexico peaked in April and domestic deliveries peaked in May or June. The historic drop in prices as domestic berries hit the markets in bulk suggested that exporting costs were high enough for Mexican growers that expanding exports during this period was relatively unattractive. In recent years, we have not observed a significant shift in strawberry acreage away from northern California growing areas, which deliver strawberries later in the season, and towards southern regions, where strawberries come in earlier (CSC, 2011), which might offer a domestic explanation for this shift in the pattern of relative prices throughout the year, so the currently observed pattern of relatively lower April prices is consistent with the US market becoming more attractive for Mexican growers wishing to export for more of the season or US growers facing rising costs in their peak production periods. It could also be that unobserved changes in crop timing associated with the use of MeBr alternatives have shifted the timing of peak deliveries in some parts of the state.

Investigating trends in imports and exports of fresh strawberries in more detail, however, does not provide strong supporting evidence for the hypothesis that increased Mexican imports are driving intra-year changes in relative prices. Imports of fresh strawberries to the United States, almost exclusively from Mexico, have indeed grown substantially, continuing a trend observed well before MeBr restrictions began. They have more than doubled since 2004 (ERS, 2011b and Table G-1, ERS, 2011a). The share of Mexican imports in domestic consumption has changed less, however, trending slowly upward since the mid-1980s and now around 8%.[8] This may reflect increasing retail availability and consumption in the off seasons for domestic strawberries as well as increased April exports from Mexico.

United States exports also grew during this time, rising more than 50% from 2004 to 2010 (Table G-2, ERS, 2011a). The bulk of these exports go to Canada, which consumes considerably more strawberries than are produced there. The increase in tonnage of exports to Canada is very similar to the increase in imports from Mexico, suggesting that changing price patterns over time cannot be cleanly ascribed to trade advantages for Mexican growers selling in the United States. Domestic exports could well increase the scarcity of domestic berries at peak periods, driving domestic prices up. Strawberry exports do peak in May (ERS, 2011a, Tables G6–G8). Unfortunately, import and export data by month are only available for a few years, making it difficult to discern trends over time with confidence.

Also affecting trade patterns in North America may be the promulgation of Country of Origin Labeling (COOL) regulations in the United States (http://www.ams.usda.gov/AMSv1.0/COOL). For the 2009 and subsequent seasons all fresh strawberries sold in the United States were required to carry labels indicating where they were grown and packed. One expectation of supporters of this policy was that consumers would prefer domestic products over imports, and this may have reduced the vulnerability of California growers to cheaper imports from Mexico in particular. Carter and Zwane (2003) argue that this was in essence a (costly) protectionist policy. Van Ittersum et al. (2007) note that consumers may prefer domestic or local region products both because they believe them to be better or safer, or because they have a preference for

[8] Calculations based on ERS (2011b) yield slightly different shares than those given in ERS (October 2010, Table F-14).

supporting growers in geographic regions that they identify with. Either of these would help California growers and hurt Mexican exporters in the domestic market. While we cannot isolate any impact of this over the short period since the rules have been established, it remains clear that the majority of the US market continues to be served by domestic growers.

The MeBr alternative iodomethane has been approved for use in Mexico and a commercial launch there is planned for 2012 (ALC, 2010). As an Article 5 country, Mexico has until 2015 to phaseout MeBr under the Montreal Protocol; however, the government of Mexico has committed to completely phaseout methyl bromide by 2012 (UNEP, 2010),[9] by which point it seems likely that growers there will be able to use iodomethane and California growers will use continuing allocations of MeBr and any of several alternatives which show little to no yield changes in current research (summarized in USDoS, 2012). Costs for various production inputs and growing conditions will of course vary and be drivers of comparative advantage in international trade as with any commodity. It is unlikely that changes in land use in California or Mexico have been driven by an expectation of continued MeBr use in Mexico after it is curtailed in the United States.

Additionally, increases in imports may reflect changing trade advantages unrelated to MeBr phaseout in the United States. From 2002 to 2009, imports of Mexican lemons increased from negligible to a major trade commodity, increasing to 54 times initial levels. Avocados increased eleven fold, raspberries increased eight fold, pineapples were up 250%, and pecans and cocoanut meat also increased more rapidly than fresh strawberries. Tangerine, lime, and mango imports grew more slowly than strawberries but still rose significantly (ERS, 2011a, Table G-1). Trade changes driven by NAFTA or other drivers of increased globalization should not be ascribed to the ongoing MeBr phaseout without more substantial evidence than we are able to find.

5. California strawberry production cost estimates

Looking at the various sample budgets available from Cooperative Extension in California (UC Cooperative Extension, 2001a–c, 2004a–d, 2006, 2010, 2011a–b), we do not observe clear links between decreasing availability of MeBr and costs or profits. 2010 and earlier reports note that alternatives to MeBr are available and in use, but the sample budgets assume fumigation with MeBr and chloropicrin (or 'Pic'); Pic allows for significantly lower rates of MeBr application in areas where MeBr had previously been used alone. Of the two 2011 reports one notes that methyl bromide availability is limited and does not specify a fumigant in the line-item budgets and the other uses Pic alone.

In the geographically central of the three largest growing regions, fumigation costs as a share of total costs were 2.4% in the 2001 sample budget, 3.7% in 2004, 3.5% in 2006 and 2.9% in 2011. For the same 3 years estimated net returns were 1.6, 14.2, 7.6, and 3.2% of total costs. In the main growing region to the south we have budgets for 2001, 2004, and 2011 which show a decline in fumigation costs as a share of the total, from 6.0 to 5.7 to 3.1%, while net returns increased from 9.5 to 13.4% and then dropped to 2.2%. In the northernmost growing region, budgets for 2001, 2004 and 2010 show increasing fumigation costs (5.2, 5.4 and 6.9% of total costs, respectively) and fluctuating net returns (6.6, 9.4 and 4.0%). These numbers offer some insights into input and production costs, in particular suggesting weakly declining fumigation costs and yielding some evidence of declining net revenues in the most recent years, but we note that the sample budgets are designed to offer a general understanding of costs and revenues using current methods rather than to support rigorous economic analysis.

Critical Use Nominations themselves are another source of data on trends in production costs and revenues. The nominations through 2013 give a baseline yield rate for fumigation with 100% methyl bromide and discount it by some fraction for each alternative pest control regime. While detailed budgets are not provided, annual CUNs for CUEs also include estimates of the economic impacts of MeBr as compared to alternatives.[10] These estimates are developed to support the case that additional exemptions to use MeBr in California are needed to avoid 'significant market disruption,' which is a key part of the standard established in Decision IX/6 of the Montreal Protocol to define a use as critical. Alternatives are shown with associated yield estimates and implied costs to producers facing changed yields and other practices. For 2006–2013 CUNs, the baseline MeBr yield estimates fluctuate a bit, dropping by around 15% from 2006 to 2008 levels in 2009–2010 and then rising again for 2011–2013 nominations. Reported yields per hectare are well below those reported in the sample budgets referenced above, typically around 40–50,000 kg/ha in recent CUNs, with some alternatives in the 30–40,000 range in earlier nominations, while first year strawberry yields in the sample budgets are around 60–80,000 kg/ha and the most recent second year yield reported is over 50,000 kg/ha (UC Cooperative Extension, 2011c). The yield loss associated with moving from MeBr to a mixture of 1,3-dichloropropene (1,3-D) and chloropicrin is steady at 14% throughout, suggesting that the loss rate estimate was not revised over time but simply applied to the MeBr number for a given year. This alternative is the only one included in every nomination[11]; metam sodium (MS) and a mixture of Pic and MS were excluded from 2010 to 2009, respectively, and a mixture of Pic and MeBr was not added until the 2010 nomination. Iodomethane is included for the first time in the 2013 nomination.

Projected strawberry prices drop by about 30% from 2010 to the 2011 nomination estimates, and they remain at this low level through the 2013 nomination. This price, $1.37/kilogram,[12] is well below current and recent reported grower receipts (ERS, 2010); it is not clear why recent nominations have used such a low baseline price. This price drop helps explain why the estimated value of MeBr use as opposed to 1,3-D+Pic can be relatively stable, ranging between $43–68 per kilogram for 2006–2013 nominations, while the figure for "percentage loss in net revenues" swings up to 1269% in 2011 and subsequent years, after previously being estimated at 55 and 87%. While the loss to net revenue is appealing as a proxy for disruption suffered by growers, the nominations note that the

[9] In 2008, Mexico's MeBr consumption was below consumption allowed under the Montreal Protocol. As of 2010, those implementing the National Methyl Bromide Phase-Out Plan for Mexico (the United Nations Industrial Development Organization (UNIDO) along with the governments of Italy, Spain, and Canada) intended to eliminate the remaining MeBr (approximately 900 ODP tonnes) by 2012, provided requested monies from the Multilateral Fund were received. The plan initially proposed that the strawberry sector convert near the end of the phaseout because "strawberry growers were reluctant to reduce MB consumption" (UNEP, 2010, p. 5). However, Mexico's strawberry growers have since requested immediate assistance in order to accelerate completion of the phaseout.

[10] These figures are all reported in nominal dollars, as the requests are filed a few years in advance of the proposed use, and do not specify nominal or real figures. Additionally, many of the numbers do not change from year to year, suggesting that the precision of the estimates is not such that deflating them should drive conclusions.

[11] It is worth noting that the 1,3-D mix is not available to all growers, as many California townships restrict 1,3-D use (Carpenter et al., 2001) and some counties restrict Pic application. This may be why the extension service budgets above exclude it, and this may also make it difficult to draw statewide conclusions on the basis of variation in yield estimates between 1,3-D alone and in combination and MeBr.

[12] The CUN itself reports 'units'; we believe these to be kilograms based on matching with previous California nominations.

required gross revenues less operating costs are "difficult to measure and verify" (USDoS, 2004–2011). Net revenues are sensitive to the implied change in gross revenues of much lower strawberry prices even in the absence of significant cost shifts, and smaller net revenues produce bigger percentage changes for a given nominal cost increase or yield decrease.

As this article was being finalized for publication, the 2014 Critical Use Nomination for field strawberries in California was made public. It requests 415 metric tonnes of MeBr for field strawberries, a bit over a 20% decline from the request for 2013. The drop in requested acreage to be treated is about 50%, suggesting decreasing use of MeBr in combination with other chemicals and thus at higher rates, while the baseline fumigant in the economic impact table is now a mixture of MeBr and Pic rather than MeBr alone. The economic impact analysis shows no yield losses for any alternative, a substantially higher output price for growers of $2.51 per unit, a roughly 60% increase in reported yields to nearly 80,000 kg/ha, and greatly reduced or even negative loss measures. The estimated loss or gain as a percentage of net revenue ranges from −9% (for an alternative using iodomethane) to 5% across all reported alternatives (USDoS, 2012). Chloropicrin alone yields an increase in net revenue of 2% relative to the baseline. Thus the key driver of the request is now the limited access in some specific areas to use of some of the alternative fumigants, or the requirement for buffer zones around schools and residential areas. However, the township caps that limit 1,3-D are being reached in regions where strawberry acreage has grown substantially since the US agreement to phaseout methyl bromide. It is difficult to argue that a sub-state regulatory decision that limits the amount of acreage in all crops that can be treated with certain pesticides represents a substantial disruption of the California strawberry market due to the elimination of methyl bromide.

It is interesting to note that with the exception of the 2006–2008 nominations the economic impact estimates in the CUNs assume no price gap per unit produced using MeBr and using alternatives. Wolverton (2012) indicates that in 2006–2008 the change in prices was used to reflect anticipated planting delays and subsequent later deliveries of crops to market for growers using alternative fumigation practices rather than broader market impacts. Constant output prices across alternatives with significantly differing yields suggest that these economic impact estimates assume no market price responses to significant supply swings (including projected yield losses of up to 30% for California growers, which would certainly affect the domestic and North American markets), and thus do not account for the significant amount of any cost increase that will be passed along to consumers as the market reaches a new equilibrium price (see Norman, 2005 for detailed discussion of the impact of relatively inelastic consumer demand for fresh strawberries on market prices and the distribution of the burden of rising production costs). If all acres not receiving exemptions were using alternatives with substantially lower yields and similar or increased costs, we would expect market prices to rise and moderate reductions in profits.

While we do not observe profits directly in the way that we do acreage and revenues, it is difficult to reconcile the history of CUN figures for California yields and costs using alternatives with the increasing use of alternatives and the increasing yields per acre and increases in total acreage noted above. The continued expansion in acres noted above is not consistent with an industry facing large losses as the phaseout continues; basic economics tells us that rising profits attract entry into an industry and falling profits drive exit, as more remunerative investments are sought for the land and capital previously employed in the failing sector. It seems likely that modifications of farming practices in concert with the use of non-iodomethane MeBr alternatives have been increasingly successful at preserving yields in those areas that are doing without MeBr either altogether or at least in some years. Input substitution as the price of fumigation relative to other inputs into the strawberry growing process rises – altered weeding practices or schedules, perhaps, or alternate cultivars or crop rotations – would be expected to lower the costs of compliance with the phaseout process. We have found no evidence suggesting zero input substitution characterizes this industry, and any substitutability across inputs will reduce cost burdens on growers. Learning by doing should also lower costs and gaps in yields across different pest control strategies over time, as growers and fumigation contractors become accustomed to using alternatives. Further and perhaps most significantly, it seems that the calculations used to support the granting of CUEs in this sector do not allow for the ability of growers to share cost increases with consumers, who may by their numbers and relatively inelastic demand bear the majority of any remaining burden without individually experiencing price increases as economically disruptive.

6. Additional drivers of change and trends

While per capita consumption of fresh berries by Americans has continued to rise since 2004, it is not obvious that this is driven by rising per capita incomes as earlier data suggested to Norman (2005). Mean and median household and per capita income trends were disrupted by the global recession, with US median household income falling in 2008, 2009 and 2010, mean household income falling in 2007, 2008, 2009 and 2010, and per capita income falling in 2009 and 2010 (Historical income tables, www.census.gov). With a relatively short data period to contend with and a lack of detailed information about changes in income distribution

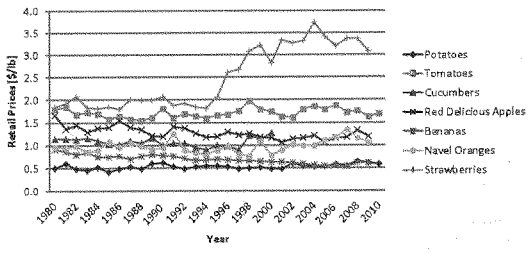

Fig. 3. US fruit and vegetable real retail prices.

and the relationship between income and strawberry consumption, disentangling trends in prices, consumption, and income to estimate relationships is imprecise.

One thing we do note in this market is that while prices of many fresh fruits and vegetables, including strawberries, have trended slightly downwards since 2008 (ERS, 2010 Table 12 and October 2011 Table A-7), over a longer time horizon, we observe a marked difference in fresh strawberry prices, which have increased by 85% from 1994 to 2008, compared to the prices of some other fruits and vegetables, which have largely been stable or increased to a much lesser extent (Fig. 3). Per capita consumption of fruits overall remained constant from 1994 to 2008, while per capita vegetable consumption initially increased from the mid-90s to 2000 but declined subsequently. This suggests that significantly increased strawberry consumption in the face of rising or stable prices in recent years is not likely to be driven by a decline in the price of strawberries relative to substitute fruits and vegetables. Changes in income, tastes, and preferences as well as the increased availability of strawberries at all times of the year are combining to support increased per capita and total strawberry consumption.

7. Conclusion

We offer an ex-post analysis of the impact of the mandated phaseout process for methyl bromide on California strawberry growers to date. Ex-ante estimates of the economic impact of the elimination of MeBr were required by and influential in the CUN and CUE processes, in contrast with either a benefit-cost approach including public health and environmental protection gains, as required by many of the domestic environmental policies of Parties to the Montreal Protocol, or with the Essential Use Exemption process used for other ozone depleting substances eliminated earlier in the ozone protection regime. While this is not an ex-post analysis of the originally expected complete phaseout, and thus cannot be directly compared with ex-ante predictions based on the complete elimination of MeBr use, it does offer insight into the gap between predictions and outcomes of a strawberry industry moving away from this ozone depleting pesticide while facing import competition from a major trading partner with a more lenient phaseout schedule.

Contrary to many ex-ante predictions and concerns expressed by stakeholders, California strawberry growers have thrived in recent years relative to both domestic and foreign competitors. They have successfully worked to ensure that MeBr has been available for significant fractions of their significantly expanded acreage, increased exports, and continued to enjoy rising yields and revenues as well as increased demand from consumers. The interim years between the planned elimination of MeBr and the increasing success of alternatives as detailed in the 2014 CUN and other reports have been years of expansion in the face of global recession and increased imports from Mexico, and successful navigation of technical and regulatory changes. Industry data suggests that the real burdens associated with changing agricultural practices have not kept this sector from profitability and growth in a challenging economic environment, though we cannot know how much faster growth might have been if MeBr use had continued unabated.

Alarming numbers in the CUNs sent to the Parties to the Montreal Protocol are not consistent with the success of California strawberry growers in aggregate as use of MeBr has been reduced. Nor are they consistent with basic economics. The 'economic disruption' standard of the CUE process was not intended to require the Parties to permit application of MeBr on new acreage to allow limitless expansion of a given industry using MeBr, and it is difficult to justify ongoing exemptions to support expansion rather than protect existing growers and growing regions. If all the new acres in production since 2005 are being managed profitably without MeBr, and existing acres are using less MeBr less often while overall and per acre yields and revenues rise steadily, it seems we have reached a point where alternatives are demonstrating successes for field strawberries in California.

References

Arysta Lifescience Corporation (ALC), 2010. Iodomethane Approved in Mexico and Morocco. http://www.arystalifescience.com/release/Mexico_and_Morocco_Reg.pdf.

Arysta Lifescience Corporation (ALC), 2012. Arysta LifeScience Suspends MIDAS® in United States. http://www.arystalifescience.com/release/MIDASPress3-20-12FINAL.pdf.

Badulescu, Dan, Baylis, Kathy, 2005. Pesticide Regulation Under NAFTA: Harmonization in Process?" No. 24163. Commissioned Papers from Canadian Agricultural Trade Policy Research Network.

CalAccess, 2011. California automated Lobbying and Campaign Contribution and Expenditure Search System. Available at: cal-access.ss.ca.gov (last accessed August 2011).

California Department of Food and Agriculture, 2011. California Agricultural Resource Directory 2010–2011. Available at: http://www.cdfa.ca.gov.

California Strawberry Commission (CSC), 2011. Acreage Survey. Annual reports available at: http://www.calstrawberry.com/commission/asurvey.asp (last accessed August 2011).

Carpenter, J., Gianessi, L., Lynch, L., 2000. The economic impact of the scheduled U.S. Phaseout of Methyl Bromide. National Center for Food and Agricultural Policy, Washington, D.C.

Carpenter, J., Lynch, L., Trout, T., May-June 2001. Township limits on 1,3-D will impact adjustment to methyl bromide phase-out. California Agriculture 55 (3), 12–18. doi:10.3733/ca.v055n03p12.

Carter, C.A., Zwane, Alix Peterson, 2003. Not so cool? Economic implications of mandatory country-of-origin labeling. Agricultural and Resource Economics Update 6 (5), 5–7.

Carter, C.A., Chalfant, J.A., Goodhue, R.E., Han, F.M., DeSantis, M., 2005. The methyl bromide ban: economic impacts on the California strawberry industry. Review of Agricultural Economics (Now Applied Economic Perspectives and Policy) 27 (2), 181–197.

Center For Responsive Politics, 2011. Database available at: www.opensecrets.org (last accessed August 2011)

Chawkins, Steve, Marcum, Diana, March 21, 2012. Methyl iodide distribution to halt in U.S. Los Angeles Times.

Clark, Victoria, 2001. Enforcement of pesticide regulation in California: a case study of the experience with methyl bromide. Golden Gate University Law Review 31. http://digitalcommons.law.ggu.edu/ggulrev/vol31/iss4/5.

DeCanio, S.J., Norman, C.S., July 2005. Economics of the 'Critical use' of methyl bromide under the Montreal Protocol. Contemporary Economic Policy 23 (3), 376–393.

DuPuis, E.M., Gareau, B.J., 2008. Neoliberal knowledge: the decline of technocracy and the weakening of the Montreal Protocol. Social Science Quarterly 89 (5), 1212–1229.

Economic Research Service, United States Department of Agriculture, March 2010. US Strawberry Industry Spreadsheet Files. Available at: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1381 (accessed August 2011).

Economic Research Service, United States Department of Agriculture, October 2011a. Fruit and Tree Nut Yearbook Spreadsheet Files. Available at: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1377.

Economic Research Service, United States Department of Agriculture, May 27, 2011b. Fruit and Tree Nuts Outlook. FTS-347.

Economic Research Service, United States Department of Agriculture, March 30, 2011c. Fruit and Tree Nuts Outlook FTS-346.

Federal Register, April 28 2011. Protection of Stratospheric Ozone: The 2011 Critical Use Exemption from the Phaseout of Methyl Bromide Proposed Rule, Federal Register, vol. 76 (82), 23769–23781 pp.

Gareau, B.J., DuPuis, E.M., 2009. From Public to Private Global Environmental Governance: Lessons from the Montreal Protocol's Stalled Methyl Bromide Phase-out. Environment & Planning A 41 (10), 2305–2323.

Gareau, Brian J., 2008. Dangerous holes in global environmental governance: the roles of Neo-liberal discourse, science, and California Agriculture in the Montreal Protocol. Antipode 40 (1), 102–130.

Gareau, Brian J., 2010. A critical review of the successful CFC phase-out versus the delayed methyl bromide phase-out in the Montreal Protocol. International Environmental Agreements: Politics, Law, and Economics 10 (3), 209–231.

Gareau, Brian J., 2012. The limited influence of global civil society: international environmental non-governmental organisations and the Methyl Bromide Controversy in the Montreal Protocol. Environmental Politics 21 (1), 88–107.

Goodhue, R.E., Fennimore, S.A., Ajwa, H.A., 2005. The economic importance of methyl bromide: does the California strawberry industry qualify for a critical use exemption from the methyl bromide ban? Review of Agricultural Economics (Now Applied Economic Perspectives and Policy) 27, 198–211.

Kent-Monning, Laura, 2007. Student comment. Endless exemptions: an environmental justice critique of the ongoing use of methyl bromide. Golden Gate University Environmental Law Journal, 175–208.
Norman, C.S., 2005. Potential impacts of imposing methyl bromide phase out on US strawberry growers: a case study of a nomination for a critical use exemption under the Montreal Protocol. Journal of Environmental Management 75, 167–176.
Porter, I.J., Trinder, L., Partington, D., 2006. Validating the Yield performance of Alternatives to Methyl Bromide for Pre-Plant Fumigation. TEAP/MBTOC Special Report. Available at: www.unep.org/ozone/teap/Reports/TEAP_Reports/.
United Nations Environment Programme (UNEP), 2005. Report of the seventh meeting of the Conference of the Parties to the Vienna Convention for the Protection of the Ozone Layer and the Seventeenth Meeting of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer. Dakar, December 12–16, 2005. http://ozone.unep.org/Meeting_Documents/mop/17mop/17mop-11e.pdf.
United Nations Environment Programme (UNEP), 2010. Project Proposal: Mexico. UNEP, Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol, Sixteenth Meeting, Montreal: 12-14 April 2010. http://multilateralfund.virtual.vps-host.net/files/60/6034.pdf.
United Nations Environment Programme (UNEP), 2011a. Report of the Technology and Economic Assessment Panel Evaluation of 2011 Critical Use Nominations for Methyl Bromide and Related Matters. October 2011. http://ozone.unep.org/Assessment_Panels/TEAP/Reports/TEAP_Reports/TEAP-CUN_2011-Final-Report-October2011.pdf.
United Nations Environment Programme (UNEP), 2011b. Decisions Adopted by the Conference of the Parties to the Vienna Convention at its Ninth Meeting and by the Twenty-Third Meeting of the Parties to the Montreal Protocol – ADVANCE. Undated, downloaded December 2011. http://conf.montreal-protocol.org/meeting/mop23-cop9/draft-reports/Draft%20Reports/COP9-MOP23_%20decisions.pdf.
United States Department of State, 2004. Methyl Bromide Critical Use Nomination for Preplant Soil Use For Strawberries Grown for Fruit in Open Fields on Plastic Tarps (For 2006 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2005. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberries Grown for Fruit in Open Fields (Prepared in 2005 for 2007). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2006. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberries Grown for Fruit in Open Fields (Submitted in 2006 for 2008). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2007. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberries Grown for Fruit in Open Fields (Submitted in 2007 for 2009). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2008. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2008 for 2010 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2009. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2009 for the 2011 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2010. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2010 for the 2012 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2011. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2011 for the 2013 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2012. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2012 for the 2014 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
University of California Cooperative Extension, 2001a. Sample Costs to Produce Fresh Market Strawberries, Central Coast Region. Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2001b. Sample Costs to Produce Strawberries, South Coast Region – Santa Maria Valley. Bendixen, W.E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2001c. Sample Costs to Produce Strawberries, South Coast Region – Ventura County. Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004a. Sample Costs to Produce Strawberries, Central Coast Region. Bolda, M.P., Tourte, L.J., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004b. Sample Costs to Produce Strawberries, South Coast Region – Santa Barbara County, Santa Maria Valley. Bendixen, W.E., Takele, E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004c. Sample Costs to Produce Strawberries, South Coast Region – Ventura County. Daugovish, O., Takele, E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004d. Sample Costs to Produce Strawberries, San Joaquin Valley. Molinar, R.H., Yang, M., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2006. Sample Costs to Produce Strawberries, South Coast Region – Santa Barbara County, Santa Maria Valley. Takele, E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2010. Sample Costs to Produce Strawberries, Central Coast Region, Santa Cruz and Monterey Counties. Bolda, M.P., Tourte, L.J., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2011a. Sample Costs to Produce Strawberries, South Coast Region – Ventura County, Oxnard Plain. Daugovish, O., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2011b. Sample Costs to Produce Strawberries, South Coast Region – Santa Barbara and San Luis Obispo Counties, Santa Maria Valley. Dara, S., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2011c. Sample Costs to Produce Second Year Strawberries, Central Coast Region, Santa Cruz and Monterrey Counties. Bolda, M.P., Tourte, L.J., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
Urevich, Robin, December 7, 2011. Many farmers shun methyl iodide on strawberry fields. The Bay Citizen. http://www.baycitizen.org/environmental-health/story/methyl-iodide/.
van Ittersum, Koert, Meulenberg, M.T.G., van Trijp, H.C.M., Candel, M.J.J.M., 2007. Consumers' appreciation of regional Certification labels: a pan-European study. Journal of Agricultural Economics 58 (1), 1–23.
Wolverton, Ann, March 2012. United States Environmental Protection Agency. Retrospective Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies. National Center for Environmental Economics, Available at: http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/RetroCost.html.
Wozniacka, Gosia, Midas, Strawberry. Pesticide Methyl Iodide, Will Be Pulled from Market by Arysta LifeScience Inc. Associated Press, March 21, 2012. http://hosted.ap.org/dynamic/stories/U/US_Farm_Pesticide_Methyl_Iodide.

Mr. WHITFIELD. Thank you, Mr. Doniger.

At this time, Ms. Keeler, you are recognized for a 5-minute opening statement.

STATEMENT OF MICHELLE CASTELLANO KEELER

Ms. KEELER. Thank you.

As Congressman Bilbray stated, my family grows cut flowers in the San Diego area of California where we employ over 200 employees. We farm approximately 400 acres at any given time, have over 50 varieties of flowers growing on our farm. Unlike other farms, you have to picture our farm sort of like a patchwork quilt because we just don't have one product; we have several products. So you might have 2 acres of tulips next to 10 acres of lilies next to 20 acres of myrtle, so there is all kinds of things taking place. And each of those squares is constantly changing in terms of the crops, cultivating times, diseases, pests, irrigation needs, and the market demands.

We are very concerned by EPA's arbitrary cuts of our allocations with no real burden of evidence showing a feasible or technical alternative exists for certain crops. We are also concerned about situations that are emerging on our farms requiring emergency clean-up applications of methyl bromide.

As a grower, we have a limited number of tools in our toolbox, and when you take a tool away from us, it puts pressure on the remaining tools. And when you leave us with only weak tools, we become as weak as the tools are. As soon as these tools become useless, we have to walk away, and sadly, many growers are starting to walk away from growing their crops.

Please understand, we are using alternatives whenever possible, and in some instances, they work for a short time. But then issues start to pop up. A good example is nut grass. We have been using alternatives such as Telone, chloropicrin, and Vapam, and while they did a decent job for a little while of knocking down the nut grass, it never eliminated it and after a few years these popped back up and take over our crop. We then find ourselves applying excessive amounts of these so-called alternatives. So not only are we compounding the use of alternative chemicals, we are also finding now later on that there is a detrimental effect to our crops, which forces us to prematurely disk under our flowers and we are disking under our investment as well. A periodic application of methyl bromide is more effective and we believe it is safer.

We also have difficulty in the cut flower industry because we can't fit our growing practices into one neat formula due to this ever-changing patchwork quilt that I described earlier. In these squares we have perennials, annuals, bulb crops, seed crops, and shrubs. Our crops at Mellano & Company can have a planting value of $60,000 an acre, and some of these perennial crops will be in the ground from anywhere from 5 to 25 years. We can't afford to put plants like this that are this expensive into dirty soil. We also can't predict when in that 5 to 25 years we will be replanting this crop based on issues that pop up. So periodic applications—it is difficult for us to fit into an application process because it is not every year. It might be in 5 years; it might be in 8 years.

The cut flower industry has converted many, many crops over to alternatives, but in a few instances, alternatives do not exist. This year, the cut flower industry submitted a similar application to EPA as in the previous few years. However, EPA determined we had no need and submitted nothing to the international body. We understand EPA assumed methyl iodide would be a drop-in replacement for our entire industry despite the fact that we provided scientific information showing that methyl iodide was not useful to California growers. We can't afford for EPA to make assumptions in our dynamic industry about our growing practices without understanding our industry first. Not only is methyl iodide not a replacement in California, the manufacturer withdrew sales of that compound in the U.S., so now, what does our industry do?

The United States agricultural community has complied with the CUE requirements where no alternatives exist, despite the fact that this process is cumbersome, time-consuming, and costly. We are willing to do so because in a few instances, we still need this strong tool in our toolbox, yet our applications continue to be arbitrarily reduced without any or inadequate scientific explanation. So now we are left with weak tools or with nothing at all.

I personally cannot understand why EPA can so easily make these cuts. Every miniscule cut that they make means so much to our survival and so little in the grand scheme to the other parties. Why is our government hurting us? And we are being hurt. In the floral industry, many growers, including my family, is cutting back on our crop mix to a very limited number of varieties to ensure that we have access to the proper growing tools. This means fewer varieties available and certainly nothing new in the marketplace. Thus, other developing countries are taking on these varieties and providing them to the consumer, which begins the decline of our business.

People are in pain. Our family farm is in pain. And it is something that Congress can do something about. Please reaffirm the CUE process beyond 2014, ensure that EPA protects its American growers with scientifically sound reasoning, and make available the tools we need to grow our crop, especially in emergency rescue and cleanup situations. Thank you.

[The prepared statement of Ms. Keeler follows:]

STATEMENT BEFORE THE

SUBCOMMITTEE ON ENERGY AND POWER

ENERGY AND COMMERCE COMMITTEE

U.S. HOUSE OF REPRESENTATIVES

HEARING ON

"U.S. AGRICULTURAL SECTOR RELIEF ACT"

submitted by

MICHELLE CASTELLANO KEELER
Vice President
MELLANO & COMPANY
SAN LUIS REY, CALIFORNIA

on behalf of the

SOCIETY OF AMERICAN FLORISTS

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Members of the Committee, we thank you for this opportunity to present testimony on behalf of the U.S. floriculture industry. Continued availability of methyl bromide to U.S. flower growers is of great importance to our industry. We are complying with the Montreal Protocol. However, our industry is in danger because we are not being treated fairly under the terms of the Treaty.

The Society of American Florists (SAF) is the national trade association representing the entire floriculture industry, a $32 billion component of the U.S. economy. Membership includes about 10,000 small businesses, including growers, wholesalers, retailers, importers and related organizations, located in communities nationwide and abroad. The industry produces and sells cut flowers and foliage, foliage plants, potted flowering plants, and bedding plants. Our products compete in an international marketplace.

In crop value, nursery and greenhouse crops have surpassed wheat, cotton, and tobacco and are now the third-largest crop in the U.S. – behind only corn and soybeans. Nursery and greenhouse crop production now ranks among the top five agricultural commodities in 28 states, and among the top 10 in all 50 states. Growers produce thousands of varieties of cultivated nursery, bedding, foliage and potted flowering plants in a wide array of different forms and sizes on 1,305,052 acres of open ground and 1,799 million square feet under the protective cover of permanent or temporary greenhouses, across the United States.

U.S. growers, whose ability to compete in that international marketplace is often at stake, are very concerned that their rights under the Montreal Protocol be supported by the U.S. government. Methyl bromide is a critical management tool in many kinds of production, particularly in Florida and California. The combination of methyl bromide and chloropicrin has long been used to control weeds, nematodes and plant pathogens like Pythium. While some industries have found acceptable alternatives, floriculture has struggled to find an acceptable alternative despite substantial investments in research. The production of field-grown cut flowers, some in-ground shade house flowers and caladiums rely on availability of methyl bromide for economically viable crops.

We greatly appreciate today's hearing, and we also greatly appreciate your introducing this important legislation, the U.S. Agricultural Sector Relief Act. We strongly support this bill and hope that Congress will move to enact it.

My testimony today will focus on four major points:

1. The U.S. needs to be more forceful in defending the rights and needs of U.S. growers. EPA should not deny or reduce a Critical Use Exemption (CUE) application unless it has substantial evidence that there are technological and economically feasible alternatives. The State Department should more actively push the U.S. nomination, rather than play defense.

2. We need to have assurance that the CUE process will continue after 2015, which is the clear intent of the treaty.

3. EPA should work with us to establish regulations implementing the "emergency event exemption" allowed by the Protocol. We need an emergency cleanup process that will allow us to go into our fields every few years and clean up the pests and diseases that have developed during the times when we were using the less-effective alternatives. There are other situations, as well, where an emergency event exemption is appropriate.

4. The Quarantine and Preshipment (QPS) Exemption is also clearly provided for under the Protocol and must continue in order to protect international trade.

I. **THE U.S. NEEDS TO BE MORE FORCEFUL IN DEFENDING THE RIGHTS AND NEEDS OF U.S. GROWERS'. EPA SHOULD NOT DENY OR REDUCE A CUE APPLICATION UNLESS IT HAS SUBSTANTIAL EVIDENCE THAT THERE ARE TECHNOLOGICAL AND ECONOMICALLY FEASIBLE ALTERNATIVES. THE STATE DEPARTMENT SHOULD MORE ACTIVELY PUSH THE U.S. NOMINATION, RATHER THAN PLAY DEFENSE.**

Under the terms of the Montreal Protocol, U.S. growers are entitled to a CUE if practicable and economical alternatives are not available. Efforts have been made by the floral industry to find alternatives, and a significant market disruption would result from lack of availability of methyl bromide. U.S. growers have complied with the terms of the treaty, but we are not receiving the exemptions to which we are entitled.

Today we are faced with a political process that appears to be attempting to force U.S. growers to discontinue completely the use of methyl bromide despite the absence of suitable feasible alternatives. Without access to this necessary input, U.S. growers will be rendered non-competitive in the global marketplace. This will force many to cease operations, killing jobs and causing significant harm to the local communities in which we operate at a time of great economic uncertainty.

The basic CUE process works as follows:

1. U.S. growers prepare a very detailed application for EPA, describing their efforts to find alternatives, the reasons why alternatives do not work, and the economic reasons why methyl bromide must continue to be used.
2. EPA reviews this application ostensibly to ensure that the U.S. applications are complete and accurate. **However, EPA as a matter of course has reduced the amounts we request, and we question those reductions.**
3. EPA submits the U.S. application to the Secretariat of the Montreal Protocol.
4. The U.S. application and all other applications are reviewed by MBTOC and TEAP (the "scientific committees" of the Montreal Protocol governing body). **Significant reductions are typically recommended by those advisory groups again, we believe, without scientific justification.**
5. While technically at the full Protocol meeting, the parties to the treaty consider and vote on the CUE nominations, they essentially simply adopt the recommendations of MBTOC/TEAP.

The U.S. cut flower and foliage industry has participated in the CUE process since it was established because it is the only meaningful way we can possibly access methyl bromide to meet our needs. While the Montreal Protocol deals with the phase-out of the production of methyl bromide, the Protocol also clearly provides for a CUE. In short, an application can be made for continued use of methyl bromide if efforts have been made to find alternatives. If technologically and economically feasible alternatives are not available, then CUE applicants should be able to access methyl bromide.

Yet this provision is not being followed in the implementation of the Protocol. Despite having submitted CUE applications substantiating their need for the product in accordance with the provisions of the Protocol, U.S. growers are being forced to take arbitrary cuts in their requested

levels, with absolutely no scientific reasoning and no justification. That is not the Protocol that the U.S. signed and the U.S. government must not accept it.

A. EPA's Arbitrary Reductions

The California and Florida cut flower industry has applied for and been granted a CUE for a limited amount of methyl bromide in every year until this one. The applications are submitted three years in advance due to the lengthy review and approval process. For the past several years, the industry has requested about 70.5 metric tons of methyl bromide for California and over 50 metric tons for Florida.

In 2009 (for 2012 use), the international treaty had approved just 47 metric tons for cut flowers (California and Florida). In 2010 (for 2013 use), EPA's Critical Use Nomination to the international body requested 47 metric tons of methyl bromide for cut flowers. In a move resulting in virtually zeroing out Florida due to the registration of the alternative methyl iodide, MBTOC recommended, and the parties to the Protocol approved, just 40 metric tons for cut flowers for 2013 use. This was a significant reduction from what the industry needs and had requested in its CUE application. Those reductions were made even though there were no changes in the scientific information or circumstances known to EPA or MBTOC.

Cut flower producers again submitted to EPA the application for the 2014 CUE in September 2011. However, the 2014 application submitted by EPA to the international Montreal Protocol body in February 2012 did not include ANY allocation for cut flowers. In fact, of the ten categories of soil fumigation that were approved in 2013, the U.S. nomination for 2014 included only one – that for field-grown strawberries. It did not include applications for the other nine: cucurbits, eggplant, nursery stock, fruit/nuts, cut flowers, orchard replants, peppers, strawberry runners, or tomatoes. The only material change in circumstances from the prior year was the registration of methyl iodide in California.

EPA relied heavily on the registration of methyl iodide in California to conclude that methyl bromide would no longer be necessary. However, in our original application to EPA we clearly noted that methyl iodide at the label rate approved in California made it unlikely that the compound would be available or useful to California growers. Furthermore, we noted that the required buffer zones and the intense public opposition to the use of methyl iodide made it even more unlikely that the compound would be usable. Yet EPA continued to assume that methyl iodide would be a "drop-in" replacement for methyl bromide, ignoring the information provided in our application.

Then, shortly after the U.S. nomination was submitted to the Montreal Protocol, the manufacturer of methyl iodide, Arysta, withdrew sales of that compound in the U.S. Thus, EPA's assumption that methyl iodide would be a "drop-in" replacement for methyl bromide is now completely invalidated. We are encouraging EPA and the State Department to submit a supplemental request for 2014 this coming year or early next year – but it is expected that the criteria MBTOC/TEAP will use for reviewing the supplemental application will be even more stringent. We are making efforts to bolster the CUE application to EPA, but we are very concerned that our need will not be met.

B. Mellano & Company

EPA needs to better understand the complexity of our cropping systems and why something that works in one part of the world won't necessarily work for us. Simply dismissing our application by saying, in essence "It works in X country or state, so it should work for you" is not acceptable. Particularly in the case of ornamentals, the cropping systems and timing are so complex that it is

imperative for EPA to understand and acknowledge why methyl bromide is so important to our operations.

We at Mellano & Company farm over 400 acres (employing over 200 employees) and grow over 50 different crops of flowers and greens, with upwards of 20 different varieties within each of those crops. Unlike other agricultural farms, you have to envision our farm as a patchwork crazy quilt, with each square constantly changing in terms of crops, cultivating times, disease, pests and irrigation needs – and market demands.

We cannot fit our growing practices into one neat formula because we are ever changing and cannot afford to let our ground sit unused and idle. We must respond quickly to market demands, as well as issues with pests and diseases, and have access to the tools necessary to prepare our land for these changes in time to produce a saleable crop.

We will continue to work with EPA to ensure they have a clear understanding of our issues. But in the meantime, EPA is reducing our application amounts and we cannot afford these unscientifically based cuts.

In addition to the factors referred to above which make the use of methyl iodide impossible, the other alternatives are not adequate to protect us against soil pests and diseases, despite EPA's assumption that they "should" work. Just because research shows that an alternative will work in one country of the world, or in one part of the U.S. for one crop, does not mean that that same alternative will work for other crops in different economic, climatic, or soil conditions.

Our crops can have a planting value of $60,000/acre. Some proprietary plants can cost as much as $40,000/acre. We simply cannot afford to put such high-value plants into dirty soil with the risk of compromising the crop. We currently have over 50 different species in production between annual and perennial cut flowers on our farm alone. In the state, there are many more than that. Each one has a different yield, cost and profitability profile, as well as a cropping system that could be unique to that species

Consider these other points that apply to our farm:

- The cost of failure is very high when applications don't work.
- Hand-weeding is not an option in the U.S., due to the cost and to Cal-OSHA worker issues.
- For bulb-producing plants, the second season can result in rogue plants, causing production and harvesting issues.
- Drip-applied materials on sandy, hillside farms just don't work well. On high-sand soils such as those at our farm, lateral movement is minimal and therefore effectiveness of drip-applied materials is restricted to a narrow strip, rather than to the whole flower bed.
- Yield alone does not tell the whole story: plant vigor, plant height, stem thickness are also important. Yield must be accompanied by good quality.
- Methyl bromide is now very costly – up to $3300/acre. We obviously are seeking viable alternatives, yet have not yet found them.
- We have perennial crops as well as annual ones. Those perennials, depending on the crop, must be productive for between 5 and 25 years. Soil diseases can and will reduce that lifespan significantly. We need a "clean start." One fumigation every few years will help to "clean up" the soil to prevent carryover and recurrence of disease.
- For perennials, the most important need is for disease and nematode control. For annuals, we need disease, weed and nematode control. For some diseases, if the pathogen overwhelms a perennial crop the crop must be replanted, those replant acres require a very serious clean-up treatment before the new plants go into the ground.

- True long-term rotations are virtually impossible to achieve, and fallowing expensive land is not cost-effective.

Those points are typical of the ones we have made, year after year. We do our best, in our annual applications to EPA, to explain why the variety and complexity of our cropping systems make it difficult to find alternatives to methyl bromide. Yet year after year, EPA reduces the amount we say we need, when they submit the U.S. application to the international body. And this year, with no warning and despite the fact that we thought we had provided them with all of the information they needed, they eliminated our application altogether.

EPA should not deny or reduce a CUE application unless it has substantial evidence that there are technological and economically viable alternatives. We ask that Congress put this requirement into law.

C. MBTOC/TEAP Arbitrary Reduction

MBTOC/TEAP (the "scientific advisory committees" of the Montreal Protocol) are tasked with reviewing CUE applications to make sure they are based on sound science. After this review, MBTOC/TEAP makes a recommendation to the parties as to what each country's allocation should be. That recommendation is supposed to be based on their scientific reasoning.

Our applications, already reduced by EPA, are presented to MBTOC/TEAP. We are frustrated when the MBTOC/TEAP recommendations are reduced further with no scientific justification.

The following quotation from one MBTOC/TEAP report on the CUE nominations is particularly revealing of the unscientific and biased nature of the MBTOC decisions:

> *"MBTOC assumed that an alternative demonstrated in one region of the world would be technically applicable in another unless there were obvious constraints to the contrary e.g., a very different climate or pest complex." [Report of the TEAP, October 2004, page 5]*

This assumption is completely invalid and unjustified. This kind of "assumption" is not based on science. The U.S. has provided detailed scientific information on why certain alternatives available to other countries will not work in the U.S. Not only do climate and pest complexes differ, but the economies differ as well. An alternative, which might be economical in a developing country, may not be usable in the U.S., where cost/profit margins are considerably slimmer and labor, environmental compliance, and chemical costs are very high.

It is absolutely essential that MBTOC and TEAP be required to provide scientific justification for their decisions and detailed rationales of their recommended cuts to the nominating party. Without understanding why MBTOC and TEAP are recommending cuts, it is impossible to answer or defend a nomination, and we are forced to accept what can only be classified as an arbitrary reduction. Our State Department cannot argue effectively on our behalf so long as this charade of scientific review is allowed to continue.

D. The Negotiations at the Meeting of the Parties are Political, Not Science-Based

According to the agenda, the discussion period of the international meetings is directed around the CUE process of the Montreal Protocol. However, the underlying agenda for most parties has nothing to do with the Protocol treaty terms.

It is the clear intent of some countries, particularly the European Union representatives, to force a year-by-year decline in CUEs approved by the Parties. Such discussions and goals are contrary to

the Treaty. The Treaty provides for the CUEs in cases where practicable and economical alternatives do not exist. The Treaty does *not* require that CUEs should decline year by year.

Discussion at the international meetings imply that the U.S. applies for too much methyl bromide under its CUE application, and the amount should be reduced and phased out over time. Under the Montreal Protocol, if no economical and feasible alternatives exist the industry can utilize the CUE process.

The United States' agricultural community has complied with the CUE requirements, despite the fact that they are cumbersome, time-consuming and costly. Yet our applications continue, year after year, to be arbitrarily reduced, without any or with very inadequate scientific explanation.

We believe that it is also noteworthy to point out the efforts that our industry has to go to in order to try and participate in the Protocol process to advance their nomination. For example, in just considering the venues for the Meetings of the Parties under the Protocol, since 2003 those meetings have been held in such locations as Nairobi, Kenya, Prague Czechoslovakia, Dakar Senegal, New Delhi, India, Doha, Qatar, Port Ghalib, Egypt, Bangkok Thailand, and Bali Indonesia. These are not the easiest or necessarily safest locations to travel to. In short, we have to travel to distant lands to participate (however limited that participation is allowed to be) with governments of the world that hold our future in their hands.

The foregoing does not even take into account the other meetings that are held by MBTOC/TEAP that first will consider the US CUE nominations. The procedures of those committees are such that direct participation in their meetings for NGOs is essentially precluded. However, we are forced to live with their decisions. When we have raised these issues with the EPA and State Department, their response is essentially this is all controlled by the Protocol and there is nothing they can do other than encourage us to submit "robust" CUE applications which ostensibly will make it more difficult for the advisory committees to reject or reduce the US nominated amount. You can imagine how unsettling this all is to us.

The State Department should more actively advance the U.S. nomination rather than playing defense.

II. WE NEED TO HAVE ASSURANCE THAT THE CUE PROCESS WILL CONTINUE AFTER 2015, WHICH IS THE CLEAR INTENT OF THE TREATY.

We have now reached the point where EPA appears to be considering a complete phase-out of methyl bromide after 2015. That kind of complete phase-out is completely contrary to the Montreal Protocol, which clearly allows use of methyl bromide after 2015 if no feasible alternatives are available.

Nowhere in the Montreal Protocol is there any requirement that countries cannot avail themselves of the CUE process. Yet the political agenda of some of our trading partners and others involved in the international meetings is to push for just that – a requirement that CUE's would stop being issued after a certain date. .

In addition, and equally important, as circumstances change (failure of alternatives, changes in regulatory status, or changing a use from QPS to CUE), increasing a methyl bromide request is justified under the treaty. We ask that EPA be directed specifically to recognize that increases may be necessary and appropriate.

We ask for legislative direction to EPA and the State Department to continue the CUE process, in compliance with the terms of the Montreal Protocol.

III. EPA SHOULD WORK WITH AFFECTED INDUSTRIES TO ESTABLISH REGULATIONS IMPLEMENTING THE "EMERGENCY EVENT EXEMPTION" ALLOWED BY THE PROTOCOL.

EPA should work with impacted industries to develop an "emergency clean-up" process that will allow us to go into our fields every few years and clean up the pests and diseases that have developed during the times when we were using the less-effective alternatives.

After years of trying to use methyl bromide alternatives that are less effective, and having a CUE amount of methyl bromide below the level we really need, we are seeing pest and disease build-ups in our soils. This results in reduced yields and reduced quality. EPA needs to (as is allowed under the treaty) work with us to develop a way for us to have methyl bromide available as an emergency clean-up tool, every few years, to counter this kind of buildup.

After a few years of using alternatives to methyl bromide for soil fumigation, many of the U.S. growers notice a gradual (or sometimes an intense) build-up of weeds and diseases. A periodic "clean-up" with methyl bromide would allow us to use the alternatives during the intervening years without production losses – yet would also allow us to keep growing our crops once the level of pests and diseases in the soil has gotten to the point where the fumigation alternatives simply can't get the soil clean enough.

As noted above, Mellano & Company produces perennial crops as well as annual ones. Those perennials, depending on the crop, must be productive for between 5 and 25 years. Soil diseases can and will cut that lifespan significantly. One fumigation every few years will help to "clean up" the soil to prevent carryover and recurrence of disease.

There are other situations in which an "emergency event" would require an exemption. For example, if there is no existing CUE but if a situation arises where a person who owns a farm, nursery, or food processing or storage facility suddenly requires fumigation and has no other alternatives, or if alternatives have suddenly become unavailable (as is the case with methyl iodide or sulfuryl floride), then an exemption for such an emergency event should be permitted.

The Montreal Protocol specifically allows such an exemption, under Decision IX/7, and EPA must move to establish reasonable regulations implementing procedures for granting emergency exemptions. **Furthermore, the 20 tons of methyl bromide which is the maximum authorized under Decision IX/7 should be the maximum on a per-farm or per-facility basis, and not a yearly U.S. nationwide maximum.**

IV. THE QUARANTINE AND PRESHIPMENT (QPS) EXEMPTION IS ALSO CLEARLY PROVIDED FOR UNDER THE PROTOCOL AND MUST CONTINUE IN ORDER TO PROTECT INTERNATIONAL TRADE.

Political forces are also pushing for the elimination of the QPS exemption. Methyl bromide is an established and important tool used at the ports to eliminate infestations of pests. It is equally important as a preshipment tool in meeting quarantine requirements of international and interstate shipments.

As trade increases, we are increasingly subjected to incursions of foreign pests and diseases, which can cause enormous economic or environmental damage. We simply cannot afford to

ignore the continuing need for methyl bromide as one very important tool in preventing those infestations.

VI. CONCLUSION

We contend that keeping methyl bromide production levels at 2011 levels would not have a meaningful impact on the restoration of the ozone layer, and those are levels with which agriculture can live. Yet continuing to try to reduce methyl bromide production and use to zero will have a very meaningful impact on the U.S. economy and our ability to continue producing many very important agricultural commodities. We are continuing to try to comply with the Montreal Protocol as it is written, but we need your help.

Perhaps the most troublesome aspect to this story is that while our allocation is being reduced, our competitors in lesser-developed countries will continue to have methyl bromide available for their use for several years. U.S. growers, in an increasingly international economy, need better and better tools to remain competitive.

The U.S. industry has fulfilled the terms of the Montreal Protocol. It is in compliance. Year after year, we have prepared and submitted CUE requests, based on the amounts we need. However, both EPA and MBTOC/TEAP have each year made significant, and, we believe, scientifically unjustified cuts to our requests. The result is that each year since this process started, our allocations have decreased significantly from the allocation of the previous year, and, of course, from our requested amount.

The State Department must defend us under the terms of the protocol or walk away. The Montreal Protocol does not require getting U.S. CUE allocations to "zero-use" over time. The treaty clearly provides that until economic and practical alternatives are found, so long as continued research is being done, the industry should have CUEs.

The United States government must support the U.S. agricultural economy in ensuring that methyl bromide remains available to growers, until suitable alternatives are found and can be implemented. We cannot simply bow to decisions which appear to be predetermined and which will put our agricultural sector at a very significant competitive disadvantage in the international marketplace.

The phase-out of methyl bromide is a critical issue for U.S. agriculture. We thank you for your interest and assistance in reaching a reasonable solution to what is rapidly becoming a crisis for many producers, and the workers they employ across the United States.

Mr. WHITFIELD. Thank you, Ms. Keeler.
And Mr. Murai, you are recognized for 5 minutes.

STATEMENT OF MARK MURAI

Mr. MURAI. Good morning, Mr. Chairman. Chairman Whitfield, Ranking Member Rush, and members, thank you for holding a hearing on this very important issue. My name is Mark Murai and I am a third-generation strawberry farmer and president of the California Strawberry Commission, representing all of California's strawberry growers, shippers, and processors.

Farmers lead the way in the world to find alternatives. The United States has eliminated over 90 percent of ozone-depleting products and the ozone layer is healing faster than predicted. As we all know, legacy fluorocarbons, CFCs, from a variety of consumer products such as plastics, foam, solvents, and fire extinguishers——

Mr. WHITFIELD. Sorry. You can continue.

Mr. MURAI [continuing]. Are the largest impact on the ozone layer. Because these legacy fluorocarbons have a long life, the scientists forecast it will be another 39 years before the ozone layer is fully restored. But methyl bromide can also impact the ozone layer, and I am proud to say the strawberry farmers have taken this seriously. We have innovative new farming techniques such as drip fumigation and employed new technologies such as emission reduction measures to reduce our methyl bromide imprint.

California strawberry farmers are also leaders in organic production methods. These farmers grow more organic strawberries than all other 49 States combined. In fact, nearly 1 out of 5 California strawberry farmers grows both organic and conventional.

By combining all of these approaches, California strawberry farmers transition to non-methyl bromide alternatives faster than any other strawberry farmers in the world. And unfortunately, we have learned that there are still some diseases that can only be treated by methyl bromide.

In the late '90s, I made the decision to phase down my farm's use in methyl bromide ahead of the official 2005 deadline. I was past chairman of our Research Committee and an officer of the Commission, so I believed my family's farm should demonstrate that using alternatives were feasible. I was confident; I was cavalier. The first year, the yields looked comparable. The second year, my new plants didn't look so good, a little peaked. And by the third year, my field was dying before I picked my first berries. Calling your banker is a difficult call to make having to explain your field is dying, and notwithstanding a miracle, I would not be able to pay back my crop loan that year. And by the way, I need to borrow more money for next year's planting in a few months. That is a tough call to make.

But the worst part was telling my family that we are deep in the hole and our soil is now contaminated with disease. That is a tough thing for a farmer to swallow. So farmers need clean soil.

As you can see in my written testimony, I am not alone in my experience. After multiple years of repeated use of alternatives, we learned that alternatives do not work on all the soil-borne diseases.

In 2008, we saw the emergence of new diseases that resulted in widespread crop failure.

The CUE process needs to be improved. In 2011, a new fumigant called methyl iodide was approved for use in California. Everyone thought the fumigant would be an effective treatment for these tough soil-borne diseases. EPA immediately rushed to try and force farmers to use methyl iodide. EPA stated, "our 2013 critical use nomination assumes an aggressive transition rate to methyl iodide of 7 percent per year between now and 2013 and resulting in a reduction of 21 percent." When I heard this, I could hardly believe my ears. Doesn't EPA know about the community concerns in California? We specifically made a trip to EPA to show news clips and newspaper articles to give them a flavor of what we were going through back in California and how our communities and State and legislators were in an uproar around this compound. There was an obvious disconnect between DC and our farming communities. And we believed at best our transition, if this product was registered, would be at a rate of maybe 1 to 2 percent and that was aggressive.

Well, 4 months ago, the manufacturer decided that this controversy was too big and they cancelled methyl iodide in California. We immediately advised EPA and asked that they restore the 21 percent but they did not take any action to request a supplemental CUE for 2013. I wanted to believe our government would work to ensure that our critical needs were met within the rules of the treaty, but this has not happened. At every turn, there is always another arbitrary reason our application should be cut. This is just not right. Our farmers have followed all the rules, but now EPA doesn't want to follow the rules. They should substantiate their new reasons with data standards that we are held to. I should be able to go back and tell our growers that the system is fair, the interpretations are correct, and we should all just live with it, but I can't.

The new science report on methyl bromide CUEs, perhaps what is most frustrating is that nobody seems to be following the science. Scientists have always described methyl bromide as quickly dissipating in about 1 year and having a relatively smaller impact compared to other ozone-depleting products. The newest scientific assessment by NOAA, NASA, UNEF, WMO, and the EU concludes the ozone layer is improving faster than predicted due to legacy products that were required by 39 years to fully restore the ozone layer and continued use of methyl bromide will add less than 73 days to the 39 years. More specifically, the report stated, "the scientific assessment of ozone depletion 2010 is the product of 312 scientists from 39 countries of the developed and developing world who have contributed to its preparation and review, 191 scientists prepared the report, and 196 scientists participated in the peer-review process"—196. They said methyl bromide "continuing critical use exemptions at the approved 2011 level indefinitely would delay the return of the equivalent effective stratospheric chlorine 1980 levels by .2 percent of a year.

Mr. WHITFIELD. Mr. Murai, your testimony is very interesting and you have gone over considerably, so if you would try to summarize it here, we would appreciate it.

Mr. MURAI. Sorry about that.

So what is the benefit to the economy of allowing continued use of methyl bromide while the California Department of Food and Agriculture commissioned an economic study and they said if there is no methyl bromide and no methyl iodide, the California communities will lose over $1.5 billion annually and more than 23,000 jobs annually.

So if all the scientists and economists are accurate and the environmental impact of continued use of methyl bromide CUEs would just add no more than 73 days to a 39-year schedule while the economic downside for not allowing this would be $58 billion and 897,000 jobs over those same 39 years, I just ask please bring some common sense to this issue and restore our CUE. Thank you for your time.

[The prepared statement of Mr. Murai follows:]

U.S. HOUSE OF REPRESENTATIVES

Testimony Before the Sub Committee on Energy and Commerce

Hearing on U.S. Agricultural Sector Relief Act of 2012 & The Asthma Inhalers Relief Act of 2012

Mark Murai, President
California Strawberry Commission

7/18/2012
Washington, D.C.

PREPARED TESTIMONY OF MARK MURAI

At Congressional Hearing:

Sub Committee on Energy and Commerce

July 18, 2012 in Washington, D.C.

Good morning Mr. Chairman and Ranking Member.

My name is Mark Murai. I am a third-generation strawberry farmer and president of the California Strawberry Commission. I represent all of California's strawberry farmers, shippers, and processors.

Thank you for holding a hearing on the topic of the Montreal Protocol. It is critical that all of us achieve economic and environmental progress together.

Farmers Lead the World to Find Alternatives

The United States has eliminated over 90% of ozone depleting products and the ozone layer is healing faster than predicted[1]. I am proud to say that strawberry farmers have taken this seriously. We have innovated new farming techniques (such as drip fumigation) and employed new technologies (such as emission reduction measures) to reduce our methyl bromide imprint.

California strawberry farmers are also leaders in organic production methods. These farmers grow more organic strawberries than all other 49 states combined. In fact, nearly one out of five California strawberry farmers also farm with organic methods.

[1] *Scientific Assessment of Ozone Depletion: 2010.* National Oceanic and Atmospheric Administration, National Aeronautics and Space Administration, United Nations Environment Programme, World Meteorological Organization, European Commission

Largely due to our commitment, the U.S. Environmental Protection Agency (EPA) awarded California strawberry farmers with the 2008 Stratospheric Ozone Protection Award for transitioning more strawberry acres to alternatives, faster than any other place in the world.

We are not resting on this success. We continue to innovate and seek alternatives. Most recently, we expanded our partnership with California's EPA in a joint research project aimed at finding fumigant alternatives. As these efforts move forward, it is essential that EPA adopt a more balanced approach that recognizes our accomplishments as well as the realities of farming.

Farmers Need Clean Soil

Specifically, strawberry farmers require clean soil, free of harmful bacteria, fungus, and pathogens. To fully grasp the seriousness of soil disease, one only needs to remember the Irish potato famine, where an entire nation and crop was decimated by germ-infested soil.

The same is true of our crop: in the past century, strawberries have been repeatedly wiped out by disease. Notwithstanding its damage to the ozone, methyl bromide revolutionized farming because it cleaned the soil, protecting our plants and livelihoods.

When EPA told us to replace methyl bromide with other fumigants we did so. At first, we switched to drip applied alternatives. However, after multiple years of repeated use of the alternatives, we learned that they did not work on all of the soilborne diseases. In 2008, we saw the emergence of new diseases that resulted in widespread crop failure[2]. The following images show the impacts.

[2] Dr. Tom Gordon, *Professor and Chair, Department of Plant Pathology, University of California, Davis,* letter to Dr. Dan Legard. July 25, 2008.

2008, California Strawberry fields in a state of collapse after being treated with non-methyl bromide alternatives that were not effective against soil borne disease.

The CUE Process Needs to be Improved

In response to this new data, we submitted a request to EPA for a Critical Use Exemption (CUE) that would allow us to clean the soil of these diseases. We proposed that we could reduce methyl bromide use by using the alternatives for several years and then cleaning the soil with methyl bromide once every three or four years. In other words, we proposed a system to rotate different treatments that would achieve both reduced use of methyl bromide as well as clean soil.

Unfortunately, the EPA responded by telling farmers to use methyl iodide instead. More specifically, EPA stated, "Our 2013 critical use nomination assumes an aggressive transition rate to methyl iodide of 7% per year between now and 2013, resulting in a reduction of 21%..."[3] ...However, methyl iodide registration has been canceled in California and the registrant has withdrawn the product.

[3] *EPA Communique to the Montreal Protocol,* via the U.S. Department of State. August 25, 2010,

We requested that EPA restore the amount of methyl bromide immediately, but they have not yet taken any action to help the farmers.

New Science Report on Methyl Bromide C.U.E.'s

The newest scientific information by 312 international scientists sponsored by NOAA, NASA, UNEP, WMO, and the E.U. report that:

- The ozone layer is improving faster than predicted.
- It will require about 39 years to fully restore the ozone layer to 1980 levels.
- Methyl bromide C.U.E.'s will have virtually no effect on the 39 year schedule.

More specifically, the report stated,

> *"...the Scientific Assessment of Ozone Depletion: 2010 is the product of 312 scientists from 39 countries of the developed and developing world who contributed to its preparation and review (191 scientists prepared the report and 196 scientists participated in the peer review process)."*
>
> ***"Methyl bromide:** Continuing critical-use exemptions at the approved 2011 level indefinitely would delay the return of EESC to 1980 levels by 0.2 year."*

In other words, indefinite use of methyl bromide at 2011 C.U.E. levels would delay the repair of the ozone layer by 73 days.

What is the benefit of allowing continue use of methyl bromide?

The California Department of Food and Agriculture commissioned an economic study by the University of California Davis. This report states that if there is no methyl bromide and no methyl iodide, California communities will lose over $1.5 billion annually and more than 23,000 jobs annually[4].

[4] *Costs of Methyl Iodide Non-Registration: Economic Analysis.* Goodhue, Rachel, Howard, Peter, Howitt, Richard. California Department of Food and Agriculture. May 2010.

If all of the scientists and economists are accurate, the environmental impact of continued methyl bromide C.U.E.'s would add less than 73 days to a 39 year schedule, while the economic benefit will be $58 billion and 897,000 jobs, over those same 39 years.

Please help to bring some common sense to this issue and restore our C.U.E.

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DAVIS, CALIFORNIA 95616-8680

25 July 2008

Dan Legard, Ph.D.
Director of Research
California Strawberry Commission

Dear Dan:

As per your request, I am providing you with a brief summary of observations and laboratory results related to recent problems affecting strawberry fruit production fields in the Oxnard/Camarillo area. In June of this year, dead and dying plants were sampled in four fields that received pre-plant bed fumigation with something other than methyl bromide. Plants from three of these fields were similar in that a species of *Fusarium* grew directly from the water conducting tissue (xylem) in the crown. In some cases, the same fungus was also recovered from petioles. It is very unusual to recover fungi from within the vascular tissue unless they are pathogenic. Thus, although not all tests have yet been completed, it highly likely that the fungus recovered from diseased strawberry plants is a vascular pathogen. Such a pathogen, a specialized strain of *Fusarium oxysporum*, is known from Japan and may have been introduced into California. Most likely prior use of effective fumigants prevented the pathogen from becoming established. In the absence of such treatments, there is a great risk that this pathogen will become more widespread and have a significant negative impact on strawberry production throughout California.

In the fourth field, although symptoms appeared superficially similar to those in the other three fields, *Fusarium* was not recovered from any of the sampled plants. Instead, *Macrophomina* grew luxuriantly from the crown tissue of all plants. Thus, it appears that at least two different fungal pathogens may be responsible for the increasingly common collapse problems observed in Southern California. As with *Fusarium* it seems likely that problems caused by *Macrophomina* will become more common in the absence of recourse to effective fumigants, such as methyl bromide.

Please let me know if I can provide any further information on this.

Sincerely,

Thomas R. Gordon
Professor and Chair
Department of Plant Pathology

Mr. WHITFIELD. Thank you.

And I thank all of you for your testimony.

At this time, we will have some questions for you and I will recognize myself for 5 minutes of questions.

Mr. Murai, Mr. Doniger in his testimony said that California strawberry growers have led the pack in coming to Congress playing the hardship violin. And he said that your growers have done very well, you have increased your yields, you have increased the strawberry acreage, and that you all are doing very well. But from what you said, that doesn't sound like that is the case. Now, have you increased your yields? Have you increased your acreage or——

Mr. MURAI. Yields have increased and it has barely kept us floating. The margins are razor thin. I think the economic studies only show one side of the story, and I don't think I would even really be here if we were doing well, right?

Mr. WHITFIELD. Yes.

Mr. MURAI. I think this is a priority and an important issue because the growers are in a risky situation, very difficult to plant. The bankers are even asking about what are you doing to ensure——

Mr. WHITFIELD. How much do you borrow to put out a crop?

Mr. MURAI. It is about $20 to $22,000 per acre per year.

Mr. WHITFIELD. And what about you, Ms. Keeler?

Ms. KEELER. At the high end, we are at $60,000, so between $20 and $60,000 depending on the varieties. I——

Mr. WHITFIELD. Per acre.

Ms. KEELER. Per acre.

Mr. WHITFIELD. And Mr. DiMare?

Mr. DIMARE. The operating costs alone are around $10,000 an acre. That doesn't include harvesting or land cost or anything like that.

Mr. WHITFIELD. Mr. Costanza?

Mr. COSTANZA. Our operating cost per acre is between $10 and $12,000 an acre per year.

Mr. WHITFIELD. Yes. Now, from my understanding, it is very difficult to obtain a critical use exemption for methyl bromide, is that correct, Mr. Costanza?

Mr. COSTANZA. Yes. In our case, we were told we were going to have Midas to use this year.

Mr. WHITFIELD. OK. What about you, Mr. DiMare? Have you tried to get a critical use exemption?

Mr. DIMARE. Yes, it is an exhausting process.

Mr. WHITFIELD. Ms. Keeler?

Ms. KEELER. Yes, we have been part of the process from the beginning. And like I said earlier, it is a very time-consuming process, and private sector, we are doing a tremendous amount of research looking for these alternatives. There seems to be this idea that we are not doing this research looking——

Mr. WHITFIELD. Right.

Ms. KEELER [continuing]. For alternatives and we just want this simple free ticket for methyl——

Mr. WHITFIELD. Right.

Ms. KEELER [continuing]. Bromide. It is not an easy process.

Mr. WHITFIELD. Yes. Mr. Murai?

Mr. MURAI. Yes, Mr. Chairman, every year.

Mr. WHITFIELD. Yes. Mr. Doniger mentioned that in other countries, Mexico, Italy, so forth, that they are using less methyl bromide and being quite successful. What would be your reaction or statement or comment about that? Or do you have any information about it, any of you?

Ms. KEELER. In our industry, I can comment to that. Mexico produces some pretty unsophisticated flowers, so they have no need for it. And my family immigrated from Italy and we still have some connections there, and in the EU, the same thing is happening there. The EU is off-shoring a lot of their flowers over to Africa. And so like we are seeing flowers going down to the South American countries. The Italian growers are getting rid of the same products we are getting rid of for the same problem——

Mr. WHITFIELD. Yes.

Ms. KEELER [continuing]. And they are being grown in Africa for some of those countries.

Mr. WHITFIELD. You know, one of the common things that seems to be coming through a lot of hearings that we have is that we are hearing a lot of concerns about EPA that many people in various businesses dealing with EPA view them almost as an adversary. And I would just like to ask you, do you view EPA as a partner trying to help solve a problem or do you view them as an adversary?

Mr. MURAI. Well, the actions result in an adversarial result. I would say we work closely and try to collaborate and really flesh the data out. You know, like Mr. Doniger said, we want to put up a nomination that is credible and we are using the best data.

Mr. WHITFIELD. Yes.

Mr. MURAI. And so I think we try to have a collaborative effort but there is nobody listening over there.

Mr. WHITFIELD. So you feel it is an adversarial relationship, is that correct?

Mr. MURAI. Yes, at times——

Mr. WHITFIELD. Ms. Keeler, what about you?

Ms. KEELER. Yes, like Mr. Murai, I hate to use that word because we have been trying to work with them and so we are all going to this international body together——

Mr. WHITFIELD. Yes.

Ms. KEELER [continuing]. But at the end when our application just gets denied and we don't really get the scientific research of why our crops were denied, it is——

Mr. WHITFIELD. OK. Mr. DiMare——

Ms. KEELER [continuing]. Hard to say we work together.

Mr. WHITFIELD [continuing]. What about you?

Mr. DIMARE. I feel basically the same way they do. We try to work in concert with them——

Mr. WHITFIELD. Mr. Costanza, how do you feel?

Mr. COSTANZA. I invited EPA out to our farm——

Mr. WHITFIELD. Yes.

Mr. COSTANZA [continuing]. And their minds were made up before they got there.

Mr. WHITFIELD. OK.

Mr. COSTANZA. They didn't want to hear what we had to say.

Mr. WHITFIELD. OK.

Mr. COSTANZA. They didn't want to see what we had to show them.

Mr. WHITFIELD. Now, without methyl bromide and this methyl iodide, is there something else you can use?

Mr. DIMARE. Well, it depends on where you are at in the country. Even in the State of Florida we have from one end to the other Telone cannot be used in south Florida because of the groundwater issue——

Mr. WHITFIELD. Yes.

Mr. DIMARE [continuing]. But we do use that as one of the alternatives in other places——

Mr. WHITFIELD. Yes.

Mr. DIMARE [continuing]. As well as others. Methyl iodide that they are talking about is gone in the U.S. It is off the shelf. They have taken it away so that is not an alternative anymore.

Ms. KEELER. And some of those alternatives have different buffer requirements, so for us in San Diego you can't really picture a farm like out in the middle of Iowa.

Mr. WHITFIELD. Yes.

Ms. KEELER. We have houses and industry coming right up to us. So buffer zones, township caps put a lot of limitations on——

Mr. WHITFIELD. Well, my time is expired but I mean it is pretty clear that all four of you feel like methyl bromide is essential and that is my impression.

Mr. Rush, I recognize you for 5 minutes.

Mr. RUSH. Well, and thank you, Mr. Chairman.

Mr. Doniger, somehow I am feeling like I am a registration clerk at heartbreak hotel when I listen to the testimony of some of the witnesses here. And, first of all, you raised your finger up because you wanted to react or respond to something that I think Ms. Keeler said. Is there something that you wanted to respond to?

Mr. DONIGER. Well, I wanted to make one point in connection with the issue of whether the relationship with EPA is adversarial. If anything from the environmental perspective I see the EPA bending over backwards to service these applications, to consider these applications. I thought they were grossly too large in the beginning. The numbers have come down. That is true. But I would offer you one factoid to think about. To my knowledge, there has not been one lawsuit filed against EPA for denying these applications. There has not been one agricultural association or individual grower who has taken EPA to court over these supposedly too-small allocations. What other industry hasn't sued EPA? It is very hard to take the matter that seriously if that is the situation we have. I mean I don't want to encourage these guys to sue EPA but everybody does.

Mr. RUSH. This industry is one of EPA's favorite industries, then, whether they are being adversarial.

Let me just move on. What are some of your biggest concerns with the definition of critical use in the discussion draft that is before us today?

Mr. DONIGER. Well, the most serious problem is the—the two problems are, one, putting into law a list of critical uses. The idea is supposed to be dynamic, that some uses would start out being

critical, and then as alternatives were found, they would no longer be critical and they would drop off the list. And that in fact is what has happened. Now, some of the growers can have concerns about individual decisions but that is the way it is supposed to work. You work your way to alternatives and then that use is no longer a critical use exemption. So why would we go back to the original list?

The second thing is how is it going to work now? A grower can write on a piece of paper I need x tons. I don't have to tell you why. I don't have to give you any information or evidence about what I tried and whether it works and so on. It is now up to you, EPA, to tell me why I don't need that many tons and you would have the obligation, EPA, to go abroad to the other countries and say this is what my guys say they need. So where is the support for it? The reason that the exemptions have been granted—and more than 88 percent, I think, nominations have been granted—is that the U.S. comes in frankly with a bulldozer of a case for each one. And that starts with the growers being challenged frankly to come up with a very convincing case, that they have tried all the alternatives, that they don't work in these particular situations and thus the methyl bromide is still needed. When you get a case that is sound, the nominations are forwarded and the nominations are granted.

Mr. RUSH. Do you share my concerns with the provision of the bill that would shift the burden of proof to the EPA and that a requested use of the exemption is unwarranted?

Mr. DONIGER. Yes, I mean that is what I am saying leads to the counterproductive result because if the U.S. goes to the other parties and says this is the piece of paper I got. I don't have any scientific backup or I don't have the full backup I used to have, but my guys say they need it so I say I need it. It is not a very persuasive case. And it is more likely to lead to the nominations being turned down than the current situation.

Mr. RUSH. How would this bill impact the Clean Air Act in your opinion?

Mr. DONIGER. Well, right now, the Clean Air Act allows for the critical use exemptions and that is the process under which the nominations have been made for the last seven years and the requests have been made by the government to the treaty parties and that is the process that is working. The folks here are concerned, some of them, that, gosh, there is some expense involved, there is some work involved in making the applications. And even the best applications you only get, you know, roughly 90 percent of them approved by the parties.

Remember that all the other strawberry-growing and tomato-growing countries in the western world have stopped using methyl bromide. So they look at these applications and say what is going on? Why can't the U.S. do what we do in Australia, Greece, Italy, Spain with respect to strawberries and tomatoes? And it is a tough sell. So if EPA doesn't get the full dossier of data from the growers, they are not going to be able to make that sale and I don't think they should make that sale.

Mr. WHITFIELD. Gentleman's time is expired.

At this time, I recognize the gentleman from Oregon, Mr. Walden, for 5 minutes.

Mr. WALDEN. Mr. Chairman, thank you. And I want to thank our panel of witnesses, appreciate your testimony and the answers to the questions the subcommittee has posed.

Mr. Murai, do you want to take what the gentleman just said, so when it comes to dealing with strawberries and all, what is your take on what he just said about the international situation and be able to explain why every other country doesn't use methyl bromide and we need to?

Mr. MURAI. I think those growers need a process that they can come to a hearing like this and voice their opinions, because I visited those growers and they are under extreme pressure of disease. They are exporting strawberry-growing to Morocco. They are exporting the problem rather than dealing with it in their own community and that is what our California strawberry growers are trying to do. We are trying to deal with it in our own community but the rules keep changing every page we turn. And that is what we want. We need transparency, we need accountability, we need data coming back that shows the argument coming back, not just arbitrary. The process is broken. I don't want to say we are adversaries but it is broken and it needs to be fixed. I want to go back to my growers and say this is the way it is, guys, or ladies. This is the way it is. But I can't say that with conviction because I know how broken it is.

Mr. WALDEN. I appreciate that. You know, methyl bromide has obviously been used in nursery crops in Oregon. It is a nursery business, of course, one of our biggest in Oregon. I know they had a big outbreak of potato cyst nematode in Idaho recently. And while they don't usually use methyl bromide for potatoes, it has been successfully used against potato cyst nematode, which, as you know, can just wreak havoc on potatoes if it gets away from them. And I know the industry is conducting research to find alternatives but none have been found to date. Can any of you speak to the potato side of the world and what happens in that respect?

Mr. MURAI. I can't speak to the potato crop but I would only add that the strawberry industry went through the same types of mass destruction. And what we are trying to do is provide food for the world with a consistent supply of healthy nutritious food, and I think we go to school and we learn the newest techniques and we try to innovate——

Mr. WALDEN. Um-hum.

Mr. MURAI [continuing]. To try to avoid mass destruction of crops. We don't need to go back to the potato famine days. Why do we have to revisit that where people are suffering? That is not what our intent is, and as farmers, we want to feel good about what we do and provide that food and we will work within the rules. But the rules and the structure and the process must be corrected.

Mr. WALDEN. And can you elaborate on the efforts that have been undertaken by the strawberry sector to identify potential alternatives?

Mr. MURAI. We have invested over $10 million over the last 15 years to look at steaming the soil using anaerobic soil disinfestations. We are looking at growing strawberries in substrate, peat moss, coconut coir, but there are other issues around that. How

sustainable is that when our strawberry industry would use up the North American supply of peat moss in 1 year? Or steaming takes 21 hours to steam an acre of strawberries right now. How much fossil fuel is needed, how much emissions are needed to steam one acre? You know, 20 hours.

Mr. WALDEN. How many acres do you have in production, strawberries in California?

Mr. MURAI. Thirty-eight thousand acres in California.

Mr. WALDEN. That is a lot of steaming.

Mr. MURAI. And the——

Mr. WALDEN. Or you could just try and grow them here where we have steam all the time, or at least today, or a lot of hot air.

Mr. MURAI. The funny part is you have to soften the water before you put it through the steamer. So we have to have a water softener on the road with the long hose that takes it to the big steaming machine, and the steaming machine creeps along, inches, and covers 1 acre in 21 hours.

Mr. WALDEN. So what does that mean to your cost, your ability to compete?

Mr. MURAI. There is not enough time in the year to put your crop in.

Mr. WALDEN. So I guess the question is how do these other countries grow strawberries without using methyl bromide? Do they just have different pests and different issues?

Mr. MURAI. They are trying to grow in substrate. If you go into like northern European areas, they are growing in a lot of the coconut coir ——

Mr. WALDEN. I see.

Mr. MURAI. —but even that is becoming controversial there. So, you know, you move to one solution but it creates other problems.

Mr. WALDEN. Got it.

Mr. MURAI. And I think that is where we need a comprehensive look and a realistic look, right?

Mr. WALDEN. Yes, I appreciate that. I know my time is expired. I grew up on a cherry orchard and represented a lot of ag interests in Oregon, farmers and ranchers that just feel like there is a whole onslaught out of the Federal Government that is going to shut down our way of life in the West and especially on the farms.

Mr. MURAI. We are California farmers and we want to stay in California.

Mr. WALDEN. Yes. Well, we Oregonians want you to stay in California. It has been an issue dating back—no, I am just kidding. Yes, but——

Mr. MURAI. That is a good one.

Mr. WALDEN [continuing]. We want you to come up and spend your money in Oregon, then go back. Thank you. Thanks for your testimony.

Mr. WHITFIELD. Mrs. Capps, you are recognized for 5 minutes for questions.

Mrs. CAPPS. Well, thank you, Mr. Chairman.

As my colleague knows, I was trained as a nurse in Oregon and I moved to California so, you know, I guess it can go both ways, just an aside. And actually, I want to thank you because I know this is not the same as standing in the fields, but we are getting

close to getting the feeling of what the various challenges are to complying with regulations that I believe in with all my heart but that are complicated and need to have a discussion. If you can't be there to smell the strawberries and see for ourselves what the peppers are like in the fields, we need this kind of discussion. We need this back-and-forth and this give-and-take.

And I was going to continue the same line with you, Mr. Murai. I have got two Californians here I am going to pick on for my time. I know growers have put millions of dollars into developing alternatives to methyl bromide. Could you continue this explanation of why your growers are putting so many valuable resources into finding these alternatives? And you are not doing it just because of the Montreal Protocol. It is not just that.

Mr. MURAI. I think we are trying to improve and innovate our practices to be an example for the world. And the regulatory environment and the environmental laws are very strict in California. It is a whole other layer, and I believe that is what the world bodies don't understand is the sovereign power within California to have those laws, but the California growers will meet that challenge. We have invested our resources, we have put in a lot of time, we have lost a lot of crop——

Mrs. CAPPS. Um-hum.

Mr. MURAI [continuing]. In this time frame and we have had a lot of hurt. And I think that is why we believe in what the Montreal Protocol is doing and we want to be part of the solution, but we also have to understand if there are exemptions due to critical use, they should be recognized and held to a standard as the applicant is doing. So if there is a change in the nomination put forth to the United Nations unbeknownst to the California strawberry growers and in our application, we should understand why they are doing that and what data backs that up.

Mrs. CAPPS. OK. Ms. Keeler, would you agree that the flower growers are similarly committed to phasing our methyl bromide and finding alternatives?

Ms. KEELER. Absolutely. I can only repeat what Mr. Murai just said. Our industry is absolutely committed. We have a much more dynamic industry with so many different crops and varieties, so there has been a tremendous amount of research that maybe something works in one crop, we try it in a different crop. We have actually teamed up with the strawberry growers. We share our information——

Mrs. CAPPS. Yes.

Ms. KEELER [continuing]. University, private sector, we put in so much research into this. And like Mr. Murai said, we want to cooperate. We believe in the Montreal Protocol.

Mrs. CAPPS. Well, as Mr. Murai told me before, you are there, you breathe the air, your families are suffering whatever health consequences there are to whatever you put into the soil.

I wanted to move on if I could—I didn't mean to interrupt you—but Mr. Murai, you mentioned the CUE process, which I am going to expand on just briefly. When the critical use exemption process is working, growers get the methyl bromide they need while you also phase out its use and incentivize the development of viable alternatives. No matter how well designed, however, no complex

international system can fully anticipate every issue that may come up down the road, and that is why we always need to be looking at ways to improve and adapt the system to the current needs of its stakeholders while still moving forward, ultimately achieving its original goals.

Mr. Murai, I am aware of several fields in Ventura County, California, which is in my district, that have had some issues transitioning to Telone. And I know that California has banned certain alternative chemicals like methyl bromide for its cancer-causing and water-polluting qualities, yet EPA has not responded accordingly. Perhaps, Mr. Murai, you could expand on that just a little, touch on the types of flexibility and coordination that could be built into the current system to help prevent these problems in the future.

Mr. MURAI. Well, we are very intentional on maximizing the alternatives that are available within the law and we explain that in our application every year. And what changes, though, sometimes when you are using some of these alternatives, they don't do a thorough enough job. And so in order for a family farm not to abandon their land, they need to be able to have a way to clean that soil up and make it healthy again. And, you know, in this global economy, we are moving products back and forth and think new pests are coming in, new diseases, and there has got to be a mechanism. The authors of the protocol were very smart and that is why they wrote it in the critical use exemption because they anticipated there might be critical needs.

Mrs. CAPPS. Could I ask for time to ask one further question? I know I have used my time.

Mr. WHITFIELD. Yes, your time has expired.

Mrs. CAPPS. All right.

Mr. WHITFIELD. Thank you.

Mrs. CAPPS. Thank you.

Mr. WHITFIELD. At this time, I would like to recognize the gentleman from Texas, Mr. Barton.

Mr. BARTON. Mr. Chairman, my questions are for the second panel, so I am——

Mr. WHITFIELD. OK.

Mr. BARTON [continuing]. Going to defer or yield back.

Mr. WHITFIELD. Then I recognize the gentleman from California, Mr. Bilbray.

Mr. BILBRAY. David, would you upgrade me on the latest status? We are talking strawberries and I know we have had a conflict and have consistently had a conflict between EPA and ag on importation of certain issues. What alternative to methyl bromide has the ag people put on importation of strawberries, the fumigation of those fruits? Do you know——

Mr. DONIGER. I think you are asking, Congressman, about quarantine of pre-shipment?

Mr. BILBRAY. Yes.

Mr. DONIGER. And I am not sure I precisely understand your question——

Mr. BILBRAY. We have run into——

Mr. DONIGER [continuing]. And I am not sure I know the answer.

Mr. BILBRAY. You know, when I was working the Air Resources Board when I got over here we had this big conflict because the accord we were trying to follow but then we had the Federal Government mandating the use of methyl bromide as a condition of importing certain fruits——

Mr. DONIGER. Right.

Mr. BILBRAY [continuing]. And vegetables.

Mr. DONIGER. So one of the problems in that field, which is outside the scope of this bill, is double-dosing where the importing country requires the treatment even though it may have been treated on the way out of the exporting country. So I think there has been some progress made in reducing that kind of double-dosing.

Mr. BILBRAY. But they are still looking at methyl bromide as being their——

Mr. DONIGER. Well, this is an area where sulfuryl fluoride may be quite promising and——

Mr. BILBRAY. Maybe, but, you know, I——

Mr. DONIGER. No, I mean more than that. It is almost ready to be approved as a substitute for methyl bromide in certain quarantine uses. And sulfuryl fluoride was mentioned in the beginning if I may——

Mr. BILBRAY. No, no, no, no, wait, wait a minute.

Mr. DONIGER. I just want to make sure people——

Mr. BILBRAY. Let me double back——

Mr. DONIGER [continuing]. Understand that NRDC is opposed to the withdrawal of the tolerances for sulfuryl fluoride.

Mr. BILBRAY. OK. My biggest concern is that we have known since the early '90s there was a conflict between our mandated procedures in one department and a treaty that we were agreeing to in another. And it has been at least 15 years, if not 20 years, we still haven't kind of put that together.

Mr. DONIGER. The treaty doesn't cover quarantine and pre-shipment.

Mr. BILBRAY. OK.

Mr. DONIGER. I believe it should but it doesn't. So there are no restrictions on quarantine and pre-shipment use of methyl bromide under the treaty.

Mr. BILBRAY. OK. I appreciate you clarifying that. It is frustrating to me to see the government that says this is so essential that we reduce the use and everything else.

And Mr. Chairman, you know, my family has been personally affected by diseases directly related to the ozone issue. So I really believe, you know, this is a concern. But it is a reasonable application of the concept. I think any law, no matter how good intentioned, if there isn't a reasonable application, there is going to be major problems of not only unforeseen adverse impact but also unforeseen inefficiency in acquiring the original goal. And that is one of the things I want to address.

And Dave, why I asked you about that is that we talk about priorities in the Federal Government but it isn't reflected by our actions at getting to go. We always love to say no. It is easier to say no. But getting to go, getting to an alternative answer, we know what is bad but getting to what we are willing to say is good takes

20 years at a time that we are saying the ozone is being depleted as we speak, people are going to be dying, but don't ask me to rush to finding a viable alternative. And I think there is an obligation that those of us in the system, if we want to claim the moral high ground like some members on this committee love to do, that we are saving lives and we are avoiding this and that, we have more of a responsibility than just saying no. We have a real obligation to find a yes and doing it quicker than 20 years down the pike.

Mr. DONIGER. Well, the one thing I think we can all agree on is that there has been—all of the witnesses here can agree on—is there has been a lot of progress in phasing down methyl bromide. If you had this hearing 5 years ago—actually, you did have this hearing 5 years ago—the crisis of impossibility of terrible impact was at the then current level where we are now down some 80 or 90 percent below that. And that is why the critical use exemption process is there. If the case can be made, the exemption should be granted.

Mr. BILBRAY. I just worry we are quick here to put regulations on to outlaw stuff and we are not quick here at creating the vehicles to create an opportunity to make that product obsolete. In other words, just outlawing something is not answering the problem. The problem is identifying the problem and then finding an alternative answer to be able to move things forward without the social economic impacts and the health impacts that may be related.

Mr. DONIGER. There has been a fair amount of USDA research and we would have supported there being more to help the growers find these alternatives.

Mr. BILBRAY. Well, I would just say 20 years is pretty slow.

Mr. WHITFIELD. The gentleman's time is expired.

At this time, I recognize the gentleman from Louisiana, Mr. Scalise, for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman, appreciate you having this hearing on these two bills that——

Mr. WHITFIELD. Mr. Scalise, I am sorry. I didn't see Mr.——

Mr. SCALISE. Oh, I will yield to the gentleman from Michigan.

Mr. WHITFIELD. OK, you go ahead and then I will come back to Mr. Dingell. Thank you.

Mr. SCALISE. All right. Thank you, Mr. Chairman. I thank the former chairman, the gentleman from Michigan.

As we are talking about strawberries, I, you know, represent a city called Ponchatoula, and the Ponchatoula strawberries I would argue are the plumpest, juiciest, most bright red. We could probably have a taste test and we would both enjoy it. But, you know, I look at these new regulations and, you know, really have concern about what it is going to mean to those strawberry farmers in Ponchatoula just as it is a concern to those of you in whether it is California, Michigan, all across the country. Do you all have any estimates on how many jobs are at risk if this industry is threatened with the inability to use methyl bromide? I will just start with you, Mr. Costanza, and we can go down. Any kind of estimates on job losses that may be in play?

Mr. COSTANZA. On our farm presently we have about 125 employees. I am 30 employees short for harvest. We are leaving prod-

uct in the field. In the local economy in the State and Federal level, there is about four jobs for every farm worker I have on the farm. So the economic impact across the country if we are out of business is dramatic.

And I would like to mention that I have been to your district and I have visited some of your growers, Anthony Liuzza being one of them——

Mr. SCALISE. I know him well.

Mr. COSTANZA [continuing]. Looking for an alternative to use other than methyl bromide.

Mr. SCALISE. And what have you all been able to come up with?

Mr. COSTANZA. Nothing. We need a product that is affordable and that will produce——

Mr. SCALISE. And effective.

Mr. COSTANZA [continuing]. A crop that the public demands. Now, these European countries, they will accept a lower quality berry. Americans won't accept that quality. So——

Mr. SCALISE. And it is my understanding that under the protocol, developing nations are exempt from this. They don't even have to comply what is being imposed on you, but a developing country that competes against you would not have to comply, is that correct?

Mr. COSTANZA. My understanding that is correct but the other thing is accountability. How are you going to account for what goes into Mexico from China? How are you going to account for what goes into some of the European countries from China? How are you going to account for what goes into Morocco? Because they produce a lot of methyl bromide in China because we pay for the plant to be built.

Mr. SCALISE. Yes. And then that would be just more jobs outsourced, exported that we lose that go to foreign countries.

I want to ask Mr. Murai, because you represent the California growers, if you can give me any kind of estimates on jobs as well, kind of similar questions as I was asking Mr. Costanza. I am not sure if you have met Mr. Liuzza as well but he is a good man.

Mr. MURAI. Our California Department of Food and Agriculture commissioned an economic study with the University of California Davis, and their latest numbers show that without methyl bromide and without methyl iodide now, they are anticipating California communities would lose over $1.5 billion annually and more than 23,000 jobs annually.

Mr. SCALISE. How many jobs?

Mr. MURAI. Twenty-three thousand.

Mr. SCALISE. Just in California that would be lost?

Mr. MURAI. Just California coastal communities.

Mr. SCALISE. OK, thank you.

Mr. DiMare, if you can answer the same question?

Mr. DIMARE. I can't speak from a study standpoint on the data or statistics but just from our own perspective, on the one farm location that we have where I am at in central Florida is about 5 to 600 people, but for the whole company we are in the thousands. We employ thousands of people.

Mr. SCALISE. OK. And then Ms. Keeler.

Ms. KEELER. I don't have specifically those numbers. I could get them to you. The California cut flower industry is a $10 billion industry from farm to florist, so it is a pretty big industry. Our farm alone employs over 200 people for 400 acres. But I could get the stats to you afterwards.

Mr. SCALISE. OK. And then we don't have any kind of indirect jobs. You know, we are looking at this regulation. Unfortunately, if this was the only one, you could kind of isolate it and deal with it, but we have seen time and time again it is far from this one. We have already seen job losses in other industries due to EPA coming out with regulations that do nothing to address the problems they are concerned about. I mean if you are concerned about carbon emissions, jobs that are being sent overseas from greenhouse gas regulations, those countries where we lose our jobs to, they emit even more carbon.

You know, you look at this, you know, the farms, it is going to go to developing countries. These jobs will go to developing countries that under definition can still use the product. And so you just cost American jobs. You do nothing to reduce usage of the product. And again, it is one more regulation that makes no sense. I know we have got legislation that we passed called the REINS Act that tries to rein in some of these radical regulations.

But I know I am out of time. I appreciate the discretion, Mr. Chairman, and I yield back.

Mr. WHITFIELD. The gentleman's time is expired.

Mr. Doniger, you want to make a comment.

Mr. DONIGER. I would just like to correct the record on a couple of points. 1) Mexico is ending its use of methyl bromide this year, 3 years before the obligation. They have an obligation under the protocol to end it in 2015. They are ending it in 2012.

Mr. SCALISE. I don't know if you are correcting the record because other witnesses are shaking their head no.

Mr. DONIGER. Well, I am sorry. That is fact. The second fact I want to correct is that the United States didn't pay for or contribute in any way to the production capacity of China from methyl bromide, and it is because of this treaty that their production and use is also coming down. The treaty protects Americans because it controls the dangerous chemicals and the impact on the stratosphere around the world. We cannot protect our people by ourselves. That is why we need——

Mr. SCALISE. Can Mr. DiMare respond? Because it looks like he disagrees——

Mr. WHITFIELD. Well, now, the time is up but I am just going to make one other comment. You had asked the question about jobs and Mr. Murai in his testimony pointed out I believe that the California Department of Agriculture said without methyl bromide, that there would be a loss of 23,000 jobs annually, is that correct?

Mr. MURAI. Yes.

Mr. WHITFIELD. OK. At this time I recognize the gentleman from California, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman, and thank you, Mr. Dingell, for allowing me to ask my questions.

Mr. Doniger, the whole idea of the protocol international agreement is that we are not going to give an advantage to other coun-

tries. We are going to require everybody to reduce what is a threat to all of us in this planet. And in the case of CFCs, U.S. acted unilaterally and then moved forward. I sometimes think if we had that problem today, we would probably treat it the way we are treating greenhouse gases. They are not doing anything, we are not going to do anything. Cost us jobs? Well, we are not going to allow that to happen. And of course the result is every day we hear about another drought destroying the crops and I am sure more crops are being destroyed by the drought which I think has to do with global warming and climate change than the issue that we are discussing today, which is an important one but a very narrow one.

The bill freezes an outdated list of approved critical uses. As a result, sectors that have completely phased out the use of methyl bromide during the last 7 years would be allowed to use methyl bromide again. Incredibly, as I understand it, even golf courses would once again be allowed to seek critical use exemptions.

Let me ask, does anyone on the panel think that we should amend the Clean Air Act to allow sectors that have completely eliminated the use of methyl bromide to start using it again? No one? Do you think that we ought to allow sectors of our economy that have completely eliminated the use of methyl bromide to start using it again?

Mr. MURAI. Yes, because they were eliminated under false pretenses of an alternative being available and that alternative has been now taken off the market.

Mr. WAXMAN. I see. What alternative has been taken——

Mr. MURAI. Methyl iodide.

Mr. WAXMAN. I see. So you would let them—we would go back and allow methyl bromide——

Mr. MURAI. For critical use exemption——

Mr. WAXMAN. For critical use exemption.

Mr. MURAI [continuing]. Under the critical use exemption process.

Mr. WAXMAN. Well, do you think it makes sense to have a critical use exemption to allow golf courses—to allow the turf grass to be preserved with methyl bromide?

Mr. MURAI. I think if it is under the law, if it is within the law, it is within the law.

Ms. KEELER. And I think that is what Congresswoman Capps was asking earlier when she was talking about the flexibility and her time ran out. I can't speak to golf courses. That is not my area. But in some areas we thought we found an alternative in a certain crop and we tried it, and this is our commitment to the protocol. But sometimes you try something new and after 3, 4, 5 years, you find out there is a problem. A new disease develops. Something you thought was taking place didn't. So I think what Mr. Murai is saying if there is adequate information for a critical use exemption, whether it is golf courses, strawberries, flowers, that is how the protocol was written.

Mr. WAXMAN. Mr. Murai, the California strawberry growers are by far the largest remaining users of methyl bromide in the United States. I know you have concerns with the amount of methyl bromide available to your industry, but do you really think that this

legislation is the most constructive way to go about addressing these concerns?

Mr. MURAI. I think there could be several approaches and I think this has probably gotten to a point where we were so frustrated that we needed people to listen. We tried to collaborate with EPA. We tried to introduce what we best thought best information, put forth a package of application for the critical use exemption. If they could tell us otherwise based on data, then, you know what, that is how it is. But they weren't providing that data back, Congressman, and that is what bothered me about the system is when you can make a cut based off methyl iodide and now methyl iodide is gone, so what happens now with all the CUEs that have gone by the wayside because of this alternative? There needs to be some resolution to that.

Mr. WAXMAN. But I am concerned——

Mr. MURAI. There are no alternatives coming off the shelf ready for the field.

Mr. WAXMAN. I am concerned about the provision of the bill that would allow growers to obtain methyl bromide without a critical use exemption for so-called emergency events. This could create a big loophole that would allow for the use of large quantities of additional methyl bromide. Mr. Doniger, my understanding is that a Montreal Protocol decision allows for the use of methyl bromide in true emergencies. Do you know how many times this emergency event provision has been invoked?

Mr. DONIGER. Yes, it has been invoked twice and they were true emergencies, once by Canada and once by Australia. It was not a routine thing and that is what this bill would allow. Emergencies would become routine. It would be like every time you don't have enough money in your bank account, you just declare an emergency and write another check.

Mr. WAXMAN. Well, Ms. Keeler, in your testimony you argue that growers should be allowed to develop an emergency cleanup process that will allow you to go into your fields every few years and use methyl bromide to clean up any pests or diseases that have developed, is that right?

Ms. KEELER. What I was referring to, in our industry we have perennials we have to take out of the fields when certain diseases pop up. So we don't have situations in many of our crops where it is an every-year process. So the way that the protocol is set up in the application process, it is very difficult for us to fit in because we aren't scheduled.

Mr. WAXMAN. So it is not an emergency. It is the opposite of emergency. They are planned, routine use of methyl bromide without a critical use exemption.

Ms. KEELER. Well, I am referring to a cleanup process that would allow us to go in and clean those fields up when——

Mr. WAXMAN. Mr. Doniger, what do you think of that idea?

Mr. DONIGER. Well, I think if this problem of not needing it every year, you figure that out, you build that into the critical use exemptions. If the case can be made for it, that is what the critical use exemption process is for. The committee is approaching this as though there is no exemption and we need to create one. Actually,

there is one already and it is working. We don't need to enlarge it.

Mr. WAXMAN. Well, Mr. Murai doesn't think it is working.

Mr. MURAI. I think it has worked well for a while and I think lately in the last 2, 3 years it has gotten very tenuous because there hasn't been a real listening to what is really happening in the field. And so when we come to EPA with our package to demonstrate the need, it is very easily put forth, here is what you can do. In this case, methyl iodide was put forth and you are going to transition 21 percent in 3 years. I don't think so but OK. That went away. Now, there is no restoration for any of the crops that were dependent on methyl iodide based on EPA's aggressive nature with that product.

Mr. WAXMAN. So you think EPA is not being reasonable in deciding when emergency event should take place and this exemption should be allowed?

Mr. MURAI. Yes, I believe they are not being reasonable and I believe the rules change at every corner. And that is where I want to be able to go back to our growers and say, hey, the process is the process and it is correct, it is transparent, their interpretations are right on the science, and it is fair and we have to live with it. But I can't honestly go back to my growers and speak with conviction that that is the process right now. And that is what I am talking about today is that this process needs to be corrected.

Mr. WAXMAN. OK, thank you.

Thank you, Mr. Chairman.

Mr. WHITFIELD. At this time, I recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy. I am sorry.

Mr. WHITFIELD. Go ahead, Mr. Griffith.

Mr. GRIFFITH. Thank you, Mr. Chairman. I do appreciate that.

Mr. DiMare, a couple times Mr. Doniger has said that Mexico is outlawing the use this year or ending the use this year of methyl bromide, and each time you have indicated at least with your body language that you didn't agree with that, so I am giving you an opportunity now to explain what disagreement is with that or other statement regarding the use in other countries of methyl bromide you might have disagreed with Mr. Doniger on.

Mr. DIMARE. Well, you know, I don't know that that is written into law there, but I will believe that when I see it.

Mr. GRIFFITH. Trust but verify, is that what you are saying?

Mr. DIMARE. I am sorry?

Mr. GRIFFITH. Are you saying trust but verify?

Mr. DIMARE. That is correct.

Mr. DONIGER. It is a commitment that Mexico has made under the Multilateral Fund, which is part of the Montreal Protocol and it is in writing. It is referenced in my testimony.

Mr. GRIFFITH. I understand.

Mr. DONIGER. And it is firm.

Mr. GRIFFITH. I think what Mr. DiMare is saying, though, that illegal drug trafficking takes place, you know, on both sides of the border. It is written into law but he will believe that they stop using methyl bromide when he sees it because he is not sure they

are going to follow the law. I understand what you are saying but I understand what he is saying, too.

Mr. DONIGER. It is harder to get methyl bromide than it is to get illegal drugs.

Mr. GRIFFITH. And that is what, apparently, even the people who want to use it legally are saying and it is one of the reasons we need the bill is that it is harder to get methyl bromide than it is to get the illegal drugs. And they have got a concern and they are hoping that maybe it can be a little easier so they can use this substance legally and appropriately.

Along those lines, Mr. Doniger, is there anything in this bill that would force the EPA or the State Department out of compliance with the protocol?

Mr. DONIGER. I think what would happen, Congressman, is that if the United States went forward with unsupported applications, they would be turned down. And that would be the normal operation of the protocol but it wouldn't be a good result for my colleagues here on this panel. They want the nominations to succeed, not to fail because they weren't supported.

Mr. GRIFFITH. But inherently there is nothing in this bill that would put us out of——

Mr. DONIGER. Yes, actually, I believe the emergency exemptions provision would be grossly out of line with the protocol and freezing the critical use list, you know, permanently at the 2005 list would be contrary to the protocol.

Mr. GRIFFITH. All right. And if I might ask Ms. Keeler and others who have talked about this, and feel free to jump in, because I am not as familiar with methyl bromide, I don't know what happened that made methyl iodide—what were the negative effects that we decided as a country to take methyl iodide out of the mix—either one of you—as a potential fix for using methyl bromide?

Mr. MURAI. I think methyl iodide was identified as an effective fumigant but the science on health effects was debated and there were two sides of the science. And it was deemed a cancer-causing agent and so it caused definite uproar in the communities. And as growers, we were just as sensitive to that and we believed that the process of science and examination should go forward. And so we weren't resting on that product as being the replacement for methyl bromide and that is what we tried to articulate back to EPA is that we aren't convinced this will be the tool for California or the Nation.

Mr. GRIFFITH. And then am I also hearing the testimony correctly when I was listening to your opening statements, the four of you that are in production of various types of vegetables or fruits that to replace the methyl bromide you are using a lot more pesticides and things that would get into the water supply? Is that accurate? And Mr. Costanza, you want to comment on that?

Mr. COSTANZA. When using methyl bromide eliminates a lot of sprays across the field that we are going to have to do with methyl bromide. As far as Midas is concerned, I am concerned about my workers because it is not worker-friendly, whereas methyl bromide is easier to work with and it is less risky to my employees. But one of the biggest worries I had about Midas was the fact that it could affect my workers more than anything else. But this was the re-

placement the EPA gave us, said we were going to have, and then that is gone. So they promised us that we would have a drop-in replacement. And the reason I am here is because we don't. If somebody has got a magic wand here that I could use, I don't want methyl bromide. But you don't have a replacement.

You know, if I need a blood transfusion today and I am A positive and you don't have A positive and you give me something else, you are going to kill me. But with methyl bromide it worked. And my customers demand the product that it produced. My employees liked the product because it yielded more fruit. And they get paid an incentive on volume. They made more money. So why don't produce it? The chain stores are going to go to where it is if they have to import it. It doesn't matter if it comes from—you know, you could fly anything anywhere from the world today. You know, I have got Chinese product in the stores in my hometown. My grandson was eating Chinese-produced diced pears, not American, Chinese. We don't need that. We can do it here. But all you are doing is eliminating jobs and exporting the production to other countries. Give me a break.

Mr. WHITFIELD. The gentleman's time is expired.

At this time I recognize the gentleman from Michigan, Mr. Dingell, for 5 minutes.

Mr. DINGELL. Thank you.

I am very sympathetic with the witnesses here. I am very much concerned about their views and their need for a pesticide, but I have a feeling that we are like the surgeon who conducted a superb operation in which the patient died. I don't see here, Mr. Chairman, EPA. They have a story to tell. Where are they? I don't see here the Department of Agriculture. I don't see here others who could tell us whether there are substitutes or why those substitutes are available or not available.

I note here as I am looking at it the annual critical use exemption summary. I don't know whether the panel has seen this or not but it shows a continuing decline in the exemption that has been given by the folks up at the Montreal Protocol. It started out they were getting about 10,000 tons and it is down now to less than 2,000 tons. My concern here is that every time we have seen this, it has gone down and down and down but I don't see any real prospect of getting relief through the Montreal Protocol. If I look, they have consistently been below what the farmers have requested and they have not given the amount that the farmers say they need.

And we are going to take this legislation to the floor after virtually no hearings. We have had a panel and I am sure the panel are most respectable of folks in their fields, but we haven't heard a word from the government agencies. Frankly, I am in the view we ought to have EPA up here and let us find out what the facts are from EPA's view. I am in the view we ought to hear from Department of Agriculture. Let them tell us what is the need but I don't see that. So we are going to take this bill to the floor, probably pass, and then when it passes it goes to Senate. And it is going to sink out of sight.

And if it doesn't sink out of sight in the Senate, it is probably not going to be signed by the President and it is going to be opposed with utmost diligence by the environmentalists, and I don't

think this committee is going to afford the relief that quite frankly our agriculture community needs. I don't think that we are going to see them get the opportunity to have new pesticides that will address the concerns of our farmers. And I see us lining up if the dire predictions I hear today are to be realized, I see just nothing but trouble coming from this legislation. And I see under the legislation the farmers tell EPA what they go to the Montreal Protocol with and the Montreal Protocol takes a look at it and says, well, we are just not going to do that. So the farmers walk away and the farmers got nothing and there is no methyl bromide or anything else that is available to help our farmers with their problem.

So we are giving our farmers the most successful operation, but when we are done, the patient is going to fall off the table and he is going to die. And we are going to have a huge fight on the floor and everybody is going to get all torn up, but the farmers aren't going to get the relief that they need or they want. And to me that is not only bad policy but it is very bad legislating and it is going to leave this committee quite frankly looking kind of whoosh because we really didn't do the job that we should have done in terms of having an intelligent bunch of hearings where we heard the witnesses.

And, you know, I warned about this in earlier times. I remember one morning Chairman Staggers brought in the swine flu bill and we had a great big hearing on swine flu and my friend John Moss, who was a member of the committee, and I, we said this is a hell of a way to do business. We don't have the vaguest idea what this is going to do. So we had a magnificent program for the production of vaccine. We produced a hell of a lot of vaccine. We absorbed liability for everything from the building burning down while the patient was in it to being raped or assaulted in the parking lot. And lawyers said oh, my, isn't this wonderful? So they rushed out and had swine flu seminars at which they told everybody how to sue the government. We wound up with about $7 billion of liability. They developed this wonderful inoculant but they never found the damn disease and they never found the virus. And the government got about a $7 billion liability and the trial lawyers had a wonderful time and made lots and lots of money.

I am not going to say that that is what is going to happen here but I think we are working most diligently to create red faces on the members of this committee, and I just hope, Mr. Chairman, that you will slow down and you will bring in the witnesses from the Department of Agriculture, witnesses from EPA, and maybe somebody else and let us find out why they are not producing what our agriculture needs and exposing them to what looks like is the work product of a snake oil salesman.

I yield back the balance of my time.

Mr. WHITFIELD. Thank you very much. I might add, Mr. Dingell, that we do have a document from the EPA making comments on this particular legislation, even though they are not here today. But we do have comments from them.

At this time——

Mr. DINGELL. If you want EPA up here, they will come and the committee will support you. And if you want the Department of Ag-

riculture up here, they will come and the committee will support you. And that is the way to do the business. Let us find out——

Mr. WHITFIELD. We don't want to sit around and subpoena them every time we ask them. We try to work with them and——

Mr. DINGELL. Did you invite them, Mr. Chairman?

Mr. WHITFIELD. We did invite them, absolutely.

Mr. DINGELL. And did you get on the phone and say we want to have you up here? I have run committees for about 20 years and I am somewhat knowledgeable——

Mr. WHITFIELD. We contacted them one month ago about this hearing.

Mr. DINGELL. I never had any trouble getting anybody in here. I have watched my Republican colleagues waiving subpoenas and throwing them around here like confetti, and they don't get anything done. But it is fairly simple, let them know, By the Great Horn Spoon, you are coming and we are going to have you up here.

Mr. WHITFIELD. See, our goal is to accumulate the esteem and respect that you have so that when we ask them, next time, they will show up immediately.

Mr. RUSH. Mr. Chairman, with all due respect I have to join in here with Mr. Dingell. You know, here we have this hearing and we are going to finish maybe these hearings by 1:30, maybe 2:00. And then at 4:00 the markup starts. You know, that is not enough time. I think that if we delay this pending markup, I will certainly join in with you and I am sure Mr. Waxman would and the chairman of the full committee would. We would join with you if you want to do a telephone call, request that the EPA appears before a hearing we could schedule tomorrow morning, I am sure we would be able to do that—or the following day. But just to rush pell-mell into a markup less than probably 2 hours after a hearing on this obviously very important matter in your opinion, I think that is ludicrous on its face.

And so I would strongly suggest and recommend that you consider postponing your markup until we are able to get EPA and USDA here so they could have some testimony from the departments.

Mr. WHITFIELD. Mr. Rush, you and I both know that whether Democrats are in control or Republicans are in control, there are times when the other party does not agree with the procedure. There were a lot of things, for example, about the healthcare procedure bill we didn't agree with, and I have a number of letters. I have farmers talking to me all the time, milling companies all the time about methyl bromide, the importance of methyl bromide. And we have this panel of witnesses that reflects the agriculture community, reflects the environmental groups, and we are going to intend to have opening statements today at 4:00. And I guess the markup is scheduled for tomorrow at 10:00.

Mr. RUSH. But Mr. Chairman, why the hurry? Why do we have to hurry up and get this done? Why——

Mr. WHITFIELD. We are trying to be responsive to the agriculture community——

Mr. RUSH. I would like to have the opportunity to invite, along with yourself, along with Mr. Waxman, along with Mr. Upton, to request that the EPA appear before the markup. I would like to

have that opportunity and I would respectfully request that we be given an opportunity. Mostly Democrats and the Republicans send invitation over the phone, however you want to send it, email it, asking them to show up for a hearing before we go into a markup.

Mr. WHITFIELD. Now, have you had the opportunity to read their comments on this bill?

Mr. RUSH. Mr. Chairman, I want to ask them questions. I want them sitting right there at that table so that we can have a vigorous debate or discussion and ask questions and ask them some important questions that I and other members of the committee want to get some answers to. The departments need to be here.

Mr. WHITFIELD. Well, we invited them and you know what, I would be happy to join with you, Mr. Waxman, and we can sit down with EPA between the subcommittee markup and the full committee markup and we can ask them all the questions you would like to ask them.

Mr. RUSH. It should be public and every member of this committee should have that opportunity.

Mr. WHITFIELD. We will invite the public in.

Mr. RUSH. And in fact, Mr. Chairman, I don't know why we can't delay the markup for 24 hours if necessary so that we can be responsible and have some real deliberative discussions with the administration, with the EPA, and Department of Agriculture. I don't see what——

Mr. WHITFIELD. So you prefer to do it on Friday instead of tomorrow?

Mr. RUSH. Yes, and we can do it on Friday. I don't have any reason why that isn't OK, but we need to get the EPA and the Department of Agriculture at the witness table.

Mr. WHITFIELD. Well, listen, I really do thank you and Mr. Dingell for your comments. And like I said, we will make sure that you get a copy of this. And like I said, I would be happy to join you all in having EPA come up and talk to us, but we do believe that this is an important issue. A lot of jobs are at stake.

And at this time I think, Mr. Olson, you are the only one who hasn't asked questions, so I recognize Mr. Olson from Texas for 5 minutes.

Mr. OLSON. And I thank the chair. And welcome to our witnesses. I appreciate your time and your expertise this afternoon.

One of the largest annual festivals back home in Texas 22 is the Strawberry Festival in Pasadena, Texas. It just was completed this past May and so because of those strawberries, American strawberries, strawberry production in America is important to me. Beyond strawberries, I am concerned about some of the comments you made, Mr. Doniger. You essentially said that citizens who are impacted by the loss of methyl bromide have an avenue to have their objections heard, and that is a lawsuit suing the EPA. That apparently is how the NRDC sees a remedy for people who are impacted by loss of methyl bromide. But I am curious if the people working on the farms think a lawsuit is a viable alternative.

So my first question is for you, Mr. Costanza, and I will work down to the other three. Do you have the money, the time, and the resources to sue the EPA?

Mr. COSTANZA. No. When I was using methyl bromide on the other crops, I was paying a lot higher income tax. My employees were paying a lot higher income tax than they are now. So both my employees and myself, our incomes have been reduced because we are not using methyl bromide. And to sue the EPA, where am I going to get this kind of money from? You know, we are a family farm. Our margins are 2, 3 percent.

Mr. OLSON. So a lawsuit is not a viable alternative for yourself?

Mr. COSTANZA. Not unless you got some money.

Mr. OLSON. We got a spending problem here in Washington, see. No, we don't have the money, sir.

Same question to you, Mr. DiMare. Do you have the time, money, and resources to sue the EPA?

Mr. DIMARE. We are in the business of farming. We are not in the business of suing people. We are just looking for an alternative that is viable. If methyl bromide is the only product, this will not be disputed. The only product out there that did kill all the pathogens that it killed, all the weeds that it killed, all the alternatives that are out there are lesser, OK, which increases our cost, decreases our yield, which is not a productive way to do business.

Mr. OLSON. And probably lose jobs as well, just like——

Mr. DIMARE. Well, the jobs will follow, yes. As we know it, the type of farming we do will go under.

Mr. OLSON. Ms. Keeler, same question for you, ma'am. Do you have the time, money, resources to sue EPA?

Ms. KEELER. No, we barely have profit margins. I have to repeat what Mr. Murai said earlier and we appreciate the opportunity to be here to tell you our story. It should be not an adversarial situation with EPA. We in our government should have a conversation about what is going on on our farms. We don't expect you all to know how to run a flower farm. That is what we do. But we can come here and tell you and tell EPA how that is taking place and the struggles that we have.

And Mr. Murai made a wonderful comment earlier. Italy, Greece, they don't have the opportunity to come and talk to their governments. At the very first international meetings that I attended, I actually went and talked to the Italians and the French because we know what they are growing. And we basically said how are you guys going to grow these cut flower products without methyl bromide? And they said we are not. The EU came to us and told us this is what the EU is agreeing to. There was no discussion. The Italians were on a vacation and all these international locations at the meetings because there was nothing for them to talk about.

So, no, we don't have the money, no, we don't want to sue EPA. We want to be here, discuss with you, discuss with EPA and follow the CUE process the way it is laid out and get our allocations when necessary.

Mr. OLSON. Thank you. And finally, for you, Mr. Murai, being a strawberry man, very special to my heart with the passing of the Strawberry Festival, so I mean again, same question. Do you have the time, resources, money to sue EPA?

Mr. MURAI. Our time and resources should be invested in researching alternatives to methyl bromide. That is where our efforts should be. And the process just broke down. It needs to get fixed.

People need to listen, get their boots dirty, and clean their ears out because it is just not computing. And we are not making things up. It is based on real data, real science, and I think the EPA really needs to prove to all of us that they have legitimate reasons for reducing our nominations or eliminating them.

Mr. DONIGER. So instead what these folks are doing is coming to you at no small expense and asking you to change the law, not to get EPA to carry out the law but to change the law, to tilt the playing field in their direction. All I am saying is there is an existing law and an existing process. Let us make it work. It does work in my opinion. And use all the tools that people have under existing law. If we change it——

Mr. OLSON. Mr. Doniger, with all due respect, sir, the four panelists sitting next to you disagree completely with that statement there. I mean EPA is hurting their business, is killing their jobs, and again that is not EPA's role. I mean again we need to get the Federal Government off the peoples' backs and let the American people grow their products, create jobs in this country. That is the biggest challenge we have right now.

I guess one more question for you, last one, Mr. Costanza.

Mr. COSTANZA. I don't want the EPA to change their rules. I just want them to do what they told me they were going to do. They were going to get me a viable, affordable alternative and they have not. So until they give me a viable, affordable alternative, give me the CUEs.

Mr. DONIGER. Mr. Costanza hasn't even requested one——

Mr. COSTANZA. That is not correct.

Mr. DONIGER [continuing]. Since 2007.

Mr. COSTANZA. No, that is not correct.

Mr. OLSON. Well, we will settle that later, gentlemen.

Again, one commonsense thing from Mr. Murai——

Mr. COSTANZA. We are in the process of doing it now.

Mr. OLSON. Dirt on the boots, wax out of the ears, that is how we get through this problem. Thank you. I yield the balance of my time.

Mr. WHITFIELD. OK. Time is expired.

That concludes questions for the first panel. We appreciate all of you being here and talking to us about——

Mr. RUSH. Chairman, I ask unanimous consent to insert three items related to methyl bromide into the record. And one is a recent article from the Journal of Environmental Medicine citing that the California strawberry industry is experiencing rising crop yields while methyl bromide use declines. And there are also two letters from the California growers describing their success with alternatives to methyl bromide.

Mr. WHITFIELD. Well, without objection.

[The information follows:]

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Moving away from methyl bromide: Political economy of pesticide transition for California strawberries since 2004

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ABSTRACT

We examine the progress of the phaseout of the use of the pesticide methyl bromide in the production of California field strawberries. This phaseout is required under the Montreal Protocol and has been contentious in this sector, which receives exemptions from the schedule initially agreed under the treaty, and in international negotiations over the future of the Protocol. We examine the various ex-ante predictions of the impacts on growers, consumers and trade patterns in light of several years of declining allocations under the Critical Use provisions of the Protocol and the 2010 approval of iodomethane for use in California and subsequent 2012 withdrawal of this alternative from the US market. We find that, contrary to ex-ante industry claims, the years of declining methyl bromide use have been years of rising yields, acreage, exports, revenues and market share for California growers, even when faced with a global recession and increased imports from Mexican growers who retain the right to use the chemical under the Protocol. This has implications for the Protocol as a whole and for the remainder of the US phaseout of this chemical in particular.

1. Introduction and background

US fruit and vegetable growers using the fumigant methyl bromide (MeBr), scheduled for phaseout under the Montreal Protocol on Substances that Deplete the Ozone Layer, faced uncertainty about the cost and effectiveness of alternative chemicals and practices, and many of them applied for exemptions allowing continued use after the planned elimination of MeBr. This process was controversial – so much so that the United States suggested that they might withdraw from the Montreal Protocol, up to that point considered a model of successful international environmental policy, if their nominations for exemptions were not granted (Gareau and DuPuis, 2009). In the exemption process, which allowed exceptions to the scheduled 2005 complete phaseout date, one of the most contested uses was for strawberry farming, especially in California where many alternatives are strictly regulated or disallowed. Growers argued that none of the alternatives met the 'economic and technical feasibility' conditions of the Critical Use Exemption (CUE) rules. DeCanio and Norman (2005) discuss possible interpretations of the feasibility criteria at length, emphasizing that it cannot mean that no changes in costs or agricultural practices are required of methyl bromide users, but there is not a consensus definition of precisely what standard must be met.

Currently, the majority of CUEs for methyl bromide are allocated to the United States.[1] The share of field (rather than nursery) strawberries in total exemption requests has also grown; the 2014 US field strawberries nomination was for over 93% of the total US allocation, and was exclusively for use in California, which produces 90% of US strawberries (ERS, 2011c). In 2007 the same share was only 13% and more geographically dispersed, including uses in the southeastern US as well as California (USDoS, 2010, 2005, ozone.unep.org). Substitutes have been slower to develop in California,

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[1] For the last seven years reported, 2007–2013, approved US CUEs have been more than 75% of non-Article 5 exemptions approved globally, so US strawberry uses are a significant amount of remaining global use of MeBr. In the first year of the exemption process, US allowances were a bit over 40% of total non-Article 5 allocations. For 2013, the United States has received over 90% of approved CUE allowances. Article 5 parties, which are, roughly speaking, less developed countries, do not have to complete phaseout until 2015, but their total use peaked in 1998, and by 2010 total consumption in Article 5 and non-Article 5 countries were approximately equal (exclusive of quarantine and pre-shipment uses, which are regulated separately and excluded from the discussion throughout this paper) (ozone.unep.org).

due to different farming practices and a relatively stringent regulatory climate that has slowed the approval of some MeBr alternatives. The California strawberry crop is worth more than $2 billion annually and is the 6th highest-valued fruit crop in the state, so while the industry is small at the national level it is economically significant in the region.[2]

California growers and those negotiating the CUE process on their behalf were deeply concerned that the main source of US imports of fresh strawberries, Mexico, would not be required to eliminate the use of MeBr at the same time that California growers were scheduled to. The Montreal Protocol allows delays in the elimination of ozone depleting substances for less developed countries, and growers feared that lowered trade barriers under NAFTA would combine with a technological advantage to Mexican growers using the fumigant, leading to dramatically increased imports of fresh strawberries and reduced sales of and/or prices for domestic berries.

This work investigates how the process of phaseout has affected the California field strawberry industry and finds that management and regulatory decisions at the international, national, and state levels have allowed California growers to maintain and enhance their dominance in the domestic and North American market as the phaseout has progressed. The period between the beginning of the methyl bromide phaseout and the availability of iodomethane, the closest thing to a 'drop-in' substitute yet developed, for use in the state has been characterized by slow elimination of MeBr, rising acreage, yields and consumption, improved balance of trade, increasing domestic market share, and rising or relatively stable prices. Iodomethane itself has recently been voluntarily withdrawn from the US market, and we consider how this might affect our assessment of the phaseout process to date.

2. Ex-ante analyses of economic effects and political factors influencing phaseout

Economic analyses earlier in the process did not reach a consensus regarding the likely impacts of phaseout. Norman (2005) relied heavily on data from nominations for CUEs and found that trends in demand growth for fresh strawberries[3] and significant pass-through of cost increases to consumers were expected to outweigh the stated negative effects of production cost increases associated with use of alternative fumigants, even in the absence of direct government support, under fairly conservative assumptions, and that increased consumer costs per household would be minimal, even if they were substantial in aggregate.

Carpenter et al. (2000) simulated production, consumption, and crop prices for methyl bromide users (e.g., California) and direct competitors (e.g., Mexico) – prior to and after the 2005 MeBr ban using a spatial partial-equilibrium model. To simulate post-ban conditions, shifts in production technology and corresponding changes in production costs and monthly yields were assumed.[4] Model results suggested that following a ban, US consumers would pay higher prices for strawberries and consume fewer of them. The increased price of strawberries would outweigh increases in CA production costs for growers and, when coupled with increased acreage devoted to CA strawberry production, CA strawberry growers' gross and net revenues would increase and remain stable, respectively.

Goodhue et al. (2005) and Carter et al. (2005), on the other hand, suggested that MeBr phaseout could cause significant problems for US or California growers. The former included field trials to estimate weed control costs using MeBr and various available alternatives but were unable to estimate yield losses from the use of MeBr alternatives directly, and concluded that acreage and thus supply would have to decline significantly to raise market prices enough to eliminate the net losses to remaining growers. The latter note that a single annual demand elasticity parameterization obscures important variation in seasonal demand and supply functions and can bias estimates of losses downward, with the most significant losses accruing between mid-May and early July. Their simulation results suggest full-season losses of between 4 and 20% of revenue, with a point estimate of around 12%, excluding revenue realized from lower valued crops as acreage in strawberries decline. Neither study considered longer-term trends in the fresh strawberry market.

The design of these studies reflected concerns that Mexico, which provided (and continues to provide) more than 99% of imported fresh strawberries to the US (ERS, 2010, Table 14), was an Article 5 country under the Montreal Protocol and thus not required to eliminate MeBr until 2015, at which point their MeBr use would also have to comply with CUE standards to be permitted. NAFTA rules would make it hard to shield US growers from Mexican competition. Rising costs to US producers forced to transition away from their preferred fumigant could make Mexican imports more competitive over more of the year, reducing market share and revenues to domestic growers. Carpenter, Gianessi, and Lynch (2000) projected that after the 2005 ban – exemptions notwithstanding – increased acreage in Mexico devoted to strawberry production would be observed, and in the absence of land and water constraints, Mexico would continue to increase acreage and displace acreage in California.

On the regulators side, there was concern that significant exemptions would slow the phaseout and increase lobbying efforts at the expense of efforts to develop and implement alternate fumigation strategies. Using even the lowest estimate of the cost burden of the elimination of MeBr for California strawberries growers from Norman (2005) of $51[5] ha/year suggests that diversion of funds to directly unproductive rent seeking around CUE rights could be significant; the 2011 industry survey indicates that 15,145 ha are planted in strawberries in California, and less than 5% of that land is devoted to organic production (CSC, 2011). This implies that delays in phaseout for conventionally grown berries could be worth more than $700,000 annually (15,145 × .95 × $51 = $733,775), and any successful efforts to secure delays that cost less than this amount are profit maximizing for the industry as a whole.

The California Strawberry Commission (CSC), the most active industry group, doubled (nominal) federal lobbying expenditures from $40,000 in each of 2001–2007 to $80,000 in 2008, and expenditures have remained at that level through 2010 (Center for Responsive Politics, 2011). State nominal lobbying expenditures were about $30,000 for the 2001–2002 legislative session, as decisions about initial CUE applications were being made, and then dropped to around $3000 for the next session, rising for each subsequent legislature to a level of about $20,000 in 2009–2010 (CalAccess, 2011). It is likely, of course, that only some of these

[2] http://www.californiastrawberries.com.

[3] We focus on fresh berries throughout; in the US, frozen berries are largely a residual crop (ERS, 2011c), and as they are not perishable this market operates quite differently. Large increases in the share of production going for frozen or otherwise processed berries might suggest quality issues associated with various changes to fumigation processes, but we do not observe this in the data.

[4] The model assumes that the best alternative technology – which is assumed to be the technology resulting in the highest yield per acre for the lowest cost per acre – is selected. Given that the study was completed in 2000, the best technologies projected at the time do not entirely correspond to the alternatives actually employed during the phaseout.

[5] All figures converted to 2010 dollars using the CPI unless otherwise noted.

efforts were focused on preserving MeBr phaseout exemptions for growers. We were not able to find evidence of significant lobbying expenditures for strawberry growers in other regions. While lobbying expenditures are one indicator of lobbying efforts, the rapidity of regulatory movement – in this case, the reduction timeline – may also be suggestive. The reduction timeline in California has been much less aggressive than in other US regions, which no longer use MeBr for field strawberries, and more broadly, the reduction timeline in the US has been much less aggressive than other non-Article 5 parties. Taken together, the lobbying expenditures and reduction timeline suggest that if lobbying has slowed the phaseout of methyl bromide for strawberries in CA, it has been a rational investment for the industry, even if the costs of using alternative pesticides are a relatively small fraction of revenues and profits.

The Critical Use Exemption process involves stakeholders who use the regulated chemical, national nominations, and recommendations or analysis by the Technology and Economic Assessment Panel (TEAP) of the Montreal Protocol, leading to final amounts which must be approved by the Parties to the Protocol at their annual meeting. In the US, the Environmental Protection Agency (EPA) solicits yearly applications with supporting information on use patterns and economic impacts from growers, and then the Department of State submits these as Critical Use Nominations (CUNs). For the last year for which data are available – the nominations and final decisions for 2012 exemptions – the CSC requested permits to treat 4454 ha, which were passed on to the Parties to the Montreal Protocol, who approved 4421 of those hectares, albeit at a lower application rate than was originally requested.[6] If this smaller amount receives the low estimate of value from continued use of MeBr, CA growers have gained about $225,000 in 2012 by securing the 2012 exemptions, as well as slowing further phaseout and broader price impacts until their chief competitor in the North American fresh strawberry industry completes their phaseout. At this point Mexican growers presumably lose any price advantage gained by ongoing MeBr use, and alternative pest control practices will be more established in California.

Interestingly, this approved MeBr fumigation allowance for about 30% of California acreage annually could mean use over the majority of the growing region on an intermittent basis. The CSC notes that "[m]ethyl bromide is often being used in rotation with alternative fumigants. Many growers will use alternative fumigants for 2–3 years then rotate back to methyl bromide to clean up emerging weed and disease problems" (California Strawberry Commission, 2008. *Request for a critical use exemption for methyl bromide on strawberries for the 2011 use season.* Cited in 2013 US Field Strawberries CUN). While a move towards using MeBr every 2–3 years rather than annually is certainly a substantial reduction in MeBr applications, it is not a reduction in the geographic area reliant on MeBr as part of strawberry production, and thus reflects less progress towards achieving a permanent phaseout than the reported reductions in acreage needing treatment would suggest. Unobserved cooperation within the industry to produce this outcome would undermine the intent of the Parties to the Protocol, particularly as it could allow the use of MeBr on fields put into production after the beginning of phaseout. In California, 2009 acreage represented an increase of 89%, or 7600 ha, over the 1991 'baseline' year established for MeBr under the Protocol (ERS, 2010, Table 4). It is not possible to determine if new acreage is using MeBr on the basis of allocations currently in use, as these are not broken out by sector or sub-state geographic regions by the US EPA once exemptions are granted (Federal Register, 2011). While the United States did articulate a policy of not allowing growth in CUNs due to new acreage (UNEP, 2005), they did not specify that new acreage reliant on MeBr was not allowed even if it did not drive increasing total amounts of requested MeBr, and so the continued decline in CUNs for this sector seems to satisfy this domestic policy.

While lobbying efforts are ongoing, the CSC and other industry groups also work closely with farmers and researchers developing and testing MeBr-free growing methods. CSC reports research expenditures of over ten million dollars to date toward this end, presumably beginning in the early to mid-1990s, which suggests that research expenditures are a substantial part of the CSC budget (calstrawberry.com). Additionally, within regional nomination applications, research expenditures and funding resources have historically been reported and used to substantiate nominations.[7] Sufficient data to elicit trends in those expenditures is not available. Overall, it seems reasonable to deduce that investment in new technology hedged by investment in lobbying for continued exemptions represents an effective risk management strategy for growers and has been an influential driver of industry and regulator decision-making.

The political-economic and sociological issues around agricultural exemptions to the MeBr phaseout have been studied extensively. Clark (2001) offers an early analysis of the relationship between growers, the state of California, and the Federal EPA. Badulescu and Baylis (2006) consider the harmonization of pesticide rules under NAFTA and the possibility that that process has favored US strawberry producers. Kent-Monning (2007) raises concerns about the environmental justice implications of the use of the CUE process in California.

More recently, DuPuis and Gareau (2008); Gareau (2008, 2010, 2012) and Gareau and DuPuis (2009) argue in a series of papers that increasing pressure to provide market solutions rather than command and control ones – as evinced partly by the economic justification for exemptions to agreed phaseout schedules, which was not allowed for the previously established 'Essential Use Exemptions' granted for other ozone depleting substances in earlier stages of the Protocol – undermined the later stages of the Montreal Protocol. They further suggest that an emphasis on the credibility of estimates of private costs over estimates of public benefits will drive decision-making about exemptions in the future, while in the past a precautionary principle approach to the human and environmental risks associated with ozone depleting substances was more important. Stakeholder processes have been 'captured' to a significant degree by industry groups rather than involving a broader group more focused on the welfare of civil society as a whole. That this mode of discourse is so dominant in US policymaking is thus offered as an explanation for the ongoing use of significant amounts of MeBr in the US when other countries granted early exemptions have completed phaseout.

[6] The 2013 nominations proved very contentious in 2011; additional bilateral (including with the CSC as well as with representatives of affected nations) and TEAP meetings were added to the schedule and multiple submissions were revised and new research offered during the process (UNEP, 2011a). The decision in the advance draft report of the 23rd Meeting of the Parties reflects the MBTOC (the Methyl Bromide Technical Options Committee, part of the TEAP) recommendation (a 2013 exemption of 481.195 metric tons for field strawberries) but not that of the minority report offered by several members of the MBTOC (UNEP, 2011a,b), which recommended granting the full nomination amount (531.737 metric tons). Application rates used to calculate CUNs and CUEs and the availability of alternative pesticides in specific California growing regions were disputed within the TEAP and among governmental and nongovernmental stakeholders.

[7] Publically reported research expenditure information is incomplete – CSC has reported research expenditures as Confidential Business Information, and detailed expenditure data are not typically reported in regional nominations.

3. Progress and barriers in eliminating MeBr under the Montreal Protocol

For the first year of CUNs, 2005, 28 countries nominated critical uses. This number has declined steadily and most recently, four nominating parties (the US, Japan, Australia, and Canada) requested CUEs for 2013 (UNEP, 2011). Global CUEs for non-Article 5 countries have decreased by 94% since 2005. Use in Article 5 countries has also declined, falling below total non-Article 5 use for the first time in 2007. This decline is partly due to the support of phaseout programs paid for by the Protocol's Multilateral Fund, which is not available to non-Article 5 countries. 2010 MeBr use in Article 5 countries was 5.2% of the 1991 baseline.

Nominations by the US and requests for nominations from the California Strawberry Commission between 2005 and 2014 are shown in Fig. 1. The US, which has had the slowest average annual rate of decrease in MeBr usage of non-Article 5 countries using the CUE process, had nonetheless reduced CUN amounts by 78% from 2003 to 2013. Although the US has been accelerating the MeBr phaseout in recent years, with a large drop in the 2014 nomination, a complete phaseout has not been planned and it remains unclear when complete phaseout will be achieved.

Within the US, California is now the only state still requesting critical use exemptions for field strawberries. Porter et al. (2006) conducted a global meta-analysis of strawberry yields based on hundreds of studies and found that many alternatives produce "statistically equivalent yields" to MeBr, and thus worked to undermine arguments for exemptions related to technical feasibility. The resistance to phaseout of MeBr in California has centered on technical issues but also on economic feasibility and uncertainties associated with the availability of alternative fumigants – namely iodomethane. Approval of iodomethane for use in California was predicted for 2003, and then 2005 (Carter et al., 2005), but it was not actually available for use until December 2010. The failure of California to permit the use of iodomethane was a key rationale for the ongoing exemption request in that state (UNEP, 2011); this is consistent with the US not decreasing its CUN request between the nominating years 2010 and 2011. Since the registration of iodomethane in the 2011 growing season, however, only one California strawberry grower has used it, and that usage was small in scale (Wozniacka et al., 2012).

The registration of iodomethane by the US Environmental Protection Agency and the California Department of Pesticide Regulation was controversial due to potential public and occupational health hazards resulting from its use in pre-plant soil applications. After first denying registration of iodomethane in April 2006, the US EPA granted a one-year registration in October 2007 and, by 2008, licensed iodomethane for sale and use in the US with some restrictions on its application. Most states – with California the most notable exception – quickly followed suit by registering the fumigant. California eventually did approve the sale and use of iodomethane, but with restrictions more stringent than those imposed by the US EPA and other states. Legal challenges to the approval of this fumigant are ongoing, and an ongoing dialogue with respect to concerns about the registration of iodomethane persists between the general public, the US EPA, the California state legislature, and the risk assessment community, including government scientists involved in assessing the risk of iodomethane, a neurotoxin and possible carcinogen (Urevich, 2011). In early 2012, while no legal ruling against the use of iodomethane was made, the manufacturer announced that, based on an internal review of the fumigant and its economic viability in the U.S. marketplace, they would no longer sell this alternative fumigant in the United States and withdrew its registration in California (Chawkins and Marcum, 2012; ALC, 2012).

4. California strawberries today

US strawberries had record production levels in 2009; production, real value per unit and the total real value of the fresh strawberry crop have risen every year since 2004 according to the USDA (ERS, 2010, Table 1). Real US cash receipts have risen in every year from 2005 to 2010, the last year reported (ERS, 2011a, Table A-8). As noted above, acreage in California has also increased according to each of several data series (California Agricultural Resource Directory, 2010-2011, CSC, 2011; ERS, 2010), contrary to the predictions of declining acreage in the Carter et al. (2005) work and consistent with Carpenter et al. (2000). The ERS data go back the farthest and show that harvested acres of California strawberries have increased steadily since 1970. An OLS linear regression of acreage on time for 2001–2009 data fits well and yields an estimated increase of 650 ha/year; regressions including the earlier decades also show positive and significant trends but do not fit the data as well, suggesting that the time trend alone is not as explanatory over longer periods. These data show acreage increases in every year since 1997, with the exception of 2007, when they declined by less than 1%. Additionally, the ERS data show that the share of California acres in US strawberry acreage has grown steadily over time, from less than a third of the total in the early eighties, to more than half by the mid-90s and rising over two-thirds in 2006, where it remains.

Productivity of planted acres has also risen during this time period. ERS data on California yields from 1970 to 2009 show steadily increasing output per acre (ERS, 2010 Table 4). This trend continues for years subsequent to the onset of efforts to eliminate MeBr, though yields are, predictably, subject to weather and other conditions and thus more volatile than acreage. The share of California production in total domestic production has also grown over the time period covered, and has hovered around record highs of 88–89% since 2003. More recently, the Fruit and Tree Nuts report notes of 2010 that "last year, the increase in average yields per acre

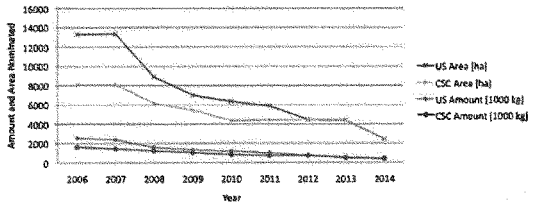


Fig. 1. US and California Critical Use Nominations, with MeBr requests and acreage.

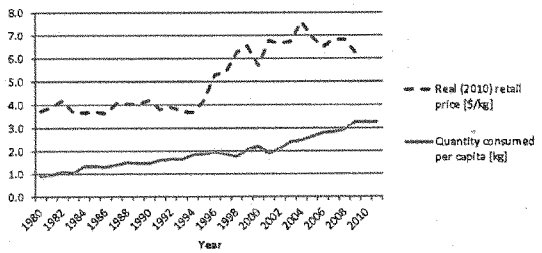


Fig. 2. US fresh strawberry prices and consumption.

in California (up 7 percent from 2009) more than made up for the decline in harvested acres (down 3 percent), resulting in a larger crop" (ERS, 2011c).

On the consumption side, we see that per capita consumption and total consumption of fresh and frozen strawberries continues to rise. In fact, per capita annual consumption of fresh strawberries has broken record levels in each year from 2003 to 2009 (ERS, 2011c; ERS, 2010, Table 12) even as real retail prices have stayed relatively stable or declined slightly. The most recent figures suggest an increase of 48% in per capita consumption of fresh berries since 2002, the last year covered in Norman (2005); with population growth that has amounted to a 67% increase in total US consumption over the same period. The continuing increase in per capita consumption as well as trends in real retail prices can be seen in Fig. 2.

We examine seasonal patterns in retail prices to evaluate hypotheses about patterns of trade raised in some of the ex-ante studies discussed above. Real retail prices in June, the period identified by Carter et al. (2005) as most vulnerable to losses in a MeBr phaseout, rose in 5 of the 10 most recent years for which data are available (2000–2009). The average of real June retail prices from 2005 to 2009 was 1% higher than for 2000–2004, suggesting no significant change in the trend over time as a driver of this observation. Looking more closely, however, and in contrast with all but 3 of the preceding 24 years of available data, we note that for 2004–2008 May retail prices were higher than April prices, reversing again in 2009. Grower prices confirm this trend; for 2005–2011, May prices to growers for fresh berries were higher than April prices in 5 years and lower in two years (http://quickstats.nass.usda.gov).

While farming is subject to significant variability from year to year, both in the various growing regions domestically and abroad, this is suggestive of an increasingly competitive market in North America. Norman (2005) predicted that the pre-2005 gap between higher April prices and lower May prices was likely to decrease in size in the absence of methyl bromide. Ex-post, we see that the gap has not just diminished but has reversed, while significant MeBr use continues. In the past, imports from Mexico peaked in April and domestic deliveries peaked in May or June. The historic drop in prices as domestic berries hit the markets in bulk suggested that exporting costs were high enough for Mexican growers that expanding exports during this period was relatively unattractive. In recent years, we have not observed a significant shift in strawberry acreage away from northern California growing areas, which deliver strawberries later in the season, and towards southern regions, where strawberries come in earlier (CSC, 2011), which might offer a domestic explanation for this shift in the pattern of relative prices throughout the year, so the currently observed pattern of relatively lower April prices is consistent with the US market becoming more attractive for Mexican growers wishing to export for more of the season or US growers facing rising costs in their peak production periods. It could also be that unobserved changes in crop timing associated with the use of MeBr alternatives have shifted the timing of peak deliveries in some parts of the state.

Investigating trends in imports and exports of fresh strawberries in more detail, however, does not provide strong supporting evidence for the hypothesis that increased Mexican imports are driving intra-year changes in relative prices. Imports of fresh strawberries to the United States, almost exclusively from Mexico, have indeed grown substantially, continuing a trend observed well before MeBr restrictions began. They have more than doubled since 2004 (ERS, 2011b and Table G-1, ERS, 2011a). The share of Mexican imports in domestic consumption has changed less, however, trending slowly upward since the mid-1980s and now around 8%.[9] This may reflect increasing retail availability and consumption in the off seasons for domestic strawberries as well as increased April exports from Mexico.

United States exports also grew during this time, rising more than 50% from 2004 to 2010 (Table G-2, ERS, 2011a). The bulk of these exports go to Canada, which consumes considerably more strawberries than are produced there. The increase in tonnage of exports to Canada is very similar to the increase in imports from Mexico, suggesting that changing price patterns over time cannot be cleanly ascribed to trade advantages for Mexican growers selling in the United States. Domestic exports could well increase the scarcity of domestic berries at peak periods, driving domestic prices up. Strawberry exports do peak in May (ERS, 2011a, Tables G6–G8). Unfortunately, import and export data by month are only available for a few years, making it difficult to discern trends over time with confidence.

Also affecting trade patterns in North America may be the promulgation of Country of Origin Labeling (COOL) regulations in the United States (http://www.ams.usda.gov/AMSv1.0/COOL). For the 2009 and subsequent seasons all fresh strawberries sold in the United States were required to carry labels indicating where they were grown and packed. One expectation of supporters of this policy was that consumers would prefer domestic products over imports, and this may have reduced the vulnerability of California growers to cheaper imports from Mexico in particular. Carter and Zwane (2003) argue that this was in essence a (costly) protectionist policy. Van Ittersum et al. (2007) note that consumers may prefer domestic or local region products both because they believe them to be better or safer, or because they have a preference for

[9] Calculations based on ERS (2011b) yield slightly different shares than those given in ERS (October 2010, Table F-14).

supporting growers in geographic regions that they identify with. Either of these would help California growers and hurt Mexican exporters in the domestic market. While we cannot isolate any impact of this over the short period since the rules have been established, it remains clear that the majority of the US market continues to be served by domestic growers.

The MeBr alternative iodomethane has been approved for use in Mexico and a commercial launch there is planned for 2012 (ALC, 2010). As an Article 5 country, Mexico has until 2015 to phaseout MeBr under the Montreal Protocol; however, the government of Mexico has committed to completely phaseout methyl bromide by 2012 (UNEP, 2010),[9] by which point it seems likely that growers there will be able to use iodomethane and California growers will use continuing allocations of MeBr and any of several alternatives which show little to no yield changes in current research (summarized in USDoS, 2012). Costs for various production inputs and growing conditions will of course vary and be drivers of comparative advantage in international trade as with any commodity. It is unlikely that changes in land use in California or Mexico have been driven by an expectation of continued MeBr use in Mexico after it is curtailed in the United States.

Additionally, increases in imports may reflect changing trade advantages unrelated to MeBr phaseout in the United States. From 2002 to 2009, imports of Mexican lemons increased from negligible to a major trade commodity, increasing to 54 times initial levels. Avocados increased eleven fold, raspberries increased eight fold, pineapples were up 250%, and pecans and cocoanut meat also increased more rapidly than fresh strawberries. Tangerine, lime, and mango imports grew more slowly than strawberries but still rose significantly (ERS, 2011a, Table G-1). Trade changes driven by NAFTA or other drivers of increased globalization should not be ascribed to the ongoing MeBr phaseout without more substantial evidence than we are able to find.

5. California strawberry production cost estimates

Looking at the various sample budgets available from Cooperative Extension in California (UC Cooperative Extension, 2001a–c, 2004a–d, 2006, 2010, 2011a–b), we do not observe clear links between decreasing availability of MeBr and costs or profits. 2010 and earlier reports note that alternatives to MeBr are available and in use, but the sample budgets assume fumigation with MeBr and chloropicrin (or 'Pic'); Pic allows for significantly lower rates of MeBr application in areas where MeBr had previously been used alone. Of the two 2011 reports one notes that methyl bromide availability is limited and does not specify a fumigant in the line-item budgets and the other uses Pic alone.

In the geographically central of the three largest growing regions, fumigation costs as a share of total costs were 2.4% in the 2001 sample budget, 3.7% in 2004, 3.5% in 2006 and 2.9% in 2011. For the same 3 years estimated net returns were 1.6, 14.2, 7.6, and 3.2% of total costs. In the main growing region to the south we have budgets for 2001, 2004, and 2011 which show a decline in fumigation costs as a share of the total, from 6.0 to 5.7 to 3.1%, while net returns increased from 9.5 to 13.4% and then dropped to 2.2%. In the northernmost growing region, budgets for 2001, 2004 and 2010 show increasing fumigation costs (5.2, 5.4 and 6.9% of total costs, respectively) and fluctuating net returns (6.6, 9.4 and 4.0%). These numbers offer some insights into input and production costs, in particular suggesting weakly declining fumigation costs and yielding some evidence of declining net revenues in the most recent years, but we note that the sample budgets are designed to offer a general understanding of costs and revenues using current methods rather than to support rigorous economic analysis.

Critical Use Nominations themselves are another source of data on trends in production costs and revenues. The nominations through 2013 give a baseline yield rate for fumigation with 100% methyl bromide and discount it by some fraction for each alternative pest control regime. While detailed budgets are not provided, annual CUNs for CUEs also include estimates of the economic impacts of MeBr as compared to alternatives.[10] These estimates are developed to support the case that additional exemptions to use MeBr in California are needed to avoid 'significant market disruption,' which is a key part of the standard established in Decision IX/6 of the Montreal Protocol to define a use as critical. Alternatives are shown with associated yield estimates and implied costs to producers facing changed yields and other practices. For 2006–2013 CUNs, the baseline MeBr yield estimates fluctuate a bit, dropping by around 15% from 2006 to 2008 levels in 2009–2010 and then rising again for 2011–2013 nominations. Reported yields per hectare are well below those reported in the sample budgets referenced above, typically around 40–50,000 kg/ha in recent CUNs, with some alternatives in the 30–40,000 range in earlier nominations, while first year strawberry yields in the sample budgets are around 60–80,000 kg/ha and the most recent second year yield reported is over 50,000 kg/ha (UC Cooperative Extension, 2011c). The yield loss associated with moving from MeBr to a mixture of 1,3-dichloropropene (1,3-D) and chloropicrin is steady at 14% throughout, suggesting that the loss rate estimate was not revised over time but simply applied to the MeBr number for a given year. This alternative is the only one included in every nomination[11]; metam sodium (MS) and a mixture of Pic and MS were excluded from 2010 to 2009, respectively, and a mixture of Pic and MeBr was not added until the 2010 nomination. Iodomethane is included for the first time in the 2013 nomination.

Projected strawberry prices drop by about 30% from 2010 to the 2011 nomination estimates, and they remain at this low level through the 2013 nomination. This price, $1.37/kilogram,[12] is well below current and recent reported grower receipts (ERS, 2010); it is not clear why recent nominations have used such a low baseline price. This price drop helps explain why the estimated value of MeBr use as opposed to 1,3-D+Pic can be relatively stable, ranging between $43–68 per kilogram for 2006–2013 nominations, while the figure for "percentage loss in net revenues" swings up to 1269% in 2011 and subsequent years, after previously being estimated at 55 and 87%. While the loss to net revenue is appealing as a proxy for disruption suffered by growers, the nominations note that the

[9] In 2008, Mexico's MeBr consumption was below consumption allowed under the Montreal Protocol. As of 2010, those implementing the National Methyl Bromide Phase-Out Plan for Mexico (the United Nations Industrial Development Organization (UNIDO) along with the governments of Italy, Spain, and Canada) intended to eliminate the remaining MeBr (approximately 900 ODP tonnes) by 2012, provided requested monies from the Multilateral Fund were received. The plan initially proposed that the strawberry sector convert near the end of the phaseout because "strawberry growers were reluctant to reduce MB consumption" (UNEP, 2010, p. 5). However, Mexico's strawberry growers have since requested immediate assistance in order to accelerate completion of the phaseout.

[10] These figures are all reported in nominal dollars, as the requests are filed a few years in advance of the proposed use, and do not specify nominal or real figures. Additionally, many of the numbers do not change from year to year, suggesting that the precision of the estimates is not such that deflating them should drive conclusions.

[11] It is worth noting that the 1,3-D mix is not available to all growers, as many California townships restrict 1,3-D use (Carpenter et al., 2001) and some counties restrict Pic application. This may be why the extension service budgets above exclude it, and this may also make it difficult to draw statewide conclusions on the basis of variation in yield estimates between 1,3-D alone and in combination and MeBr.

[12] The CUN itself reports 'units'; we believe these to be kilograms based on matching with previous California nominations.

required gross revenues less operating costs are "difficult to measure and verify" (USDoS, 2004–2011). Net revenues are sensitive to the implied change in gross revenues of much lower strawberry prices even in the absence of significant cost shifts, and smaller net revenues produce bigger percentage changes for a given nominal cost increase or yield decrease.

As this article was being finalized for publication, the 2014 Critical Use Nomination for field strawberries in California was made public. It requests 415 metric tonnes of MeBr for field strawberries, a bit over a 20% decline from the request for 2013. The drop in requested acreage to be treated is about 50%, suggesting decreasing use of MeBr in combination with other chemicals and thus at higher rates, while the baseline fumigant in the economic impact table is now a mixture of MeBr and Pic rather than MeBr alone. The economic impact analysis shows no yield losses for any alternative, a substantially higher output price for growers of $2.51 per unit, a roughly 60% increase in reported yields to nearly 80,000 kg/ha, and greatly reduced or even negative loss measures. The estimated loss or gain as a percentage of net revenue ranges from −9% (for an alternative using iodomethane) to 5% across all reported alternatives (USDoS, 2012). Chloropicrin alone yields an increase in net revenue of 2% relative to the baseline. Thus the key driver of the request is now the limited access in some specific areas to use of some of the alternative fumigants, or the requirement for buffer zones around schools and residential areas. However, the township caps that limit 1,3-D are being reached in regions where strawberry acreage has grown substantially since the US agreement to phaseout methyl bromide. It is difficult to argue that a sub-state regulatory decision that limits the amount of acreage in all crops that can be treated with certain pesticides represents a substantial disruption of the California strawberry market due to the elimination of methyl bromide.

It is interesting to note that with the exception of the 2006–2008 nominations the economic impact estimates in the CUNs assume no price gap per unit produced using MeBr and using alternatives. Wolverton (2012) indicates that in 2006–2008 the change in prices was used to reflect anticipated planting delays and subsequent later deliveries of crops to market for growers using alternative fumigation practices rather than broader market impacts. Constant output prices across alternatives with significantly differing yields suggest that these economic impact estimates assume no market price responses to significant supply swings (including projected yield losses of up to 30% for California growers, which would certainly affect the domestic and North American markets), and thus do not account for the significant amount of any cost increase that will be passed along to consumers as the market reaches a new equilibrium price (see Norman, 2005 for detailed discussion of the impact of relatively inelastic consumer demand for fresh strawberries on market prices and the distribution of the burden of rising production costs). If all acres not receiving exemptions were using alternatives with substantially lower yields and similar or increased costs, we would expect market prices to rise and moderate reductions in profits.

While we do not observe profits directly in the way that we do acreage and revenues, it is difficult to reconcile the history of CUN figures for California yields and costs using alternatives with the increasing use of alternatives and the increasing yields per acre and increases in total acreage noted above. The continued expansion in acres noted above is not consistent with an industry facing large losses as the phaseout continues; basic economics tells us that rising profits attract entry into an industry and falling profits drive exit, as more remunerative investments are sought for the land and capital previously employed in the failing sector. It seems likely that modifications of farming practices in concert with the use of non-iodomethane MeBr alternatives have been increasingly successful at preserving yields in those areas that are doing without MeBr either altogether or at least in some years. Input substitution as the price of fumigation relative to other inputs into the strawberry growing process rises – altered weeding practices or schedules, perhaps, or alternate cultivars or crop rotations – would be expected to lower the costs of compliance with the phaseout process. We have found no evidence suggesting zero input substitution characterizes this industry, and any substitutability across inputs will reduce cost burdens on growers. Learning by doing should also lower costs and gaps in yields across different pest control strategies over time, as growers and fumigation contractors become accustomed to using alternatives. Further and perhaps most significantly, it seems that the calculations used to support the granting of CUEs in this sector do not allow for the ability of growers to share cost increases with consumers, who may by their numbers and relatively inelastic demand bear the majority of any remaining burden without individually experiencing price increases as economically disruptive.

6. Additional drivers of change and trends

While per capita consumption of fresh berries by Americans has continued to rise since 2004, it is not obvious that this is driven by rising per capita incomes as earlier data suggested to Norman (2005). Mean and median household and per capita income trends were disrupted by the global recession, with US median household income falling in 2008, 2009 and 2010, mean household income falling in 2007, 2008, 2009 and 2010, and per capita income falling in 2009 and 2010 (Historical income tables, www.census.gov). With a relatively short data period to contend with and a lack of detailed information about changes in income distribution

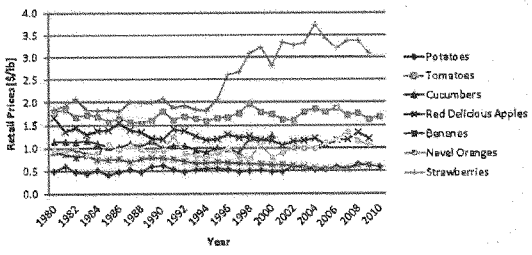


Fig. 3. US fruit and vegetable real retail prices.

and the relationship between income and strawberry consumption, disentangling trends in prices, consumption, and income to estimate relationships is imprecise.

One thing we do note in this market is that while prices of many fresh fruits and vegetables, including strawberries, have trended slightly downwards since 2008 (ERS, 2010 Table 12 and October 2011 Table A-7), over a longer time horizon, we observe a marked difference in fresh strawberry prices, which have increased by 85% from 1994 to 2008, compared to the prices of some other fruits and vegetables, which have largely been stable or increased to a much lesser extent (Fig. 3). Per capita consumption of fruits overall remained constant from 1994 to 2008, while per capita vegetable consumption initially increased from the mid-90s to 2000 but declined subsequently. This suggests that significantly increased strawberry consumption in the face of rising or stable prices in recent years is not likely to be driven by a decline in the price of strawberries relative to substitute fruits and vegetables. Changes in income, tastes, and preferences as well as the increased availability of strawberries at all times of the year are combining to support increased per capita and total strawberry consumption.

7. Conclusion

We offer an ex-post analysis of the impact of the mandated phaseout process for methyl bromide on California strawberry growers to date. Ex-ante estimates of the economic impact of the elimination of MeBr were required by and influential in the CUN and CUE processes, in contrast with either a benefit-cost approach including public health and environmental protection gains, as required by many of the domestic environmental policies of Parties to the Montreal Protocol, or with the Essential Use Exemption process used for other ozone depleting substances eliminated earlier in the ozone protection regime. While this is not an ex-post analysis of the originally expected complete phaseout, and thus cannot be directly compared with ex-ante predictions based on the complete elimination of MeBr use, it does offer insight into the gap between predictions and outcomes of a strawberry industry moving away from this ozone depleting pesticide while facing import competition from a major trading partner with a more lenient phaseout schedule.

Contrary to many ex-ante predictions and concerns expressed by stakeholders, California strawberry growers have thrived in recent years relative to both domestic and foreign competitors. They have successfully worked to ensure that MeBr has been available for significant fractions of their significantly expanded acreage, increased exports, and continued to enjoy rising yields and revenues as well as increased demand from consumers. The interim years between the planned elimination of MeBr and the increasing success of alternatives as detailed in the 2014 CUN and other reports have been years of expansion in the face of global recession and increased imports from Mexico, and successful navigation of technical and regulatory changes. Industry data suggests that the real burdens associated with changing agricultural practices have not kept this sector from profitability and growth in a challenging economic environment, though we cannot know how much faster growth might have been if MeBr use had continued unabated.

Alarming numbers in the CUNs sent to the Parties to the Montreal Protocol are not consistent with the success of California strawberry growers in aggregate as use of MeBr has been reduced. Nor are they consistent with basic economics. The 'economic disruption' standard of the CUE process was not intended to require the Parties to permit application of MeBr on new acreage to allow limitless expansion of a given industry using MeBr, and it is difficult to justify ongoing exemptions to support expansion rather than protect existing growers and growing regions. If all the new acres in production since 2005 are being managed profitably without MeBr, and existing acres are using less MeBr less often while overall and per acre yields and revenues rise steadily, it seems we have reached a point where alternatives are demonstrating successes for field strawberries in California.

References

Arysta Lifescience Corporation (ALC), 2010. Iodomethane Approved in Mexico and Morocco. http://www.arystalifescience.com/release/Mexico_and_Morocco_Reg.pdf.

Arysta Lifescience Corporation (ALC), 2012. Arysta LifeScience Suspends MIDAS® in United States. http://www.arystalifescience.com/release/MIDASPress3-20-12FINAL.pdf.

Badulescu, Dan, Baylis, Kathy, 2006. Pesticide Regulation Under NAFTA: Harmonization in Process?" No. 24163. Commissioned Papers from Canadian Agricultural Trade Policy Research Network.

CalAccess, 2011. California automated Lobbying and Campaign Contribution and Expenditure Search System. Available at: cal-access.ss.ca.gov (last accessed August 2011).

California Department of Food and Agriculture, 2011. California Agricultural Resource Directory 2010–2011. Available at: http://www.cdfa.ca.gov.

California Strawberry Commission (CSC), 2011. Acreage Survey. Annual reports available at: http://www.calstrawberry.com/commission/asurvey.asp (last accessed August 2011).

Carpenter, J., Glanessi, L., Lynch, L., 2000. The economic impact of the scheduled U.S. Phaseout of Methyl Bromide. National Center for Food and Agricultural Policy, Washington, D.C.

Carpenter, J., Lynch, L., Trout, T., May-June 2001. Township limits on 1,3-D will impact adjustment to methyl bromide phase-out. California Agriculture 55 (3), 12–18. doi:10.3733/ca.v055n03p12.

Carter, C.A., Zwane, Alix Peterson, 2003. Not so cool? Economic implications of mandatory country-of-origin labeling. Agricultural and Resource Economics Update 6 (5), 5–7.

Carter, C.A., Chalfant, J.A., Goodhue, R.E., Han, F.M., DeSantis, M., 2005. The methyl bromide ban: economic impacts on the California strawberry industry. Review of Agricultural Economics (Now Applied Economic Perspectives and Policy) 27 (2), 181–197.

Center For Responsive Politics, 2011. Database available at: www.opensecrets.org (last accessed August 2011)

Chawkins, Steve, Marcum, Diana, March 21, 2012. Methyl iodide distribution to halt in U.S. Los Angeles Times.

Clark, Victoria, 2001. Enforcement of pesticide regulation in California: a case study of the experience with methyl bromide. Golden Gate University Law Review 31. http://digitalcommons.law.ggu.edu/ggulrev/vol31/iss4/5.

DeCanio, S.J., Norman, C.S., July 2005. Economics of the 'Critical use' of methyl bromide under the Montreal Protocol. Contemporary Economic Policy 23 (3), 376–393.

DuPuis, E.M., Gareau, B.J., 2008. Neoliberal knowledge: the decline of technocracy and the weakening of the Montreal Protocol. Social Science Quarterly 89 (5), 1212–1229.

Economic Research Service, United States Department of Agriculture, March 2010. US Strawberry Industry Spreadsheet Files. Available at: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1381 (accessed August 2011).

Economic Research Service, United States Department of Agriculture, October 2011a. Fruit and Tree Nut Yearbook Spreadsheet Files. Available at: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1377.

Economic Research Service, United States Department of Agriculture, May 27, 2011b. Fruit and Tree Nuts Outlook. FTS-347.

Economic Research Service, United States Department of Agriculture, March 30, 2011c. Fruit and Tree Nuts Outlook FTS-346.

Federal Register, April 28 2011. Protection of Stratospheric Ozone: The 2011 Critical Use Exemption from the Phaseout of Methyl Bromide Proposed Rule, Federal Register, vol. 76 (82), 23769–23781 pp.

Gareau, B.J., DuPuis, E.M., 2009. From Public to Private Global Environmental Governance: Lessons from the Montreal Protocol's Stalled Methyl Bromide Phase-out. Environment & Planning A 41 (10), 2305–2323.

Gareau, Brian J., 2008. Dangerous holes in global environmental governance: the roles of Neo-liberal discourse, science, and California Agriculture in the Montreal Protocol. Antipode 40 (1), 102–130.

Gareau, Brian J., 2010. A critical review of the successful CFC phase-out versus the delayed methyl bromide phase-out in the Montreal Protocol. International Environmental Agreements: Politics, Law, and Economics 10 (3), 209–231.

Gareau, Brian J., 2012. The limited influence of global civil society: international environmental non-governmental organisations and the Methyl Bromide Controversy in the Montreal Protocol. Environmental Politics 21 (1), 88–107.

Goodhue, R.E., Fennimore, S.A., Ajwa, H.A., 2005. The economic importance of methyl bromide: does the California strawberry industry qualify for a critical use exemption from the methyl bromide ban? Review of Agricultural Economics (Now Applied Economic Perspectives and Policy) 27, 198–211.

Kent-Monning, Laura, 2007. Student comment. Endless exemptions: an environmental justice critique of the ongoing use of methyl bromide. Golden Gate University Environmental Law Journal, 175–208.
Norman, C.S., 2005. Potential impacts of imposing methyl bromide phase out on US strawberry growers: a case study of a nomination for a critical use exemption under the Montreal Protocol. Journal of Environmental Management 75, 167–176.
Porter, I.J., Trinder, L., Partington, D., 2006. Validating the Yield performance of Alternatives to Methyl Bromide for Pre-Plant Fumigation. TEAP/MBTOC Special Report. Available at: www.unep.org/ozone/teap/Reports/TEAP_Reports/.
United Nations Environment Programme (UNEP), 2005. Report of the seventh meeting of the Conference of the Parties to the Vienna Convention for the Protection of the Ozone Layer and the Seventeenth Meeting of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer. Dakar, December 12–16, 2005. http://ozone.unep.org/Meeting_Documents/mop/17mop/17mop-11e.pdf.
United Nations Environment Programme (UNEP), 2010. Project Proposal: Mexico. UNEP, Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol, Sixteenth Meeting, Montreal: 12-14 April 2010. http://multilateralfund.virtual.vps-host.net/files/60/6034.pdf.
United Nations Environment Programme (UNEP), 2011a. Report of the Technology and Economic Assessment Panel Evaluation of 2011 Critical Use Nominations for Methyl Bromide and Related Matters. October 2011. http://ozone.unep.org/Assessment_Panels/TEAP/Reports/TEAP_Reports/TEAP-CUN_2011-Final-Report-October2011.pdf.
United Nations Environment Programme (UNEP), 2011b. Decisions Adopted by the Conference of the Parties to the Vienna Convention at its Ninth Meeting and by the Twenty-Third Meeting of the Parties to the Montreal Protocol – ADVANCE, Undated, downloaded December 2011. http://conf.montreal-protocol.org/meeting/mop23-cop9/draft-reports/Draft%20Reports/COP9-MOP23_%20decisions.pdf.
United States Department of State, 2004. Methyl Bromide Critical Use Nomination for Preplant Soil Use For Strawberries Grown for Fruit in Open Fields on Plastic Tarps (For 2006 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2005. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberries Grown for Fruit in Open Fields (Prepared in 2005 for 2007). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2006. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberries Grown for Fruit in Open Fields (Submitted in 2006 for 2008). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2007. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberries Grown for Fruit in Open Fields (Submitted in 2007 for 2009). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2008. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2008 for 2010 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2009. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2009 for the 2011 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2010. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2010 for the 2012 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2011. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2011 for the 2013 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
United States Department of State, 2012. Methyl Bromide Critical Use Nomination for Preplant Soil Use for Strawberry Fruit Grown in Open Fields (Submitted in 2012 for the 2014 Use Season). Available at: http://www.epa.gov/ozone/mbr/cueinfo.html.
University of California Cooperative Extension, 2001a. Sample Costs to Produce Fresh Market Strawberries, Central Coast Region. Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2001b. Sample Costs to Produce Strawberries, South Coast Region – Santa Maria Valley. Bendixen, W.E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2001c. Sample Costs to Produce Strawberries, South Coast Region – Ventura County. Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004a. Sample Costs to Produce Strawberries, Central Coast Region. Bolda, M.P., Tourte, L.J., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004b. Sample Costs to Produce Strawberries, South Coast Region – Santa Barbara County, Santa Maria Valley. Bendixen, W.E., Takele, E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004c. Sample Costs to Produce Strawberries, South Coast Region – Ventura County. Daugovish, O., Takele, E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2004d. Sample Costs to Produce Strawberries, San Joaquin Valley. Molinar, R.H., Yang, M., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2006. Sample Costs to Produce Strawberries, South Coast Region – Santa Barbara County, Santa Maria Valley. Takele, E., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2010. Sample Costs to Produce Strawberries, Central Coast Region, Santa Cruz and Monterey Counties. Bolda, M.P., Tourte, L.J., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2011a. Sample Costs to Produce Strawberries, South Coast Region – Ventura County, Oxnard Plain. Daugovish, O., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2011b. Sample Costs to Produce Strawberries, South Coast Region – Santa Barbara and San Luis Obispo Counties, Santa Maria Valley. Dara, S., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
University of California Cooperative Extension, 2011c. Sample Costs to Produce Second Year Strawberries, Central Coast Region, Santa Cruz and Monterrey Counties. Bolda, M.P., Tourte, L.J., Klonsky, K.M., De Moura, R.L., Available at: http://coststudies.ucdavis.edu.
Urevich, Robin, December 7, 2011. Many farmers shun methyl Iodide on strawberry fields. The Bay Citizen, http://www.baycitizen.org/environmental-health/story/methyl-iodide/.
van Ittersum, Koert, Meulenberg, M.T.G., van Trijp, H.C.M., Candel, M.J.J.M., 2007. Consumers' appreciation of regional Certification labels: a pan-European study. Journal of Agricultural Economics 58 (1), 1–23.
Wolverton, Ann, March 2012. United States Environmental Protection Agency. Retrospective Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies. National Center for Environmental Economics, Available at: http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/RetroCost.html.
Wozniacka, Gosia, Midas, Strawberry, Pesticide Methyl Iodide, Will Be Pulled from Market by Arysta LifeScience Inc. Associated Press. March 21, 2012. http://hosted.ap.org/dynamic/stories/U/US_Farm_Pesticide_Methyl_Iodide.

July 17, 2012

Hon. Ed Whitfield, Chairman
Hon. Bobby L. Rush, Ranking Member
Subcommittee on Energy and Power
Committee on Energy and Commerce
House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Whitfield and Ranking Member Rush:

Please accept this letter for the record of the hearing you are holding on July 18, 2012, concerning "The Agricultural Sector Relief Act of 2012." I write to bring to your attention a number of effective and economical alternatives to the use of methyl bromide in strawberry fields and other applications. These are among the reasons I believe any bill that would slow or reverse the phase-out of methyl bromide is unnecessary and unwise.

One effective treatment method is anaerobic soil disinfection (ASD). ASD is less expensive than methyl bromide and is as effective. The technology is available. Researchers have ongoing trials.

My company, Farm Fuel Inc., has been working with researchers at University of Idaho and University of California Santa Cruz to scale up soil treatments from small test plots to farm fields. We are setting up anaerobic soil disinfection (ASD) treatments in strawberry fields in Ventura county for Driscoll and Andrew & Williams (a large commercial strawberry and tomato shipper). Trials in Watsonville are ongoing. The results in organic fields in Watsonville were so good that the Driscoll agronomist was concerned growers would want to switch to ASD upon seeing the size of fruit and robustness of plants before trials were completed and further testing done.

A quarter acre ASD trial in our Watsonville greenhouse resulted in robust healthy sage plants where Phytophora previously destroyed the entire sage planting. USDA grants are funding trials and outreach by University of California Santa Cruz researchers. Results are dramatic and consistent.

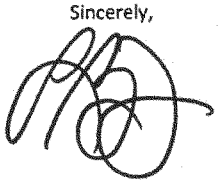
Another effective approach for applications that now use methyl bromide is mustard seed meal (MSM). MSM doesn't require tarping or large amounts of water. Mustard seed meals have had repeatable results reducing Verticillium in strawberries and nematodes in carrots. One organic strawberry grower where we did initial trials orders several tons of MSM soil amendment each year to treat problem areas. A CSA grower, High Ground Organics, raved

about the success he's had eliminating nematode damage and being able to grow straight carrots by using mustard seed meal soil amendment. Farmers buy what works.

In one apple trial (pending publication) managed organically with high soil organic matter, mustard meal treatment significantly outperformed chemical soil fumigation. It suppressed nematode pressures for two seasons while soil fumigation treatment worked for only one. The "magic" was that populations of beneficial soil micro-organisms shifted in the mustard treated blocks while the fumigated blocks, though they knocked down the disease organism populations, their numbers returned the second year. This makes sense in that a few plant feeding nematodes will increase in population over time while soils that are shifted to have higher populations of suppressive organisms keep the disease causing nematodes in check.

There is no silver bullet. ASD requires tarping and enough water to make the system anaerobic. Mustard seed meals work great for nematode control and specific soil disease problems. These two technologies do what methyl bromide fumigation does for less money and with far fewer risks to the environment and public health.

Sincerely,



Larry Jacobs
Farm Fuel Inc.
PO Box 1413
Freedom, CA 95019

Hon. Ed Whitfield, Chairman

Hon. Bobby L. Rush, Ranking Member

Subcommittee on Energy and Power

Committee on Energy and Commerce

House of Representatives

2125 Rayburn House Office Building

Washington, DC 20515

Dear Chairman Whitfield and Ranking Member Rush:

I have been farming strawberries for over thirty years. I began my career as a manager on a large conventional operation, and used Methyl Bromide/Chloropicrin fumigation technology. But after personally experiencing several exposures to these chemicals, I became wary of their effects, and began the search for alternatives. I also perceived a growing market demand for food grown without chemical pesticides and fumigants. These two factors led me to begin farming on my own in 1983.

As I was told by industry experts that I was risking abject failure if I did not use these chemicals, I hedged my risk by fumigating half my field, and left the other half un-fumigated. The following year, I noticed a slight drop in yield in the non-fumigated field, but by no means was it a disaster. In fact, the price premium for the non-fumigated product more than made up for the slight drop in yield.

Over the next several years, I moved toward organic production methods. I now farm 200 acres of strawberries, bush berries, and row crops. I'm happy to say that the market has rewarded me with great success over the last 29 years.

Since the early years, many strawberry growers have taken the same path toward reduced chemical use. In fact, the organic strawberry industry (now a significant subset of the overall industry) has grown 100-fold. There are now time-tested methods for growing strawberries without the use of Methyl Bromide---and other fumigants, for that matter.

In fact, at this point, there is significant market risk to growers who are perceived to be moving in the wrong direction by continuing to rely on toxic fumigants in general.

This is no small matter when you consider that our industry exports significant amounts of fruit

to Europe and Asia. Backtracking on our commitment to reduce MeBr usage could have the effect of significantly reducing demand in these areas of the world. This is no time to risking damage to our export markets.

I therefore urge you to stick with the program that positions the US as a leader in reducing chemical inputs in agriculture.

Sincerely,

Jim Cochran
President,
Swanton Berry Farm
Davenport, CA

Mr. WHITFIELD. And then we have some additional letters from millers and Agricultural Trade Services, Almond Processing Association, the American Farm Bureau, California Date Commission, California Walnut Commission, Florida Farm Bureau, Florida Tomato Exchange, Georgia Fruit & Vegetable Growers, Holzinger Flowers, Inc., Knappan Milling Company, Lassen Nursery, Maritime Exchange for the Delaware River and Bay, None Better Fruits & Vegetables, Star of the West Milling Company, Sunkist, Sunshine, Sunsweet, and Western Industries. Without objection, so ordered.

[The information follows:]

July 14, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Building
Washington, DC 20515

Re: U. S. Agricultural Sector Relief Bill of 2012

Dear Chairman Upton,

The language of the Bill is crisp, defining and in accordance with the terms of the Montreal Protocol.

It is of particular importance at this time that the Bill be enacted in order that the needs of the U. S. agricultural sector are properly represented in the Critical Use Nomination (CUN) process by the USEPA and, in further extension, by the Methyl Bromide Technical Options Committee (MBTOC). In too many instances an arbitrary cut in the CUN is made by our U. S. agencies for unsubstantiated reasons, prior to submission to the Parties.

The additional criteria established by an Extraordinary Meeting of the Parties of the Montreal Protocol, such as difference in purchasing costs, differences in yield per acre, percentage change in net revenue if an alterative is used, are all but ignored when the MBTOC recommends a cut in a CUN.

The Bill is properly focused and should be enacted in a timely manner.

Very truly yours,

Albert S. Marulli
Agricultural Trade Services

cc: The Honorable Henry A. Waxman, Ranking Member
House Energy and Commerce Committee

The Honorable Ed Whitfield, Chairman
Subcommittee of Energy and Power

The Honorable Bobby L. Rush, Ranking Member
Subcommittee of Energy and Power

ALMOND HULLERS & PROCESSORS ASSOCIATION

467 N. Wilma Ave., Ste 11
Ripon, CA 95366
(209) 599-5800

July 17, 2012

To:

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building, Washington, DC 20515

Copied:

The Honorable Henry Waxman
Ranking Member, House Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Ed Whitfield
Chairman, Energy and Power Subcommittee
2368 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Bobby Rush,
Ranking Member, Energy and Power Subcommittee
2268 Rayburn House Office Building
Washington, D.C. 20515

RE: U.S. Agricultural Relief Act of 2012

This letter is in support of the U.S. Agricultural Relief Act of 2012. The California Almond Industry requires the use of Methyl Bromide (MeBr) in orchards where no other viable alternatives are available to address specific conditions as detailed in the letter below. These conditions have qualified for the Critical Use Exemption up until the 2014 application when EPA determined that they were unable to include our application in the 2014 U.S. Nomination for a Critical Use Exemption (CUE) for methyl bromide.

Background

Almond growers have been funding research on soil borne pests and alternatives to soil fumigation for more than 20 years. To date the almond growers have invested more than $2.2 million in search for better tools and understanding of various soil borne pests, including rootstock resistance, testing for soil pathogens, and non-fumigant alternatives. Despite more than 20 years of research seeking methyl bromide alternatives there is still not an adequate alternative to MeBr for almonds; this is particularly true for oak root fungus, and for nematodes in heavy soils. The economic impact of these soil-borne pests is in reduced growth of the young orchard and death of trees, therefore, soil fumigants still play a significant role in the long term productivity and life-span of an almond orchard.

Almond growers who are dealing with one of the following situations will be in need of MeBr as no other technically and economically viable alternatives exist:

1) a grower replanting into an orchard with a history of oak root fungus and/or bacterial canker.
2) a grower who needs to treat individual tree holes in an existing orchard where one or more tree have died because of nematodes or oakroot fungus;
3) a grower who cannot apply Telone because of township cap restrictions
4) a grower with heavier soils, is replanting land that previous grew a tree or vine crop, or into soil that has a history of nematode, and/or oak root fungus, and/or bacterial canker issues.

EPA Response to CUE application

The CUE application submitted for California Almonds was denied with the following explanation provided by EPA.

"In the case of orchard replant in California the mixture of 1, 3-dichlororpropene plus chloropicrin is a technically and economically feasible alternative with a lower cost than methyl bromide plus chloropicrin and no yield loss. In addition iodomethane plus chloropicrin (Midas TM) is also technically and economically feasible with costs similar to methyl bromide plus chloropicrin. Finally, steam is a technically feasible non-chemical alternative but the initial investment and fuel costs may impact economic feasibility".

Concerns with EPA response

During review of this application and at the time of this response iodomethane or methyl iodide (MeI) registration was in litigation that ultimately led to the registration cancellation in California and the rest of the US. MeI is one of the three alternatives listed in EPA's response, and in our case the most viable alternative to methyl bromide, and is no longer available. EPA was aware of this situation yet did not account for this alternative not being available due to regulatory pressures.

Additionally, EPA lists steam as an alternative yet acknowledges that this is not an economically feasible alternative. Steam has been used on a trial basis and has not

been used for commercial applications. It is also has not been shown to be effective for nematodes, oak root fungus or bacterial canker.

Lastly, throughout the application process EPA did not indicate that there were any concerns with the application submitted; no questions were asked or points of clarification requested. Knowing that Mel was under litigation with a real possibility of the registration being cancelled combined with the fact that no other technically and economically feasible alternatives were introduced since the 2013 CUE was accepted we expected EPA to approve the CUE nomination for California Almonds.

Support for U.S. Agricultural Relief Act of 2012

Almonds are California's 3rd largest crop, with an estimated farm value of $3.6 billion dollars. On a value basis, almonds are also California's #1 ag export, and the U.S.' #1 horticultural export. These exports create more than 34,000 jobs. The CUE nomination for California Almonds is essential; its denial will create an economic hardship on the more than 6,000 growers of almonds, over 70% of which are family-owned small/medium sized operations.

The California Almond Industry supports the U.S. Agricultural Relief Act of 2012 as it will address the concerns listed with EPA's response as detailed above. Specifically, it requires EPA to consider the regulatory environment that may restrict the use of potential alternatives – a particular concern for California growers - , as should have been considered with Mel in the 2014 CUE application. Additionally, it puts responsibility on EPA to have substantial evidence to establish there are alternatives available that are not only technically and economically feasible but also available commercially. Lastly, we support the limit on the aggregate amount of MeBr that can be used in a calendar year as we understand and support the initiatives of the Montreal Protocol and Clean Air Act.

Sincerely,

Kelly Covello

Kelly Covello
President
Almond Hullers & Processors Association

AMERICAN FARM BUREAU FEDERATION®
600 Maryland Ave. SW | Suite 1000W | Washington, DC 20024

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f. 202.406.3606
www.fb.org

July 12, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton:

The American Farm Bureau Federation (Farm Bureau) supports passage of the *U.S Agriculture Sector Relief Act of 2012* and commends your committee for holding a hearing to review the importance of methyl bromide to American agriculture.

Methyl bromide is an indispensable pest control tool used in crop production, grain storage, food processing and general pest management. For some agricultural users, its availability is nearly essential to providing consumers the safe and reliable food they expect. Non-critical use of methyl bromide in this country was phased out in January 2005 in compliance with the Montreal Protocol as incorporated in the federal Clean Air Act. Since that time, the chemical's use has been reduced to a bare minimum as the Environmental Protection Agency (EPA) has increasingly rejected critical uses. The industry has worked to transition to viable alternatives such as methyl iodide and sulfuryl fluoride but sales of methyl iodide have been suspended and EPA has proposed withdrawing tolerances of sulfuryl fluoride. No other alternative has yet proven to be as effective.

Continued critical and emergency uses of methyl bromide need to be available. Farm Bureau is concerned that the industry has reached a critical point and that, in the end, American consumers will suffer greatly from agriculture's loss of methyl bromide. This elimination means the United States will increasingly depend on imported food sources that are potentially less regulated, less reliable and less safe.

Sincerely,

Bob Stallman
President

Cc: The Honorable Henry Waxman
The Honorable Ed Whitfield
The Honorable Bobby Rush

July 12, 2012

California Date Commission
Post Office Box 1736
Indio, California 92202
760-347-4510
800-223-8748
fax 760-347-6374
www.DatesAreGreat.com
info@DatesAreGreat.com

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Upton,

The Date Commission, a specialty crop commodity board represents 100 grower members producing 90% of California's dates. Located in the desert region of southern California, our producers generate approximately 46 million pounds of dates with a sales volume of $40 million. The industry presently comprises of 9,300 acres at variant levels of production and currently employs year round from 800 – 1200 workers. They include packing house and field labor and have the ability to expand the labor force in the future as production levels are expected to increase.

Today's hearing is meant to review the status of the Montreal Protocol as it relates to methyl bromide (MB). More importantly the hearing is meant to review the Obama administration's handling of the Critical Use Exemption (CUE) process incorporated into the Protocol's treaty. As you know the Protocol called for the complete phase out of methyl bromide in 2005 and allowed affected industries the ability to apply for a CUE if they could justify a need based the absence of technically feasible and economic alternatives. In addition we understand that there will be legislation introduced shortly to suggest changes in that process so it will provide guidance to all agricultural industries that still rely on the use of MB to remain competitive in this global economy.

The California Date industry has been a CUE holder every year since the phase out in 2005. This means that the industry has proven to EPA and then to the Parties of the Protocol that there is still a need and there are no viable alternatives. Of course the debate has been and continues to be the amount that is recommended by industry, how much EPA believes is actually needed and ultimately what is approved by the international body. This is where we think the process is broken.

First, we believe both EPA and the Protocol's technical review committees (MBTOC,TEAP) take action and rely on potential alternatives that have not been proven to be effective much less economic. Instead EPA requires the industry to prove the negative, meaning put the onus on industry to prove something doesn't work. We believe this is a fundamental weakness in the CUE process and has caused most of the grower's complaints. Not only does industry have to prove something doesn't work it has to do so numerous times over several years.

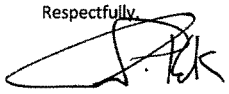
For instance in the first set of CUE's that were granted in 2005 the use of phosphine and cold storage as alternatives had to be addressed. CUE's were granted because the EPA and MBTOC concluded these were not viable or economically feasible alternatives. In 2012 we are now required again to prove these methods are not suitable alternatives. We believe the proper solution is to require

EPA and MBTOC with all the resources available to them to prove an alternative works before proposing it. Furthermore if a CUE is not granted or is reduced we believe EPA and MBTOC should be required, in writing, to say why and what information they relied on to take the action they did.

The second major complaint is the longevity and existence of the CUE process itself. It is not hard to see that both the EPA and MBTOC have taken decisions to bring the use of MB to an end. The most startling evidence of this is language in their reports and documents where they actually state that they don't see certain industries getting CUE's in the future. This obviously prejudges any application before its even been filed. Not only that but it completely ignores changing circumstances. One need only look at the events surrounding the preplant alternative "midas" or the postharvest alternative sulfuryl fluoride. Many CUE's were reduced or eliminated based on the availability of these alternatives. We now know that one is no longer on the market and the other, our own EPA has proposed be cancelled. Moreover it was EPA that forced the transition to sulfuryl fluoride only to turn around and propose its repeal. This has cost industry millions of dollars and another forced transition will be millions more. The fact is, the CUE process has no expiration date in law or regulation but the US government is acting as if it did. We believe any legislation should make this fact very clear so that growers will have the certainty of knowing what the playing field will look like when making planting decisions now and in the future.

Thank you for the opportunity to share our concerns and please take whatever action you deem necessary to improve this important process that necessarily means so much to our economic viability.

Respectfully,



Albert P. Keck
Chairman

cc: The Honorable Henry Waxman, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman
Subcommittee on Energy and Power

The Honorable Bobby Rush, Ranking Member
Subcommittee on Energy and Power

Mary Neumayr, Majority Committee Staff

CALIFORNIA WALNUT COMMISSION
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An Equal Opportunity Employer and Provider

July 16, 2012

The Honorable Fred Upton
Chairman
House Energy and Commerce
Committee
2183 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Upton:

I am writing on behalf of the more than 4,000 growers and 82 processors (handlers) who farm and market California walnuts. The vast majority of these farms are family operations having been run by the families for two or more generations. This industry, with farm gate revenue of just over $1 billion dollars in 2010/11, employs more than 60,000 individuals directly and indirectly. California walnuts are also one of the state's top exports, ranking 4th for 2010 in the UC Agricultural Issues Center export data publication.

The California walnut industry has been a CUE holder every year since the phase out in 2005. This means that the industry has proven to EPA and then to the Parties of the Protocol that there is still a need and there are no viable alternatives. Of course the debate has been and continues to be the amount that is recommended by industry, how much EPA believes is actually needed and ultimately what is approved by the international body. This is where we think the process is broken.

First we believe both EPA and the Protocol's technical review committees (MBTOC,TEAP) take action and rely on potential alternatives that have not been proven to be effective much less economic. Instead EPA requires the industry to prove the negative, meaning put the onus on industry to prove something doesn't work. We believe this is a fundamental weakness in the CUE process and has caused most of the growers complaints. Not only does industry have to prove something doesn't work it has to do so numerous times over several years.

For instance in the first set of CUE's that were granted in 2005 the use of phosphine and cold storage as alternatives had to be addressed. CUE's were granted because the EPA and MBTOC concluded these were not viable or economically feasible alternatives. In 2012 we are now required again to prove these methods are not suitable alternatives. We believe the proper solution is to require EPA and MBTOC with all the resources available to them to prove an alternative works before proposing it. Furthermore if a CUE is not granted or is reduced we

believe EPA and MBTOC should be required, in writing, to say why and what information they relied on to take the action they did.

The second major complaint is the longevity and existence of the CUE process itself. It is not hard to see that both the EPA and MBTOC have taken decisions to bring the use of MB to an end. The most startling evidence of this is language in their reports and documents where they actually state that they don't see certain industries getting CUE's in the future. This obviously prejudges any application before its even been filed. Not only that but it completely ignores changing circumstances. One need only look at the events surrounding the preplant alternative "midas" or the post harvest alternative sulfuryl fluoride. Many CUE's were reduced or eliminated based on the availability of these alternatives. We now know that one is no longer on the market and the other, our own EPA has proposed be cancelled. Moreover it was EPA that forced the transition to sulfuryl fluoride only to turn around and propose its repeal. This has cost industry millions of dollars and another forced transition will be millions more. The fact is, the CUE process has no expiration date in law or regulation but the US government is acting as if it did. We believe any legislation should make this fact very clear so that growers will have the certainty of knowing what the playing field will look like when making planting decisions now and in the future.

Thank you for the opportunity to share our concerns and please take whatever action you deem necessary to improve this important process that necessarily means so much to our economic viability.

Sincerely,

Carl Eidsath

Carl Eidsath
Technical Support Director

The Honorable Henry Waxman
Ranking Member, House Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Ed Whitfield
Chairman, Energy and Power Subcommittee
2368 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Bobby Rush,
Ranking Member, Energy and Power Subcommittee
2268 Rayburn House Office Building
Washington, D.C. 20515

FLORIDA FARM BUREAU FEDERATION
The Voice of Agriculture in Florida

July 16, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton:

The Florida Farm Bureau Federation supports passage of the U.S Agriculture Sector Relief Act of 2012 and commends your committee for holding a hearing to review the importance of methyl bromide to American agriculture.

Methyl bromide is an indispensable pest control tool used in crop production, grain storage, food processing and general pest management. For Florida specialty crop producers, its availability is nearly essential to providing consumers the safe and reliable food they expect. Non-critical use of methyl bromide in this country was phased out in January 2005 in compliance with the Montreal Protocol as incorporated in the federal Clean Air Act. Since that time, the chemical's use has been reduced to a bare minimum as the Environmental Protection Agency (EPA) has increasingly rejected critical uses. The industry has worked to transition to viable alternatives such as methyl iodide and sulfuryl fluoride but sales of methyl iodide have been suspended and EPA has proposed withdrawing tolerances of sulfuryl fluoride. No other alternative has yet proven to be as effective.

Continued critical and emergency uses of methyl bromide need to be available. Farm Bureau is concerned that the industry has reached a critical point and that, in the end, American consumers will suffer greatly from agriculture's loss of methyl bromide. This elimination means the United States will increasingly depend on imported food sources that are potentially less regulated, less reliable and less safe.

Sincerely,

John L. Hoblick
President

Cc: The Honorable Henry Waxman
The Honorable Ed Whitfield
The Honorable Bobby Rush

PO Box 147030 • Gainesville, FL 32614-7030 • Phone: 352/ 378-1321 • www.FloridaFarmBureau.org

FLORIDA TOMATO EXCHANGE

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Phone (407) 660-1949 · Fax (407) 660-1656

July 10, 2012

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton:

I am writing you on behalf of the Florida Tomato Exchange, whose growers provide 85% of the fresh tomatoes from Florida. Thank you for reviewing the Methyl Bromide issue and the impact on the American grower. The introduction of the "US Agricultural Sector Relief Act" is a very important step in keeping us in the tomato business. Florida is the largest producer of fresh tomatoes in the U. S. with harvest beginning in October and ending in June. Tomatoes are produced in five major regions of Florida and over several different soil types (sands, sandy clays and rock land soils) from extreme North Florida to South Dade County, forty miles south of Miami.

Methyl bromide has been the cornerstone soil fumigant to the full bed mulch production system for fresh tomatoes in Florida. It has enabled significant increases in productivity. This increase in yields over the last 30 years has enabled the Florida tomato industry to remain competitive with imported tomatoes from Mexico. The industry has made very significant reduction in the rate/acre it applies to the soil by adopting the use of high barrier films thus reducing the loss of methyl bromide to the environment while maintaining efficacy at lower rates of methyl bromide use.

The reduction of available methyl bromide under the Critical Use Exemption has resulted in the migration to alternatives. However, the reduction in efficacy of these alternatives in controlling the myriad of pest challenges plus the lack of alternatives on some soil types has created a serious crisis for the grower community.

The unfortunate reality in a highly competitive marketplace is that the loss of methyl bromide availability is limiting the production efficiency on many farms. This loss is changing the economics of production to such an extent that growers are being forced to carefully examine the economic viability of tomato production. If conditions continue

to erode, the economic sustainability of growing tomatoes in Florida will be lost. If this occurs, the United States will no longer grow fresh tomatoes in the field from late fall, winter and early spring. We will no longer employ worker or contribute to the domestic economy. Florida's loss will be in the tens of thousands for employment and hundreds of millions to the economy. Methyl bromide must be maintained as a tool to maintain viable domestic tomato production. Recognition of the improved application technology rate reduction should be considered as very significant factors in evaluating future methyl bromide use authorizations due to emission reductions and the extent of environmental impact.

Jobs and economic survival are in the balance for those who grow, ship and market tomatoes from Florida, the leading fresh market tomato producing state in the United States of America.

Sincerely,

Reginald L. Brown
Executive Vice President

cc: The Honorable Henry Waxman
Ranking Member, House Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, DC 20515

The Honorable Ed Whitfield
Chairman Energy and Power Subcommittee
2368 Rayburn House Office Building
Washington, DC 20515

The Honorable Bobby Rush
Ranking Member, Energy and Power Subcommittee
2268 Rayburn House Office Building
Washington, DC 20515

P.O. Box 2945, LaGrange, GA 30241
1-877-994-3842 www.gfvga.org

July 17, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building,
Washington, DC 20515

Dear Chairman Upton:

Fruit and vegetable production in Georgia is almost a billion dollar industry at the farm gate. Our growers use multiple production techniques and practices to fulfill their mission to provide U.S. consumers with safe and healthy fresh produce.

Until recently methyl bromide had been an indispensable pest control tool used in vegetable production in Georgia. As the production of methyl bromide was being phased out in recent years, researchers from the University of Georgia have developed alternatives which most Georgia producers use for their soil fumigation needs. While the alternatives work for several years, often these alternatives do not effectively control weed and soil pathogen pest over an extended period of time. There is a continued need for methyl bromide to be used periodically as a way to eliminate these pest pressures. If methyl bromide is not available for these 'critical use' needs, the economic viability of many Georgia growers will be severely damaged. No other alternative has yet proven to be effective enough to be a permanent replacement for methyl bromide.

Continued critical and emergency uses of methyl bromide must to be available. Georgia Fruit and Vegetable Growers Association is concerned that the U.S. fresh produce industry has reached a critical point. We are very concerned the American consumer will suffer greatly from the loss of methyl bromide. This elimination moves the U.S. increasingly closer to being dependant on imported food sources that are potentially less regulated and less reliable.

The Georgia Fruit and Vegetable Growers Association supports passage of the *U.S Agriculture Sector Relief Act of 2012* and commends your committee for holding a hearing to review the importance of methyl bromide to American agriculture.

Sincerely,

Charles T. Hall, Jr.
Executive Director

CC: The Honorable Henry Waxman
The Honorable Bobby Rush,
The Honorable Ed Whitfield

Dear Honorable Ed Whitfield,

I am writing in response to the pending legislation for the ban of methyl bromide without other considerations being taken into account. While methyl bromide may not be the optimal fumigant due to the risk it poses to the ozone layer, currently there are no other fumigants that are as effective while still being in a reasonable realm of price.

Holzinger Flowers Incorporated has been growing florist-quality flowers in Florida and selling them to wholesale florists along the East Coast of the United States for forty-four years. We have always grown small acreage and had a simple business ever since my father started it in 1947 in New Jersey. Due to cost restrictions recently, we now only have one worker besides myself due to the low income we have been experiencing lately because of the decreased market. Flower growers have been growing in Martin County, Florida, our current location, because of the sub-tropical climate that favors this trade as well as the efficient transport in the area as a result of the Florida Turnpike and Interstate 95, both of which facilitate the transport of cut flowers to the north with refrigerated trucks. When we first started farming in Florida, Palm City was nothing but dairy and flower farms. All of these areas are now housing developments. Because of all this urban sprawl, we cannot use other fumigants as they could pose a threat to surrounding homes and businesses and their water supplies.

Historically, one of our main crops has been freshly cut lilies including Asiatics, L.A. Hybrids, and Orientals. Due to high pressure in the market from for foreign countries, such as Ecuador, where they import lilies into the United States for nearly the same price as my company pays for bulbs, which still need to be grown, it is only a matter of time before I will have to discontinue the cultivation of this crop. This is only worsened by the various pieces of legislation, such as NAFTA and the Andean Trade Preference Act, which make it even easier for flowers grown in Central and South America to be introduced to American markets and put hardworking farmers out of business.

I have been using methyl bromide for all these years because of its convenience as a safe and effective fumigant that allows for the growth of florist-quality flowers. Methyl bromide on my farm is being applied with shank applicators in open areas and hot gassed in order to fumigate pole rows so that the fields are weed free. The current EPA restrictions on how much should be applied are already having a severe impact on the quality and quantity of product that we harvest. Methyl bromide was always applied at 425 pounds per acre at a concentration of 98% methyl bromide to 2% Chloropicrin. Now we must apply 300 pounds per acre with a concentration of 80/20. Because of this, we are losing 176 pounds of methyl bromide per acre to fumigate weed seeds, nematodes, and diseases. This reduction in the amount of methyl bromide applied per acre has resulted in significant increases in weed and nematode problems and the loss of even more active ingredient is likely to make growing these crops impossible,

Holzinger Flowers has been working with the USDA ARS of Ft. Pierce, FL over the past decade. In testing other fumigants, including methyl iodide, DMDS, steam, which is effective, however with the rising price of fuel is not cost- effective, and solarization, which does not work due to high levels of nematodes,

methyl bromide has been proven to be the only fumigant on the market to be able to fulfill our needs without using other chemicals to control nematodes which are illegal in the United States, but are legal in the countries from which flowers are imported. In my opinion, methyl bromide should be continued to be used in the floriculture industry until a safe, cost-effective, and useful alternative is found. This is what the Montreal Protocol provided Critical Use Exemptions for. We have made significant efforts to test every alternative that has been proposed and we have NOTHING for the Florida cut flower industry that can replace this fumigant and EPA has ignored this fact in their effort to completely phase this material out. The loss of this valuable fumigant will make me unable to stay in this business, and being 58 years old, I find it a difficult prospect of starting a new career in this stagnant economy while supporting a family. Also, being an employer, I, like other farmers, must also think about and try to protect the future of my employee.

I would like to thank you Honorable gentlemen for taking time to listen to my view about an important issue that affects not only mine, but the welfare of many other farming families. Apart from the floriculture industry, I am very concerned with the related food industry and how it is being dealt with. With much of our food coming from foreign countries, many of the fruits and vegetables are exposed to chemicals that are illegal to use in the United States but are being used readily at our food sources. This hypocrisy in our food and flower industries makes me feel strongly towards the increased amount of trade agreements that are being put into place which will surely make the United States a consumer in the global market rather than the self-sustaining producer it was built to be.

Thank You.

John C. Holzinger

Holzinger Flowers Inc.

Holzinger Flowers Inc.

P.O. Box 93

Palm City, FL 34991

Phone/Fax: 772-287-7269

Email: johnholziner@att.net

HOPKINSVILLE MILLING COMPANY
P.O. BOX 669
HOPKINSVILLE KENTUCKY 42241-0669
PHONE (270) 886-1231
FAX (270) 886-6407
"MANUFACTURERS OF FLOUR AND CORN MEAL"

July 16, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Upton:

I would like to thank the Energy and Commerce Committee for reviewing the situation regarding the use of methyl bromide and sulfuryl fluoride as structural fumigants.

My company manufactures corn meal and packs flour as well for the retail trade. We are located in western Kentucky and employ 20 people. Homemakers buy our products to make cornbread, biscuits, and cakes. We used to use methyl bromide as a structural fumigant about twice a year to insure our ability to manufacture a safe, sanitary product that would be acceptable to our customers. Grain products are quite attractive to insects, so we need the ability to perform periodic fumigations. A few years ago, we switched to using sulfuryl fluoride because of concerns about the availability of methyl bromide. While SF performs a satisfactory kill, it takes longer to apply the gas and air out the plant when using SF. Through better housekeeping, we have reduced the number of structural fumigations we perform to one a year. If we lose both methyl bromide and sulfuryl fluoride, then we will be very hard pressed to keep insect levels low enough to satisfy our customers and the clean food regulations. Because our plant is quite old and made of brick and wood, we cannot use heat as a fumigant because it could damage the structure.

Sincerely

Robert Y. Harper
President

C: The Honorable Ed Whitfield
Mary Neumayr

July 16, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, D.C. 20515

Dear Fred,

My name is Charles B. Knappen III and I am President/CEO of the Knappen Milling Company located in Augusta, MI. I run a family owned flour mill which currently employees forty-one (41) people. In the past, you have visited our facility here in Augusta. Our mill produces flour for the cereal industry, snack foods industry, dry blending industry and the baking industry. We also produce cleaned wheat for the cereal and snack foods industries.

I am writing you today because your Subcommittee on Energy and Power is holding a hearing on Wednesday July 18th to explore the issue of methyl bromide and to identify policy changes needed to improve the review and approval of methyl bromide Critical Use Exemptions. This hearing will be followed by the introduction of a methyl bromide bill- the U.S. Agricultural Sector Relief Act of 2012. For this I personally thank you. It is important for the Committee to review the methyl bromide situation and for introducing the U.S. Agricultural Sector Relief Act of 2012.

In my letter to you in 1997, copy attached, I told you that we were experimenting with potential alternatives to methyl bromide. We did so and found nothing better than or as economical to use as methyl bromide. We have continued to use this chemical but have been able to reduce the quantity used and still had effective general fumigations of our mill. For our facility, it has gotten very expensive to fumigate with methyl bromide but it is the best alternative for us.

If methyl bromide is outlawed entirely and there are no Critical Use Exemptions allowed, along with there being no methyl bromide available at any price, then our facility may be at risk. No other product does the job like methyl bromide and the one replacement product, (replacement does not mean equivalent to or as effective as) is now going to be eliminated due to a Proposed Order to delete SF tolerances and cancel associated uses.

I urge you, your Committee and your Sub-committees to allow the use of methyl bromide as a general fumigant in the milling industry and to make sure it is available for use in the future, at least under a Critical Use Exemption.

Yours truly,

C.B. Knappen III
President/CEO

October 2, 1997

The Honorable Fred Upton
U.S. House of Representatives
Washington, DC 20515-2206

Dear Representative Upton:

Knappen Milling Company located in Augusta, Michigan has a sixty-eight (68) year history of producing wholesome food products and providing good jobs in a rural Michigan community. Our ability to do this is dependent upon meeting government regulations for good sanitation in our facility to ensure product quality. To assure good sanitation and ultimately product quality, we depend on the fumigant methyl bromide.

I am writing to ask you to be an original co-sponsor of the legislation to be introduced by Representative Dan Miller that will delay the ban on methyl bromide.

Knappen Milling Company, like other milling companies in Michigan and around the country, has been experimenting with potential alternatives. Today however, there is no suitable replacement for methyl bromide and it is an essential tool for maintaining our sanitation program.

The Montreal Protocol, which is under the United Nations Environmental Program will ultimately ban the use of methyl bromide on a world wide basis. Less than one-half the countries that signed this treaty have agreed to set a date for the elimination of this chemical. Unfortunately, the United States is one country that has set an elimination date. None of the countries that are our agriculture competitors for exports have set a date for the elimination of methyl bromide. This means that we, as a country, will be uncompetitive insofar as agricultural exports are concerned, and there will be no benefit achieved on this environmental goal.

I urge you to co-sponsor Representative Miller's bill. Amy Steinmann is coordinating the bill for him and can be reached at 225-5015.

I look forward to your response. Thank you for considering my views.

Yours truly,

C.B. Knappen III

CC: President William Clinton

Lassen Canyon Nursery, Inc.

P.O. BOX 992400
REDDING, CA 96099-2400

PHONE 530.223.1075 FAX 530.223.6754
www.lassencanyonnursery.com
Email: mail@lassencanyonnursery.com

13 July 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building,
Washington, DC 20515

Re: Support for the US Agricultural Sector Relief Act of 2012

Dear Chairman Upton:

My brother and I own Lassen Canyon Nursery, Inc. We grow about 350 million strawberry plants on 1300 acres that we sell to commercial strawberry fruit growers. Our headquarters is located in Redding, California which is about 2 hours south of the Oregon border. Our primary growing location is a remote area of Siskiyou County, also in Northern California. Our largest market is in Southern and Central California near the Monterey coast, but we also grow and sell strawberry plants to other strawberry nurseries. Those plants are grown and distributed all over the world. For example, we sell to Canadian nurseries that in turn grow out those plants and sell the multiplied material to fruit growers in Florida. Our other large export areas are Mexico, Spain, Columbia, Tunisia, Argentina and the Dominican Republic.

It typically takes about five years to multiply a new strawberry cultivar in sufficient numbers to sell it commercially. At each step of the way Lassen Canyon uses a mixture of methyl bromide and chloropicrin to fumigate the soil. The methyl bromide/chloropicrin mixture is injected into the soil and then the soil is covered with a plastic tarp. The tarp stays in place for 5 days and then it is removed. Our planting takes place thereafter.

We fumigate because strawberry plants are susceptible to fungal pathogens as well as root nematodes. Methyl bromide kills these pathogens with an efficacy that is not matched by any alternative. Another probably more compelling reason we fumigate is that we can't export our plants even out of our county without fumigation. The county agricultural commissioners and USDA inspectors where we farm routinely monitor our

pesticide records and inspect our plant material for signs of disease and infestation. We can be prohibited from shipping any plant material that does not pass inspection. Shipping internationally requires even more inspection and record production. In addition to the inspections I have just mentioned, often the countries where we ship will either send inspectors ahead of time to look at the fields or will subject our plants to testing before they clear customs while still at the port or airport. Part of the required records review is the fumigation records.

As you read this letter, inspectors from Mexico will be at our farm in Macdoel as well as the farms of my colleagues to inspect the fields before they will authorize our plants to cross the border into Baja Mexico in September. Part of the records that they are requiring us to provide is the fumigation records. I am attaching a copy of an email outlining the schedule and record requirements so you can see that this is a real situation. Right now most of our Methyl Bromide is supplied to us through the Quarantine/Preshipment exemption. However our critical use exemption gas is also crucial for us since not every use of MB in our operation falls squarely within the QPS exemption. Further, along with critical use exemption which was inexplicably and drastically slashed by our own government this year, the QPS exemption is always being called into question when the Montreal Protocol Parties meet. It is extremely important to the strawberry plant nursery industry that we have the use of MB. There are no realistic viable alternatives. As you know the makers of Midas took that product off the market. There are crippling township caps on the use of Telone. Plus it is not as effective.

The way things are now, if nurseries lost the use of methyl bromide, our export market would vanish since there is no recognized alternative to fumigation with methyl bromide. Countries like Mexico require that plants imported into their country be fumigated with methyl bromide. In fact, our customers in Canada and the EU purchase US grown planting stock mostly because the plants are grown in soil fumigated with methyl bromide. Those foreign growers don't have access to the chemical for their operations anymore, so they rely on getting the healthiest, most vigorous planting stock they can for their nursery or fruit growing operations from us here in the United States where nurseries still have access to methyl bromide.

The future for the strawberry nursery industry will be dismal if methyl bromide is completely eliminated. The most productive varieties were developed for farming systems that include fumigation with methyl bromide at least at the nursery level. Without changes to current regulations, exports would cease. Our product simply will not meet the export requirements. Unfortunately, as I am sure you know, changing regulations is not easily done either. It is hard to say how many seasons would pass before those problems would be solved and even then the quality will not be the same. Disease pressures will mount requiring the use of more fungicides just when there is a massive push for organically grown fruits and vegetables.

The US Agricultural Sector Relief Act of 2012 is a reasonable compromise that tries to solve a real problem for growers with no other access to this essential chemical. I hope that you and your colleagues will see that as well. We here at Lassen Canyon Nursery along with my other nursery colleagues appreciate your Committee reviewing this situation and introducing this legislation. Please keep up this good work for the sake of our industry.

Very truly yours,

Elizabeth Elwood Ponce
Co-owner, Lassen Canyon Nursery, Inc.

CC: Honorable Henry Waxman via fax
Honorable Ed Whitfield via fax
Honorable Bobby Rush via fax

Liz Ponce

From:	drm2472@gmail.com on behalf of David Murray [dmurray@sundanceberryfarms.com]
Sent:	7/13/2012 4:00 PM
To:	Richard Nelson
Cc:	Richard Jose; lcn@cot.net; John Giaimo; Bruce Wall; Bruce Jensen; carl@crownnurseryllc.com; r.winn@planasa.us; Mike Fahner; Steven D. Nelson; mnelson; DANIEL/VALERIE Nelson; Jason Bird; Raymundo Carranza; Hebe Bradley; Liz Ponce; Steve Albaugh; Kim Cronin; John Sakuma
Subject:	Re: Baja Inspection Team Aug 16-19

As Richard mentioned, please be sure to have the following information available for the inspector upon arrival at your nursery:

1. Company registration at correspondent authority (Nursery/Business License)

2. Methyl Bromide application with chloropicrin permit (Restricted Materials Permit listing MB/PIC)

3. Pesticides application program (Pesticide Use Reports)

4. If field samples are taken, show a copy to have done a verification on what products are being applied and for which type of pest and diseases are used.

Thanks.

On Fri, Jul 13, 2012 at 2:53 PM, Richard Nelson <rnelson@plantsciences.com> wrote:
Nurserymen:

After having spoken with all of you I have put together the following schedule for next week's visit by the Baja Inspection Team. If you have any conflict with this schedule please advise ASAP. From experience we know that the Team may not follow a strict time schedule - for this reason I have included the cell phone numbers of each nursery representative. If you are running early (not likely) or late (more likely) please call the person that you are handing the team off to in order to advise them of timing adjustments. A & W will provide air transportation for the Team, and we will rent a vehicle in K. Falls for the Team to use while doing their inspection. Team will be staying at Holiday Inn Express in K. Falls. If there are others in your organization that need this information please feel free to forward this email to them. Please remember to have your packet of information ready to hand off to the inspector. The team will consist of the inspector, Conrado, and 1-2 growers from Baja.

MONDAY JULY 16
1. Norcal Nursery - Turlock 8:00 am - 1:00 pm (please provide a lunch for them to take on the plane)
   Richard Jose - 831-345-1969
2. PSI Nursery - Macdoel - 3:00 pm - 6:30 pm
   John Giaimo 530-398-4042 office or 530-356-4977 cell (John: please pick up rental car at K. Falls Monday evening when you take them to town)

TUESDAY JULY 17
1. PSI Nursery - Macdoel - 7:00 am - 10:00 am
   John Giaimo - see above
2. NorCal Nursery - Macdoel 10:00 am - 3:00 pm (please provide lunch)
   Richard Jose - see above
3. Cal Nursery - Macdoel 3:00 pm - 6:30 pm
   Bruce Jensen 530-949-1460

WEDNESDAY JULY 18
1. Lassen Canyon Nursery - Macdoel 7:00 am - 11:00 am (please provide lunch)
   Scott Scholer 530-604-7268
2. Planasa - Macdoel 11:00 am - 2:00 pm
   Richard Winn 530-526-9581
   Michael Delaney 949-315-0423
3. JPA Nursery - Bonanza 2:00 pm - 6:30 pm
   Bruce Wall 541-274-1743

THURSDAY JULY 19
1. Crown Nursery - Macdoel 7:00 am - 10:00 am
   Carl Anberg 530-200-0505
2. Cedar Point Nursery - Dorris 10:00 am - 2:00 pm (please provide lunch)
   Mike Fahner 541-892-8510

Plane will depart either Butte Valley or K. Falls at 3:00 pm (John: if departure is out of Butte Valley please return rental car to K. Falls)

Baja team will have their own rental car and will meet nursery representative for first morning inspection at Sharon's Restaurant in Macdoel. When you are finished with the first inspection nursery rep. should call ahead to the next nursery to advise timing and be prepared to show the team to the next nursery field or to meet back at Sharon's, Same procedure for the 3rd nursery of the day...Lunch is usually a quick stop at Sharon's and they pick up what they like, just bring a little cash to pay for the Team please.

Team will have ice chests, plastic zip locks for samples. John Giaimo at PSI office will have extra frozen ice packs if needed - just stop in and pick them up.

I will not be personally present in Macdoel next week but can be contacted via my cell at 831-750-8823 for any questions, or details, or problems. John Giaimo at PSI will also be available to assist you and the Team if needed.

Please email any questions back to me, otherwise I believe we are ready to go.

Richard

--
Dave Murray
3445 Telegraph Road Suite 104
Ventura, CA. 93003
Ph: 805-797-2514
Fax: 805-832-6006
drm2472@gmail.com

MARITIME EXCHANGE
for the Delaware River and Bay
Leading the Way to Port Progress

John T. Reynolds, Chair
Uwe Schulz, Vice Chair
Dennis Rochford, President
Lisa B. Himber, Vice President
A. Robert Degen, Esq., Secretary, Solicitor
James F. Young, Esq., Assistant Secretary
Dorothy Mather Ix, Treasurer

July 16, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building, Washington, DC 20515

RE: U.S. Agricultural Sector Relief Act of 2012

Dear Chairman Upton:

This letter is to bring to your attention to matter of great significance to the Delaware River regional port community, and international trade and commerce as a whole. At issue is the importance of maintaining the availability of methyl bromide in two particular areas: critical use exemptions; and quarantine treatments.

As information, the Maritime Exchange for the Delaware River and Bay is a non-profit trade association representing the interests of approximately 300 port and related businesses in the states of Pennsylvania, New Jersey and Delaware.

Methyl bromide is one of the principal tools relied upon as treatment for the various products shipped domestically or internationally and addresses phytosanitary concerns of varying regulatory authorities. Any decision to restrict the availability and use of methyl bromide will have an immediate and adverse impact on international trade, thereby affecting a wide variety of export and import cargoes and U.S. consumers.

Further reductions and/or the potential loss of methyl bromide for maritime uses would cause a substantial and damaging bearing on the maritime industry, its businesses and hundreds of associated jobs. It is also important to note that should other existing alternatives to methyl bromide currently under review, such as sulfuryl fluoride, be eliminated, the need for methyl bromide obviously increases.

Therefore, we urge you to maintain methyl bromide for critical use exemptions and quarantine treatments. Feel free to contact me at 215.925.2615 or at dennis.rochford@maritimedelriv.com with need for further information.

Sincerely,

Dennis Rochford
President

cc: The Honorable Henry A. Waxman, Ranking Member
House Energy and Commerce Committee

The Honorable Ed Whitfield, Chairman
Subcommittee of Energy and Power

The Honorable Bobby L. Rush, Ranking Member
Subcommittee of Energy and Power

Fred Leitz Jr.
Leitz Farms LLC
5109 River Road
Sodus, MI 49126

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building,
Washington, DC 20515

Dear Chairman Upton and members of the House Energy and Commerce Committee,

Thank you for giving me this opportunity to make comments on the problems that specialty crop growers are facing in the U.S. with regards to methyl bromide, a soil fumigant.

Leitz Farms is a specialty crop farm in Sodus, Michigan, growing strawberries, cucumbers, cantaloupes, tomatoes, and apples. We are in Chairman Upton's district. Started in 1903, my 3 brothers and I are the 4th generation and don't want to be known as the last generation to farm this land.

My father started using soil fumigants for strawberries in the late 1960's to control weeds and diseases. Back then he used a liquid fumigant and tilled the soil afterwards to seal the fumigant in the soil. In 1991we started using methyl bromide on tomatoes for the same reasons, except we used it under plastic mulch to hold the fumigant in the soil so it would do its job. The first year of using methyl bromide increased yields by 25% in tomatoes and with better management practices built around using fumigants, we have increased yields 50% over the average in 1990. With the yield increases, we could plant fewer acres thereby allowing us to do a better job of crop rotation and use less chemicals and water.

When the Montreal Protocol was approved by the Senate, we knew we had a deadline for the use of methyl bromide; it looked like the end was a long ways into the future. In 2000 I started to let Congressional leaders know the current situation for specialty crop growers was not good and we needed a legislative fix. I saw no good alternatives on the horizon to replace methyl bromide. The Congressional leaders I talked to earlier informed me around 2005 that a viable alternative replacement for methyl bromide was coming. Arysta Life Sciences had been to various members of Congress and told them they had a product as a viable replacement. We did some trials of the product, Midas, on our farm for a couple of years. The results were promising, but we still weren't able to get planted at the proper time. Planting dates were still later by a week; also we had to use a different type of mulch. Using Midas and the VIF mulch, was cost prohibitive compared to methyl bromide.

The main reason we need methyl bromide in Michigan is we don't get high enough soil temperatures to apply fumigants until mid to the late April. For us to hit market windows we

need to plant around May 5. All the alternative products don't let us plant until the middle of May and we would miss the early markets. We call this the plant back time, the time from fumigation to when a crop can be planted without the fumigant injuring the plant. Dr. Mary Hausbeck, plant pathologist from Michigan State University, conducted the largest on farm fumigation trials in the United States on our farm. Nothing compared with methyl bromide for plant back times. We then coupled this data with marketing opportunities and got economic data for the trials. The data showed we have to plant by May 5-10 to be able to hit the market window of opportunity to be profitable. Remember, farmers are price takers, not price makers.

Midas was pulled from the market this spring. Leitz Farms LLC was going to use Midas for early season plantings. Having no viable alternatives we are going without fumigation for the first time in 20 years on our early plantings.

The growers in Michigan that used methyl bromide did not have Michigan State University apply for a Critical Use Exemption (CUE) for 2012 and later years. We were going to rely on Midas for early plantings and then use other fumigants for later plantings. The Montreal Protocol was designed for this scenario. The withdrawal of Midas from the fumigant mix changed this scenario.

The critical use exemption process is fatally flawed. The EPA has chosen to reduce volumes below what the U.S. growers were granted by the Protocol every year since 2005. Growers have repeatedly stated that they do not have alternatives that are viable either from a technical or economic standpoint for some uses. The original intent of the CUE as it was written in the treaty (and approved by the U.S. Senate) was to provide a safety net for end-users until alternatives were available. The concept was clear and simple; with no alternative, you can have a critical use exemption. However this is not how the entrenched and non elected bureaucrats at EPA are administering the program. Listed are some of my concerns with the way the EPA is administering the CUE.

- EPA should not reduce the CUE volume below what the Montreal Protocol grants to the U.S. as a critical use exemption

- EPA should carefully coordinate and cooperate with USDA and the State Dept. to insure that U.S. grower interests are protected and that the annual critical use nomination should not be reduced.

- EPA's actions in regards to relying on pre-existing stocks to meet the real market demand is jeopardizing the ability of many growers to have access to the product because inventories are not evenly distributed throughout the supply chain.

- EPA's actions have dramatically increased the costs of production for U.S. growers while growers in Mexico and the rest of the developing world (including China) have access to methyl bromide until 2015.

- USDA has spent nearly $200 million in research into alternatives over the last 10 years and so far the efforts have not resulted in a replacement for methyl bromide.

-The United Nations Multilateral Fund for the Implementation of the Montreal Protocol has had over 3.6 billion contributed to it to help finance research for alternatives and to help developing countries implement the Montreal Protocol, with most of the funds coming from the United States.

-EPA should allow Michigan growers to apply for an emergency CUE for 2013-14. With the withdrawal of Midas, we don't have a good alternative for early plantings.

According to the National Oceanic & Atmospheric Administration (NOAA) presentation given at the 2007 Methyl Bromide Alternatives Conference the complete ban of methyl bromide will only result in a reduction of 2.8 parts per TRILLION in the atmosphere because methyl bromide is produced naturally. The 2.8 parts per trillion is 1/100 of what was thought when the treaty was ratified by the United States in 1992. The signatory parties to the Montreal Protocol need to come together and look at the new science and change the way they view methyl bromide. The treaty has been changed twice since its original ratification in 1987.

As you can see, the administering of the CUE process by EPA has been mismanaged. They are supposed to be working for the US grower at the meetings of the parties and they have done the opposite. The scientific evidence has changed for ozone depleting substances, especially methyl bromide. The agricultural community has been trying to get Congress to notice this for some time and I am glad you are taking a look at the problem and I encourage passing the "U.S. Agricultural Sector Relief Act of 2012."

Sincerely,

Fred Leitz Jr.
Leitz Farms LLC
5109 River Road
Sodus, MI 49126

Copies to:
The Honorable Henry Waxman
Ranking Member, House Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Bobby Rush,
Ranking Member, Energy and Power Subcommittee
2268 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Ed Whitfield
Chairman, Energy and Power Subcommittee
2368 Rayburn House Office Building
Washington, D.C. 20515

July 17, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn house Office Building
Washington, DC 20515

As President of Star of the West Milling Co., I am writing to express my concern over the elimination of the products we use to keep our flour and whole wheat products free from insects. Our company was founded in 1870 and has been a major supplier to the baking and cereal industry. We currently own and operate five flour mills, two in Michigan and one in Ohio, Indiana and New York. Our company employs 225 full time employees and 30 part time employees.

We have been dealing with the reduction of Methyl Bromide for many years. We have been working with Dow to find an effective replacement (Sufuryl Fluoride) which is now being proposed to also be phased out. With the recently passed new Food Safety Law we are required to supply wholesome, defect free products to the public. If use of these fumigants is eliminated without sufficient time to discover and test alternative ways of controlling insects, it will be impossible to meet the guidelines for food safety. Currently we have no other means to produce insect free products.

I appreciate your committee looking into this and for introducing the US Agricultural Sector Relief Act. Doing so will provide our flour milling industry and Star of the West with some assistance in resolving this challenge.

Sincerely
Star of the West Milling Co.

Arthur Loeffler
President

Cc: The Honorable Henry Waxman
The Honorable Ed Whitfield
The Honorable Bobby Rush

Sunkist

a cooperative of family farms since 1893™

Michael Wootton
Senior Vice President
Corporate Relations and Administration

Sunkist Growers
14130 Riverside Drive
Sherman Oaks, CA 91423-2313
Tel: (818) 379-7532
Fax: (818) 379-7492
mwootton@sunkistgrowers.com

July 16, 2012

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Upton,

Methyl bromide is a critically important fumigant used by the California citrus industry to meet phytosanitary regulations required by our trading partners. Since there are some insect species that are present in California, but not in other parts of the world, many export markets inspect imports to look for insects that could represent a biosecurity threat in the importing country. Sometimes insects are discovered, and in those cases the fruit is treated with methyl bromide and allowed to enter commerce.

Without the methyl bromide treatment the fruit would be sent back to the United States or diverted to another market. The California citrus industry's most important markets are in Asia and require approximately three weeks of transit time on ocean vessels before arrival. It is impractical to return fruit that is rejected in Asian markets, because the quality significantly deteriorates after a six week voyage. This means that growers usually face significant or total losses when fruit is refused entry for phytosanitary violations. Methyl bromide is the preferred treatment, because it is a broad spectrum insecticide that kills a wide range of insect species and its properties and efficacy are well known by regulatory authorities.

California growers depend on the availability of methyl bromide to maintain important export markets. In any given year, approximately one third of the California citrus crop is exported while nearly forty percent of total revenue is derived from export sales. As an example, Korea is the largest orange export market outside of North America generating over $110 million of revenue for California growers. Every container entering Korea is fumigated with methyl bromide to control California red scale and Fuller's rose beetle. Without this treatment, export sales to Korea would decline significantly along with grower returns.

In recent years, California has been subjected to a wave of invasive insect species that become important pests for growers, require more pesticide treatments, disrupt Integrated Pest Management programs or require burdensome quarantine measures for exporters. While some of these pests are introduced into California by passenger migration others enter with forest

products or agricultural imports. Methyl bromide is also an important tool that the U.S. Department of Agriculture uses to protect our industry from introductions of exotic pests in imports. Without this use, California citrus growers would be even more vulnerable to the constant pressure of invasive species.

While the quarantine uses of methyl bromide are currently exempt from regulation under the Montreal Protocol, serious efforts are being made by the European Union to weaken or remove this exemption. The U.S Environmental Protection Agency has assured our industry that they understand the importance of the quarantine uses of methyl bromide and they plan to continue to resist efforts within the Montreal Protocol to remove this important tool. We appreciate their resolve and also your interest in protecting the exemption.

The California citrus industry is gratified by the leadership you and your Committee have provided to help define reasonable uses of methyl bromide while still protecting growers and the environment.

Please do not hesitate to call on us if you have questions or require our support to maintain reasonable access to this important compound.

Sincerely,

Michael Wootton
Senior Vice President

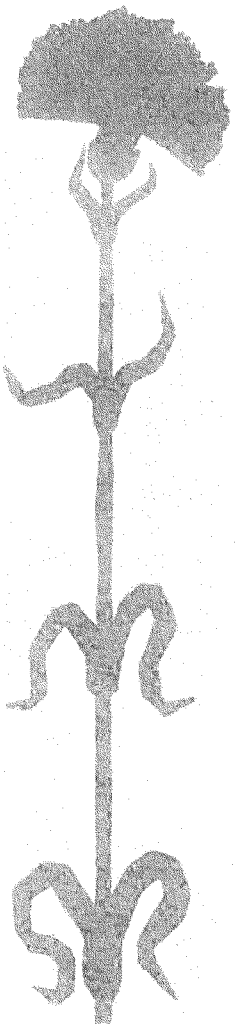
cc: The Honorable Henry Waxman
Ranking Member, House Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Ed Whitfield
Chairman, Energy and Power Subcommittee
2368 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Bobby Rush,
Ranking Member, Energy and Power Subcommittee
2268 Rayburn House Office Building
Washington, D.C. 20515

California Citrus Quality Council

Sunshine State Carnations, Inc.
P.O. BOX 573
HOBE SOUND, FLORIDA 33475-0573
TELEPHONE (772) 546-3009 • FAX (772) 546-3064
e-mail: sunshinpcuts@bellsouth.net



July 11, 2012

Dear Representative Whitfield:

My name is Eric Nissen and I am the vice president of my family's company Sunshine State Carnations, Inc. We have been growing cut flowers in Hobe Sound, Florida for over fifty years.

We use methyl bromide to fumigate our growing areas once a year in the summer months. We grow directly outside, under shade structures and under sawtooth poly roofs. The methyl bromide is used through shank application on open areas. Under the shade cloth and poly roofs it is applied through the hot gas application in order to fumigate the pole rows. We have had very good success over the years using these techniques.

We have tried Midas methyl iodide as an alternative. It proved to be less effective and almost twice as expensive. Also, this year Arista will no longer sell Midas in the US.

We have trailed paladin DMDS. Again, this is less effective to methyl bromide and it has a very strong odor, nor is suitable for fumigating pole rows.

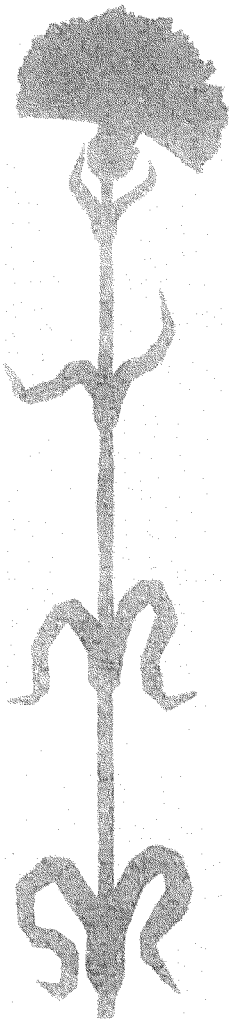
Another alternative we have used is solarization. This application takes 8 weeks to complete vs. methyl bromide taking 7 – 10 days. Also solarization is less effective than methyl bromide in controlling weeds and nematoes. In addition, solarization cannot be used on pole rows.

There is no effective alternative to methyl bromide. In the areas where we have used the alternatives, we have had a very substantial increase in weeds and disease. This has lead to a high cost of manually removing the weeds and low product yield due to the increase in diseases. Also, without methyl bromide there is no effective way to fumigate the pole rows.

Trialing these alternatives has hurt our profitability. If we are not able to use methyl bromide, we would be unable to stay in business.

Best regards,
Eric Nissen
Vice President
Cc: Mary. Neumayr@mail.house.gov

Sunshine State Carnations, Inc.
P.O. BOX 573
HOBE SOUND, FLORIDA 33475-0573
TELEPHONE (772) 546-3300 • FAX (772) 546-3064
e-mail: sunshinescts@bellsouth.net



July 11, 2012

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Best regards,
Eric Nissen
Vice President
Cc: Mary. Neumayr@mail.house.gov

SUNSWEET GROWERS INC.
901 North Walton Ave
Yuba City, CA 95993

July 13, 2012

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
28183 Rayburn House Office Building,
Washington, D.C. 20515

As Director of Industrial and Environmental Process Applications for Sunsweet Growers Inc, and a DPR Qualified Applicator, I would like to request that the CUE for methyl bromide not be withdrawn.

Sunsweet Growers Inc. is a 94 year old grower owned cooperative based in Northern California. We are the largest dried prune processor in the world. With more than 800 fulltime and over 600 seasonal employees we grow, harvest, warehouse, process, pack, and ship worldwide over 130,000,000 pounds of prunes each year. Sunsweet accounts for over half of California total prune crop.

The main post harvest pest for the dried prune industry and for Sunsweet Growers is the Indian Meal Moth. When the prunes are received from the drying tunnels they are stored in large warehouses and are pest free at this point. In the dried natural condition state prunes can be stored for up to two years. It is at this point the prunes are most susceptible to infestation and re-infestation by the Indian Meal Moth. Sunsweet uses an integrated pest management approach for controlling unwanted pest. Tools that we use include but are not limited to fumigants, fogging materials such as Vapona and IGR's, light traps, mating disruption pheromones, air curtains, automatic door closers, sanitation practices, and glue traps.

The Fumigant of choice for many years was methyl bromide, but with the phase out of methyl bromide Sunsweet has converted to phosphine fumigants where possible and ProFume in the remaining storage locations. There are several issues that limit our use of phosphine. The two biggest are the corrosive nature of phosphine gas on metal surfaces, and the time it takes to perform phosphine fumigations. We have over 413,000 sq ft of warehouse space that also house very expensive electronics and prune processing equipment. It has been estimated that it would cost $904,400.00 to retrofit our warehouses for the use of phosphine or just over $9,900,000.00 to build new phosphine friendly storage facilities. The 9.9 million to build does not include the price of the land. Phosphine fumigations require an additional 72 hours per fumigation to perform. Sunsweet currently operates on average 6.25 days per week and closes for fumigations. The additional fumigation time would require Sunsweet to extend operations to weekends. The additional labor expense to regain the lost production would be $265,680.00 alone, assuming two fumigations per year.

ProFume (sulfuryl fluoride) and methyl bromide are the only fumigants we have that meet Sunsweet's needs. The EPA is pushing to remove food tolerances for sulfuryl fluoride. The CUE for methyl bromide is being withdrawn. This leaves Sunsweet with only two options. Phosphine as the only fumigant available or utilizing cold storage and eliminate the need to fumigate all together. Sunsweet is an extremely large facility with over 15,000,000 cubic feet of prune storage spread out over 12 locations. To replace 3 of our storage location that we currently fumigate in to cold storage would cost Sunsweet approximately $28,236,150. This does not include the cost of land or reoccurring cost such as PG&E and maintenance.

SUNSWEET GROWERS INC.
901 North Walton Ave
Yuba City, CA 95993

To convert our storage facilities to phosphine friendly warehouses, or to convert to cold storage would be cost prohibitive. An expense such as either of these alternatives would be detrimental to Sunsweet. For these reasons I ask that you do not withdraw the CUE for methyl bromide.

Sincerely,

Mike Miguel
Director of Industrial & Environmental Process Applications
Sunsweet Growers Inc.

cc: The Honorable Henry Waxman
Ranking Member, House Energy and Commerce Committee

The Honorable Ed Whitfield
Chairman, Energy and Power Subcommittee

The Honorable Bobby Rush
Ranking Member, Energy and Power Subcommittee

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July 13, 2012
OUR 85th YEAR

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

Re: The U.S. Agricultural Sector Relief Act of 2012

Dear Chairman Upton:

Our company has been operating primarily in Pennsylvania, New Jersey, Delaware, and Virginia for over 85 years. We employ more than 700 people involved in various aspects of the pest management industry including quarantine and non-quarantine treatment of exported and imported products at various ports, food processing plants, warehouses and a wide range of stored commodities. Many of these treatments use methyl bromide as the required fumigant.

It is of vital importance to our business to maintain the availability of methyl bromide both for critical use exemptions and quarantine treatments, as further reductions and potential loss of the fumigant would have a significant negative economic impact on our business and the hundreds of clients we service. Further, if as is currently under review, other existing alternatives to methyl bromide, such as sulfuryl fluoride are eliminated, this would increase our need for methyl bromide.

Thank you for your consideration of this matter, which is of vital importance to our business, and for introducing the US Agricultural Sector Relief Act legislation.

Respectfully submitted,

Miriam Borja-Fisher
Western Industries

cc: The Honorable Henry A. Waxman, Ranking Member
House Energy and Commerce Committee

The Honorable Ed Whitfield, Chairman
Subcommittee of Energy and Power

The Honorable Bobby L. Rush, Ranking Member
Subcommittee of Energy and Power

Mr. WHITFIELD. At this time I would like to call up the second panel of witnesses for testimony on the Asthma Inhalers Relief Act of 2012. On that panel we have Mr. Jason Shandell, who is general counsel and secretary, Amphastar Pharmaceuticals. We have Dr. Monica Kraft, who is the professor of medicine at Duke University, president of the American Thoracic Society, and director of the Duke Asthma, Allergy, and Airway Center. We have Dr. Edward Kerwin, who is senior medical director, Allergy & Asthma Center of Southern Oregon. And we have Mr. Chris Ward, who is the former chairman of the Board of Directors of the Asthma and Allergy Foundation of America.

And I would like at this time call on Mr. Walden for the purpose of introducing Dr. Kerwin.

Mr. WALDEN. Thank you very much, Mr. Chairman. It is my honor to introduce Dr. Edward Kerwin, an allergy, asthma, and clinical research physician who traveled from Oregon out here today. We appreciate your being here. Dr. Kerwin founded the Allergy & Asthma Center of Southern Oregon in 1997, and prior to that, practiced in the area since '93.

Today, he is going to provide the committee with insight on his years of experience as a physician serving patients in and around Medford, Grants Pass, Klamath Falls, and Ashland. In addition to his role as health provider, Dr. Kerwin is a leading clinical trial investigator on issues that we will discuss today. He authored over 25 medical publications on allergy and asthma, and even previously worked for NASA on solar energy technology and space antenna projects in the '80s. So maybe Mr. Olson will be back and we can talk NASA antennas.

He is active in multiple professional trade associations, even finds time to participate in the Medford Rotary Club. And after this hearing he will be able to add testifying before Congress to his long and impressive ŕsuḿ. And with that, Mr. Chairman, we thank you for having Dr. Kerwin invited to testify today.

Mr. WHITFIELD. We have got a meeting in here for just a minute, but Dr. Burgess is going to go on and get the opening statements started and then we will be right back.

Mr. BURGESS [presiding]. So again, welcome to our witnesses. We will first hear from Mr. Jason Shandell, 5 minutes for opening statement, please.

STATEMENTS OF JASON SHANDELL, VICE PRESIDENT AND GENERAL COUNSEL, AMPHASTAR PHARMACEUTICALS, INC.; MONICA KRAFT, PROFESSOR OF MEDICINE, DUKE UNIVERSITY, PRESIDENT, AMERICAN THORACIC SOCIETY, AND DIRECTOR, DUKE ASTHMA, ALLERGY AND AIRWAY CENTER; CHRIS WARD, FORMER CHAIRMAN, BOARD OF DIRECTORS, ASTHMA AND ALLERGY FOUNDATION OF AMERICA; AND EDWARD M. KERWIN, SENIOR MEDICAL DIRECTOR, ALLERGY AND ASTHMA CENTER OF SOUTHERN OREGON

STATEMENT OF JASON SHANDELL

Mr. SHANDELL. Thank you. Good afternoon and thank you for this opportunity to testify. I am Jason Shandell, Vice President and General Counsel for Amphastar Pharmaceuticals, which is the par-

ent company of Armstrong Pharmaceuticals. We are grateful to the Members and professional staff of the Energy and Commerce Committee for their assistance in helping us to hopefully distribute the remaining units of Primatene Mist. We strongly believe that allowing Americans to have access to Primatene Mist is better than leaving it to expire in a warehouse in California.

Primatene Mist, an epinephrine inhaler with CFC as propellant was developed by Wyeth Labs in July 2008. Primatene Mist is approved for temporary relief of occasional symptoms of mild asthma. There are at least 2 to 3 million loyal Primatene Mist users in the U.S.

When our company purchased Primatene Mist brand in 2008, we knew it would be going off the market and that there were technical challenges in creating an epinephrine inhaler without CFCs. This is referred to as Primatene HFA. We accepted the challenge, and in fact, we have developed Primatene HFA and we are targeting to file a new drug application with the FDA in the fourth quarter of this year.

Because Primatene Mist was removed from the market on January 1, 2012, there is currently no over-the-counter inhaler for asthmatic patients on the U.S. market. An individual who previously used Primatene Mist must now pay to see a doctor and then buy a prescription inhaler that costs four to five times more than Primatene Mist.

We have received thousands of inquiries from users of Primatene Mist who are desperate for availability of an over-the-counter inhaler. Unfortunately, these inquiries have also cited two possible deaths because of the lack of such an over-the-counter inhaler, and I have these emails here.

Last December, we submitted a request to the EPA to allow for the sale of the remaining units of Primatene Mist based on public health and economic interests. The public health interest is growing since the untreated and undertreated asthma patient population is largely comprised of uninsured, economically disadvantaged black and Hispanic communities. This includes a large number of women and children. Without Primatene Mist, those asthmatics who have no insurance, they may have to seek care in emergency rooms, which can take many hours and cost thousands of dollars.

The company's request for enforcement discretion was denied by the EPA on December 30, 2011, citing that it would not be in the public interest to allow for the sale of the remaining units of Primatene Mist. Since the EPA did not address the economic factors raised in our original request, we again requested enforcement discretion from the EPA on January 4, 2012. The 2008 Final Rule stated that removing Primatene Mist from the market will cost consumers between $300 million to $1.1 billion. That is based on 2007 estimates. The cost to the Federal Government and taxpayers for Medicare and Medicaid could run as high as $75 million in each program, not to mention the severe financial burden that an emergency room bill can place on a family.

We have not received a response from the EPA on this subsequent request based on economic concerns.

Amphastar understands that Members of Congress have also written to the EPA expressing their concerns, and they have not received any response from the EPA as far as I can tell. The company has repeatedly asked why Primatene Mist was pulled from the market when actually there are two prescription drug inhalers that also use CFC as their propellants and they have been allowed to stay on the market through December of 2013. No one from EPA has ever explained why these two inhalers, with CFC, are allowed to remain but Primatene Mist is not.

Primatene Mist has been on the market for almost 50 years and has a safe and effective track record. To remove Primatene Mist from the market because it contains CFC with no over-the-counter replacement inhaler jeopardizes the health and safety of the 2 to 3 million Americans that have relied on this product for many years.

Amphastar believes in putting people over profits, and throughout our efforts, we have offered to distribute all of the remaining units of Primatene Mist as a donation to public health clinics. This offer has been rejected by the government. We are not interested in profiting from the sale of the remaining inventory. Therefore, we hereby commit that we will donate all the net profits from the sale of the remaining units of Primatene Mist to charity.

Amphastar believes in its product, Primatene Mist. It should be available in the United States over-the-counter so individuals who are suffering from asthma and depend on this product can enjoy instant relief when they experience asthma symptoms such as shortness of breath. We sincerely believe that there must be a readily available over-the-counter inhaler for Americans who have difficulty accessing a doctor to obtain a prescription and cannot afford to pay four to five times more for a prescription inhaler.

In closing, let me again thank the members of this committee, specifically Dr. Michael Burgess and also Congressman Mike Ross and your professional staff for holding this hearing. Our goal is to get the remaining units of Primatene Mist out of the warehouse and into the hands of the American people.

Thank you.

[The prepared statement of Mr. Shandell follows:]

Jason Shandell

VP and General Counsel

Amphastar Pharmaceuticals, Inc.

US House of Representatives

Energy and Commerce Committee

Energy and Power Subcommittee

July 18, 2012

I am Jason Shandell, Vice President and General Counsel, for Amphastar Pharmaceuticals, Inc., the parent company of Armstrong Pharmaceuticals, Inc.

Amphastar believes in placing people before profits and therefore we are grateful to the Members and staff of the Energy and Commerce Committee for their assistance in helping us to distribute the remaining units of Primatene® Mist. We strongly believe that allowing patients to have access to Primatene® Mist is better than leaving it to expire in a warehouse in California.

History:

Primatene® Mist, an epinephrine inhaler with CFC as propellant, was developed by Wyeth Labs in 1967. Amphastar purchased the rights to market the Primatene®® Mist brand from Wyeth in July 2008.

Primatene® Mist is approved "for temporary relief of occasional symptoms of mild asthma". There are at least 2-3 million loyal Primatene® Mist users.

This drug was manufactured by Armstrong Pharmaceuticals Inc. since 1984 until August of 2011. Once our allocated CFC to produce Primatene® Mist was exhausted, we stopped manufacturing the product on August 12, 2011 and shut down Armstrong's manufacturing facility plant in West Roxbury, Massachusetts.

When we purchased the Primatene® Mist brand in 2008, we knew that Primatene® Mist would be going off the market and that there were technical challenges in creating a CFC free epinephrine inhaler, referred to as Primatene® HFA. We accepted the challenges and were confident that a CFC free Primatene® HFA could be developed. In fact, we have developed Primatene® HFA in our Canton Massachusetts facility and continue to proactively work with the FDA to address their questions and requirements in order to bring the CFC free Primatene® HFA to market. We hope to submit an NDA for Primatene® HFA in the fourth quarter of this year. Primatene® HFA, like Primatene® Mist, is an epinephrine inhaler, but with HFA as the propellant,

When the Final Rule was published in the Federal Register in November 2008, requiring the termination of the sale and distribution of Primatene® Mist as of December 31, 2011, Armstrong warned the regulatory decision making parties "...that removing OTC epinephrine from the market and attempting to switch patients to prescription medications will, in Armstrong's view, have significant costs and health consequences, which can be avoided by extending the effective date to allow time for a non-ODS OTC epinephrine product to be developed before the current product is phased out." "ODS" is an acronym for Ozone Depleting Substance.

Today:

Because Primatene® Mist was removed from the market on January 1, 2012 there is NO over the counter inhaler for asthmatic patients on the US market. An individual who previously used

Primatene® Mist must now see a doctor to obtain a prescription for Albuterol and then have it filled, at four to five times the cost of Primatene® Mist (approximately $20.00 versus $108.75 to $111.59). We have received thousands of inquiries from users of Primatene® Mist who are desperate for availability of an OTC inhaler. Unfortunately, these inquires have also cited two possible deaths because of the lack of an OTC inhaler.

Our Efforts:

Last fall, we engaged Venable Law firm to assist us in requesting from the EPA, Enforcement Discretion on Primatene® Mist. Former Congressman Bart Stupak has been our lead counsel in working with the EPA.

After meetings with the EPA, two written Requests for Enforcement Discretion, with supporting government studies and documentation, were submitted last December to the EPA to allow for the sale of the remaining units of Primatene® Mist based on public health and economic interests. The public health interest is growing since the untreated or undertreated asthma patient population is largely comprised of the uninsured, economically disadvantaged, black and Hispanic communities, including a large number of women and children.

Without Primatene® Mist, those asthmatics who have no insurance or have no prescription albuterol available may have to seek care in emergency rooms and experience longer hospitalizations when experiencing asthma symptoms such as shortness of breath, and they do not have Primatene® Mist available Over the Counter.

The company's request for enforcement discretion was denied by the EPA on December 30, 2011 citing that it would not be in the public interest to allow the sale of the remaining units of Primatene® Mist.

The EPA has granted Enforcement Discretion on three occasions over the past 10 years after a Final Rule had been published for low sulfur gasoline, lead abatement certification, and Texas Low-Emission Diesel under the Texas State Implementation Plan.

Since the EPA did not address the economic factors raised in our original request, we again requested enforcement discretion from the EPA on January 4, 2012. The 2008 Final Rule stated that removing Primatene® Mist from the market will cost consumers between $300 million to 1.1 billion dollars based on 2007 estimates. The cost to the Federal Government and taxpayers for Medicare and Medicaid could run as high as $75 million dollars in each program.

We have not received a response from the EPA on this subsequent request based on economic concerns.

Amphastar understands that Members of Congress have written to the EPA expressing their concerns about the removal of Primatene® Mist from the OTC market and have not received any response from the EPA.

The company has repeatedly asked why Primatene® Mist was pulled from the market when two prescription drugs, one of which has an approved, non-CFC replacement on the market, that use CFC as their propellants, have been granted exceptions to the Montreal Protocol to stay on the

market through December of 2013. No one from EPA has ever explained why these two inhalers with CFCs are allowed to remain on the market but Primatene® Mist is not.

Primatene® Mist had been on the market for almost 50 years with a safe and effective track record. To remove Primatene® Mist from the market because it contains CFC with no replacement inhaler jeopardizes the health and safety of the 2-3 million Americans that have relied on this product for many years.

Amphastar believes in putting people over profits and throughout our efforts we have offered to distribute all the remaining units of Primatene® Mist as a donation to public health clinics. This offer has been rejected. We are not interested in profiting from the sale of the remaining inventory of Primatene® Mist. Therefore, Amphastar commits that it will donate all the net profits from the sale of the remaining units of Primatene® Mist to charity. Amphastar believes in its product, Primatene® Mist. It should be available in the US OTC market so individuals who are suffering from asthma and depend on this product can enjoy instant relief when they experience asthma symptoms such as shortness of breath. We sincerely believe that there must be a readily available over the counter inhaler for American asthma patients who have difficulty accessing a doctor to obtain a prescription and cannot afford to pay four to five times more for a prescription inhaler.

Please be advised that Amphastar will also be launching an Internet campaign to "Bring Back My Primatene®" to get Primatene® Mist back on the OTC retail market and available for the millions of Americans who are suffering from asthma and need Primatene® Mist.

In closing, let me again thank the Members of this Committee, Chairwoman Mary Bono Mack, Dr. Michael Burgess and Congressman Mike Ross, and your professional staff for holding this

hearing, developing draft legislation to allow the sale or distribution of the remaining units of Primatene® Mist, and allowing me to testify on behalf of Amphastar and Armstrong.

In conclusion, our goal is to get the remaining units of Primatene® Mist out of the warehouse and in the hands of the American people. The asthmatic population that purchases Primatene® Mist believes in our product because it works for them, it is convenient and available without having to see a doctor or they lack adequate health insurance for prescription inhalers. We are concerned about the health of the American people and we will donate to charity all net profits from the sale of the remaining units of Primatene® Mist.

Thank You.

SUMMARY

Jason Shandell, Esquire Amphastar/Armstrong Pharmaceuticals

- For almost 50 years, Primatene® Mist is approved "for temporary relief of occasional symptoms of mild asthma. There are 2-3 million loyal Primatene® Mist users.
- Because Primatene® Mist was removed from the market on January 1, 2012 there is NO over the counter (OTC) inhaler for asthmatic patients. Primatene® Mist users must now see a doctor to obtain a prescription for Albuterol and then have it filled at four to five times the cost. We have received thousands of inquiries from Primatene® Mist users who are desperate for an OTC and users cite two possible deaths because no OTC inhaler.
- Two written Requests for Enforcement Discretion were presented with supporting government studies and documentation to the EPA based on public health and economic interests. The public health interest is the growing number of untreated or undertreated asthma patient population which is largely the uninsured, economically disadvantaged, black and Hispanic communities, including a large number of women and children.
- The EPA has granted Enforcement Discretion on three occasions over the past 10 years.
- Amphastar will not profit from the sale of the remaining 1.2 million units of Primatene® Mist and it will donate all the net profits to charity.
- The asthmatic population that purchases Primatene® Mist believes in our product because it works for them, it is convenient and available without having to see a doctor or they lack adequate health insurance for prescription inhalers.
- EPA has allowed two prescription inhalers with CFC to remain on the market through 2013.

Mr. BURGESS. I thank the gentleman for his testimony.

Dr. Kraft, you are recognized 5 minutes for testimony, please.

STATEMENT OF MONICA KRAFT

Ms. KRAFT. Very good, thank you. I would like to thank the committee for allowing me to speak to you today.

I am Dr. Monica Kraft, and I am a professor of medicine at Duke University and currently the president of the American Thoracic Society. This is a specialty society made up of about 16,000 physicians who are pulmonologists with an interest in obviously respiratory issues, critical care physicians, and sleep physicians. So I also direct the Duke Asthma, Allergy, and Airway Center and have been involved in both research and care of patients with asthma. And my group and I have over 140 publications along these lines.

So it is with this professional scientific background that I come to you today to present testimony on the behalf of the American Thoracic Society on this issue of restoring epinephrine inhalers back to the U.S. marketplace. It is my strongly held view and the view of the American Thoracic Society that returning these inhalers to the U.S. market even for a limited time is ill-advised. But this view isn't just shared by me or my societies. It is also shared by several other societies, including the American Academy of Pediatrics, two asthma and allergy societies, and two respiratory therapy societies. So we are not unique in this view.

Now, when we think about asthma we think of it as a very common disease. It affects between 5 and 10 percent of the population, so most of us know someone with asthma. We also have this perception—this is at least what I hear from people—that asthma is relatively mild and not a problem when actually I certainly take care of patients with very severe disease who die of their asthma. And one of the reasons that is is because the airways are red and swollen in asthma so they become narrowed. And it is somewhat like breathing through a straw. So really the mainstay of therapy is anti-inflammatory therapy like inhaled corticosteroids. You may have heard of that.

We also use bronchodilators, which dilate the airways and we use this combination together. And in more severe asthma we may need to use oral steroids like prednisone or adopt other strategies such as focusing our allergic symptoms, which are very big triggers of asthma.

So I am here to tell you that healthcare professionals play a really critical role in the management of asthma in that we form partnerships with our patients to get them not only the best combination of medications that they need that are safe and effective but also to educate them so that they can control their disease.

So the takeaway message is the majority of cases asthma can be managed and patients with the appropriate therapy can live full and active lives.

But I would say to you today that epinephrine is not one of those medications considered safe. So I am coming to you from a safety perspective. So epinephrine is a nonselective bronchodilator. So yes, it dilates. It bronchodilates. That is good, but it also has other effects, primarily cardiac that is very concerning to me and my colleagues. This can lead to excessive cardiac stimulation, heart rate,

that can lead to heart attacks, especially in the older patients or those folks who have heart disease. And sometimes we don't always know who has heart disease.

Now, for years, the medical community has recognized the dangerous side effects of epinephrine in the treatment of asthma and recommended against its use. The American Medical Association has urged warning labels. They have encouraged FDA to consider removing inhaled epinephrine. They have requested studies to really determine does it contribute to increased asthma morbidity and mortality.

Now, I would be interested in hearing more about these deaths that we just heard mentioned in the last testimony because in speaking to my colleagues in emergency medicine—and my husband runs the emergency department at the University of North Carolina Chapel Hill—and my colleagues at Duke, their perception is since Primatene Mist has been off the market, there have been fewer severe exacerbations. And so we hypothesize that in fact patients are now getting the care that they need.

We have a mechanism to take care of those patients who are uninsured, those underrepresented minority patients. I live in Chapel Hill. I see patients from Durham. We have a very significant contingent of underserved patients that we take care of at our institution. And we can provide them with the right medication. So I don't necessarily think it is all about access.

So furthermore, the guidelines that put forth the treatment of asthma do not mention epinephrine as a viable option for treatment and I want to make sure that that is clear. The National Asthma Education and Prevention Program, put together by our own National Institutes of Health here in Washington, the U.S., have emphasized that inhaled medications are critical for asthma therapy but not epinephrine.

So the American Thoracic Society strongly encourages any patient who is using over-the-counter medications like Primatene Mist to seek care from a provider and there are ways that these patients can get help. And I am a strong advocate, again, for allowing patients to learn how to take care of their own asthma and manage their disease because it is really all about putting the power in the hands of the patient and teaching them what they need.

So if one of the goals of today's hearing is to discuss the pros and cons of enacting legislation to permanently or temporarily restore inhaled epinephrine for the treatment of asthma to the U.S. market, if the intent is to restore a safe and effective medication, I think that is a laudable cause but it is misinformed. Inhaled epinephrine is not safe for the treatment of asthma and no current clinical practice guideline calls for the use of epinephrine.

If the legislative intent is to provide access to an inexpensive drug for the treatment of asthma, then I think that is laudable but misdirected. In my opinion and that of my society and other societies, the epinephrine's risk outweigh its benefits.

And lastly, I am concerned about the message we are sending to patients. We spent a lot of time preparing patients for this transition when Primatene Mist was being taken off the market, moving towards approved asthma therapies that are effective and safe, and

I worry that putting Primatene Mist back on the market, even temporarily, may send a confusing message.

I would like to propose that Congress should be considering ways to increase patient access to healthcare professions who can work with patients to find an effective combination of drugs to control asthma. We should not be abandoning patients with serious medical conditions like asthma to self-diagnosis and self-medication with less-effective drugs that have known side effects.

So I hope this committee will keep the view of the American Thoracic Society in mind as it considers legislation on inhaled epinephrine for the treatment of asthma. I thank you for the opportunity to speak to you today.

[The prepared statement of Ms. Kraft follows:]

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Testimony of the
American Thoracic Society
before the Energy and Power Subcommittee
of the House Energy and Commerce Committee
Presented by Monica Kraft, MD
President of the American Thoracic Society
Wednesday, July 18, 2012

I am Monica Kraft MD, and I am a professor of Medicine at Duke University and current president of the American Thoracic Society. As both a researcher and a clinician, I have spent most of my professional life dedicated to the diagnosis and management of patients with asthma and I direct the Duke Asthma, Allergy and Airway Center at Duke. It is with this professional and scientific background that I offer to present testimony of the American Thoracic Society on legislation to restore epinephrine inhalers back on the U.S. market place. It is my strongly held view and the view of the American Thoracic Society, that returning epinephrine inhaler to the U.S. market, even for a limited time, would be ill advised.

This view is shared by several other physician organizations including, the American Academy of Allergy Asthma and Immunology, the American College of Asthma Allergy and Immunology, the American Association of Respiratory Care and the National Association for the Medical Direction of Respiratory Care.

As background, asthma is common and potentially life threatening medical condition where the airways of lung are inflamed, severely restricting air flow to the lung. For many people with asthma, it can feel like breathing through a straw. Asthma effects between 5 and 10% of the population, so most everyone knows someone who has asthma. Therefore, over 24.6 million Americans have physician diagnosed asthma, including 7.1 million children. While the majority of asthma patients can and will successfully manages their asthma, every year, people die as a result of asthma attacks.

In the lungs, the airways are inflamed, which means they are red and swollen which can cause them to narrow then and restrict airflow. The focus of asthma treatment is with anti-inflammatory medications, such as inhaled corticosteroids. In addition, medications that cause the airways to widen (bronchodilate) are also used. In more severe asthma, physicians try a combination of other drugs to treat asthma which may include medications to more directly treat allergic symptoms, or in the most severe cases, oral corticosteroids such as prednisone.

Health care professionals play an important role in educating patients about their asthma, including asthma triggers like tobacco smoke, air pollution, and allergens such as pet dander, cockroaches and dust mites, to find the right combination of medications, along with proper drug administration techniques to help people with asthma live full, active lives.

The take away message is that in the majority of cases, asthma can be successfully treated by working with health care professionals to find the right combination of safe and effective medications.

Epinephrine is NOT one of the medications that are considered safe for the treatment of asthma.

Epinephrine

Epinephrine is non-selective bronchodilator. This means that it has effects not only in the lung to bronchodilate but its non-selective nature means it has effects upon other organs such as the heart. Therefore, epinephrine or Primatene® can cause a significantly increased heart rate. This unwanted side effect can lead to cardiac stress and heart attacks in older patients or patients with heart disease.

For years the medical community has recognized the dangerous side effects of epinephrine for the treatment of asthma and has recommended against it use for asthma. In 1999 the American Medical Association 1) urged that warning labels on over the counter epinephrine inhalers be strengthened to warn patients about the dangers of epinephrine use, 2) encouraged FDA to consider removing inhaled epinephrine from the market and 3) requested studies to determine whether the availability of inhaled epinephrine is a risk factor in asthma morbidity and mortality. The American Medical Association again reaffirmed this position in 2009. In addition, we have not seen an increase in asthma death rates since epinephrine has been taken off the market, so I do not believe lack of access to asthma treatment is a reason to put inhaled epinephrine back on the market. Anecdotally, speaking to my colleagues in Emergency Medicine, they have seen fewer severe asthma attacks as they think more patients with asthma are following up with their physicians to get the appropriate care.

Several expert panels have produced recommendations on the treatment of patients with asthma. None of the expert guidelines recommend the use of inhaled epinephrine --like Primatene Mist--to treat asthma. The National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, has issued treatment

guidelines for management of asthma. NAEPP recommends against the use of epinephrine for treating asthma exacerbations stating:

> "Drugs of choice for acute bronchospasm: Inhaled route has faster onset, fewer adverse effects, and is more effective than systemic routes. The less beta2-selective agents (isoproterenol, metaproterenol, isoetharine, and **epinephrine**) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses. (*emphasis added*)(2)

The American Thoracic Society strongly encourages any patient who is using over the counter medications--like Primatene Mist CFC--to treat their asthma to see a healthcare provider who can help the patient develop an asthma management plan and recommend more effective and safer medications to manage the asthma. Asthma action plans are dynamic plans that help guide a patient on how to manage their asthma on good days, bad days and those days in between. I have attached a sample asthma action plan with my testimony.

Pending Legislation

One of the goals of today's hearing is to discuss the pros and cons of enacting legislation to either permanently or temporarily restore inhaled epinephrine for the treatment of asthma to the U.S. market. If the intent of the legislation is to restore a safe and effective asthma drug to the market place, then this legislative effort is mis-informed. Inhaled epinephrine is not a safe drug for the treatment of asthma. The adverse side effects of epinephrine are serious and well documented. No current clinical practice guideline for the diagnosis and treatment of asthma recommends the use of epinephrine. In fact, asthma guidelines specifically recommend against inhaled epinephrine for treating asthma.

If the legislative intent is to provide access to an inexpensive drug for the treatment of asthma, then the legislative effort is laudable, but mis-directed. Inhaled epinephrine's risks outweigh its benefits.

I am also concerned about sending a very confusing message to patients. Physicians, drug makers and retailers have spent a lot of time and effort educating patients about the Primatene Mist transition and treatment alternatives patients have now that Primatene Mist is no longer available. Putting Primatene Mist back on the market – for an indefinite period of time – will send a very confusing message to patients.

Congress should be considering ways to increase patient access to health care professionals who can work with patients to find an effective combination of drugs to control asthma. We should not be abandoning patients with a serious medical condition like asthma to self diagnosis and self medication with less effective drugs that have well known serious side effects.

I hope the committee will keep the view of the American Thoracic Society in mind as it considers legislation on inhale epinephrine for the treatment of asthma. I would be happy to answer any questions you may have.

1) AMA House of Delegates policy H-115.972 (CSA Rep.2 A-99, reaffirmed CSPH Rep. 1 A-09)
2) National Asthma Education Prevention Program– Expert Report 2 (1997) p. 64 figure 3-2.

Asthma Action Plan

For: _____ Doctor: _____ Date: _____

Doctor's Phone Number _____ Hospital/Emergency Department Phone Number _____

GREEN ZONE

Doing Well

- No cough, wheeze, chest tightness, or shortness of breath during the day or night
- Can do usual activities

And, if a peak flow meter is used,

Peak flow: more than _____
(80 percent or more of my best peak flow)

My best peak flow is: _____

Take these long-term control medicines each day (include an anti-inflammatory).

Medicine	How much to take	When to take it
Before exercise	❒ _____	❒ 2 or ❒ 4 puffs _____ 5 minutes before exercise

YELLOW ZONE

Asthma Is Getting Worse

- Cough, wheeze, chest tightness, or shortness of breath, or
- Waking at night due to asthma, or
- Can do some, but not all, usual activities

-Or-

Peak flow: _____ to _____
(50 to 79 percent of my best peak flow)

Add: quick-relief medicine—and keep taking your GREEN ZONE medicine.

_____ ❒ 2 or ❒ 4 puffs, every 20 minutes for up to 1 hour
(short-acting $beta_2$-agonist) ❒ Nebulizer, once

If your symptoms (and peak flow, if used) return to GREEN ZONE after 1 hour of above treatment:
❒ Continue monitoring to be sure you stay in the green zone.

-Or-

If your symptoms (and peak flow, if used) do not return to GREEN ZONE after 1 hour of above treatment:
❒ Take: _____ ❒ 2 or ❒ 4 puffs or ❒ Nebulizer
(short-acting $beta_2$-agonist)
❒ Add: _____ mg per day For _____(3–10) days
(oral steroid)
❒ Call the doctor ❒ before/ ❒ within _____ hours after taking the oral steroid.

RED ZONE

Medical Alert!

- Very short of breath, or
- Quick-relief medicines have not helped, or
- Cannot do usual activities, or
- Symptoms are same or get worse after 24 hours in Yellow Zone

-Or-

Peak flow: less than _____
(50 percent of my best peak flow)

Take this medicine:

❒ _____ ❒ 4 or ❒ 6 puffs or ❒ Nebulizer
(short-acting $beta_2$-agonist)

❒ _____ mg
(oral steroid)

Then call your doctor NOW. Go to the hospital or call an ambulance if:
- You are still in the red zone after 15 minutes AND
- You have not reached your doctor.

DANGER SIGNS
- **Trouble walking and talking due to shortness of breath**
- **Lips or fingernails are blue**

- **Take ❒ 4 or ❒ 6 puffs of your quick-relief medicine AND**
- **Go to the hospital or call for an ambulance** _____ **NOW!**
(phone)

See the reverse side for things you can do to avoid your asthma triggers.

How To Control Things That Make Your Asthma Worse

This guide suggests things you can do to avoid your asthma triggers. Put a check next to the triggers that you know make your asthma worse and ask your doctor to help you find out if you have other triggers as well. Then decide with your doctor what steps you will take.

Allergens

❒ **Animal Dander**

Some people are allergic to the flakes of skin or dried saliva from animals with fur or feathers.

The best thing to do:

- Keep furred or feathered pets out of your home.

If you can't keep the pet outdoors, then:

- Keep the pet out of your bedroom and other sleeping areas at all times, and keep the door closed.
- Remove carpets and furniture covered with cloth from your home. If that is not possible, keep the pet away from fabric-covered furniture and carpets.

❒ **Dust Mites**

Many people with asthma are allergic to dust mites. Dust mites are tiny bugs that are found in every home—in mattresses, pillows, carpets, upholstered furniture, bedcovers, clothes, stuffed toys, and fabric or other fabric-covered items.

Things that can help:

- Encase your mattress in a special dust-proof cover.
- Encase your pillow in a special dust-proof cover or wash the pillow each week in hot water. Water must be hotter than 130° F to kill the mites. Cold or warm water used with detergent and bleach can also be effective.
- Wash the sheets and blankets on your bed each week in hot water.
- Reduce indoor humidity to below 60 percent (ideally between 30–50 percent). Dehumidifiers or central air conditioners can do this.
- Try not to sleep or lie on cloth-covered cushions.
- Remove carpets from your bedroom and those laid on concrete, if you can.
- Keep stuffed toys out of the bed or wash the toys weekly in hot water or cooler water with detergent and bleach.

❒ **Cockroaches**

Many people with asthma are allergic to the dried droppings and remains of cockroaches.

The best thing to do:

- Keep food and garbage in closed containers. Never leave food out.
- Use poison baits, powders, gels, or pests (for example, boric acid). You can also use traps.
- If a spray is used to kill roaches, stay out of the room until the odor goes away.

❒ **Indoor Mold**

- Fix leaky faucets, pipes, or other sources of water that have mold around them.
- Clean moldy surfaces with a cleaner that has bleach in it.

❒ **Pollen and Outdoor Mold**

What to do during your allergy season (when pollen or mold spore counts are high):

- Try to keep your windows closed.
- Stay indoors with windows closed from late morning to afternoon, if you can. Pollen and some mold spore counts are highest at that time.
- Ask your doctor whether you need to take or increase anti-inflammatory medicine before your allergy season starts.

Irritants

❒ **Tobacco Smoke**

- If you smoke, ask your doctor for ways to help you quit. Ask family members to quit smoking, too.
- Do not allow smoking in your home or car.

❒ **Smoke, Strong Odors, and Sprays**

- If possible, do not use a wood-burning stove, kerosene heater, or fireplace.
- Try to stay away from strong odors and sprays, such as perfume, talcum powder, hair spray, and paints.

Other things that bring on asthma symptoms in some people include:

❒ **Vacuum Cleaning**

- Try to get someone else to vacuum for you once or twice a week, if you can. Stay out of rooms while they are being vacuumed and for a short while afterward.
- If you vacuum, use a dust mask (from a hardware store), a double-layered or microfilter vacuum cleaner bag, or a vacuum cleaner with a HEPA filter.

❒ **Other Things That Can Make Asthma Worse**

- Sulfites in foods and beverages: Do not drink beer or wine or eat dried fruit, processed potatoes, or shrimp if they cause asthma symptoms.
- Cold air: Cover your nose and mouth with a scarf on cold or windy days.
- Other medicines: Tell your doctor about all the medicines you take. Include cold medicines, aspirin, vitamins and other supplements, and nonselective beta-blockers (including those in eye drops).

U.S. Department of Health and Human Services
National Institutes of Health

National Heart Lung and Blood Institute

For More Information, go to: www.nhlbi.nih.gov

NIH Publication No. 07-5251
April 2007

Mr. BURGESS. Time is expired.

Mr. Ward, recognized 5 minutes for the purposes of an opening statement.

STATEMENT OF CHRIS WARD

Mr. WARD. Thank you, Dr. Burgess, members of the committee, for your invitation to speak today. My name is Chris Ward. I live here in Washington, DC, and I am past chairman of the volunteer Board of Directors of the Asthma and Allergy Foundation of America, and I have had asthma all my life. When I was a child, there were very few choices for treating my asthma. I have been fortunate, however, that more and better asthma treatments have come into use. I have also been fortunate to be under the care of an allergist, a specialist in the care of patients with asthma, since childhood when I was diagnosed. Now that there are a variety of safe, effective medications from which to choose to treat my asthma, I am a grateful beneficiary.

Making the epinephrine bronchodilators, Primatene Mist or others, available over-the-counter may give patients a false sense of security. I know that from a personal perspective. If patients use this medication to achieve short-term control of asthma, which is a chronic disease, when long-term control is warranted, asthma is a chronic disease and short-term symptom relief may lull patients into a false sense of security and think they have no need to follow up with a healthcare practitioner physician.

Asthma patients need professionals who can recognize levels of asthma control and recommend the most appropriate, effective medication to achieve control. Left on their own—I as well as other patients and a lot of us know that with medication over-the-counter, that patients can get into trouble. Sound public policy should provide patients with opportunities to get appropriate treatment directed by skilled professionals. Having access to epinephrine bronchodilators over-the-counter may put patients at risk if they delay getting an appropriate diagnosis and effective treatment to keep their asthma in control.

Some may argue that in the case of an asthma attack, patients need to be able to go to a drugstore or a market and buy an over-the-counter inhaler like Primatene Mist or other epinephrine inhaler. Should we recommend, however, that someone who is having an asthma emergency go to a store to buy a device rather than calling 9–1-1 or going to an emergency room or hospital? If patients need unplanned refills or replacement devices, they can contact their prescriber or even get those medications prescribed for them by a physician in an emergency room and then follow up otherwise.

Another assumption that may prove false is that patients of low-income need these medications because they are low-cost. I grew up in an area of the country where there were a lot of low-income patients, and I certainly was not a child of means. While the price of Primatene Mist may be lower than the total cost or co-pay for more effective bronchodilators, the relief from these epinephrine devices does not last as long. Thus, the long-term control and long-term cost is actually higher.

Over-the-counter access to this product may seem to erase the cost of visiting a prescriber. However, over-the-counter broncho-

dilators can promote self-diagnoses, and we are all subject to those kinds of self-treatment sometimes, which is particularly unsafe for the symptoms of asthma because it can be deadly. With proper diagnoses and treatment, people can control their asthma symptoms, avoiding high-cost interventions like emergency department visits and hospitalizations. Cutting out care by a qualified medical practitioner could be dangerous for the patient and costly to the healthcare system.

The decision to withdraw Primatene Mist from the U.S. market was made years ago. Lifting the ban may now lead to confusion. There will be little opportunity to inform patients about the nature of the change and to urge them to seek care from a professional if they think they have asthma. I have worked with professionals like Dr. Kraft many years of my life in the industry of healthcare and life sciences, worked for pharmaceutical companies and other healthcare organizations. I have also been a volunteer as a volunteer leader of the Asthma and Allergy Foundation of America, and I know that asthma is a serious chronic condition, and I know what a difference effective treatment can make and even as a child with very few available to me, I was very fortunate.

I urge you, for all asthma patients, to reject an attempt to rerelease an epinephrine inhaler to the market as an over-the-counter product. Again, I thank all the members of the committee for inviting me here to testify today.

[The prepared statement of Mr. Ward follows:]

Statement of Chris Ward

To the House Energy and Commerce Committee, Subcommittee on Energy and Power

July 18, 2012

I am Chris Ward, I live in Washington, DC, and I am a past Chairman of the volunteer Board of Directors of the Asthma and Allergy Foundation of America. I have had asthma all of my life. When I was a child, there were few choices for treating my asthma. I have been fortunate that more and better asthma treatments have come into use. I have also been fortunate to be under the care of an allergist since childhood when I was diagnosed. Now, there are a variety of safe, effective medications from which to choose to treat my asthma, and I am a grateful beneficiary.

Making epinephrine bronchodilators like Primatene Mist available over-the-counter may give patients a false sense of security if patients use this medication to achieve short term control when long term control is indicated. Asthma is a chronic disease and short term symptom relief may lull patients into a false sense of security and think they have no need to follow up with their physician.

Asthma patients need professionals who can recognize levels of asthma control and recommend the most appropriate, effective medication to achieve control. Left on their own with medication like epinephrine bronchodilators to rely on, patients can get into trouble.

Sound public policy should provide patients with opportunities to get appropriate treatment directed by skilled professionals. Having access to Primatene Mist over-the-counter can put

patients at risk if they delay getting an appropriate diagnosis and effective treatment to keep their asthma in control.

Some argue that in case of an asthma attack, patients need to be able to go to a retail drug store or supermarket to buy Primatene Mist over-the-counter. Should we recommend that someone having an asthma emergency go to a store to buy a device over calling 911 and going to an emergency room or hospital? If patients need unplanned refills, or replacement devices, they can contact their prescriber or get appropriate medications from the emergency room.

Another false assumption is that low income people need these medications because they are low cost. While the price of Primatene Mist may be lower than the total cost of or co-pay for more effective bronchodilators, the relief from these epinephrine devices does not last as long. Thus, the long term cost is actually higher.

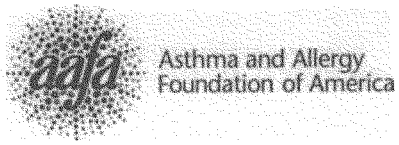
Allowing over-the-counter access to this product may seem to erase the cost of visiting a prescriber. However, over-the-counter bronchodilators can promote self-diagnoses, which is particularly unsafe for the symptoms of asthma. With proper diagnoses and treatment, people can control their asthma symptoms, avoiding high-cost interventions like emergency department visits and hospitalizations. Cutting out care by qualified medical practitioners could be dangerous for the patient and costly to the healthcare system.

The decision to withdraw Primatene Mist from the US market was made years ago. Lifting the ban now will lead to confusion. There will be little opportunity to inform patients about the

nature of this change and to urge them to seek care from a professional if they think they have asthma.

I know that asthma is a serious chronic condition, and I know what a difference effective treatment can make. I urge you, for all current and future asthma patients, to reject any attempt to re-release Primatene Mist to the US market as an over-the-counter product.

END



THE ASTHMA AND ALLERGY FOUNDATION OF AMERICA

The Asthma and Allergy Foundation of America (AAFA), founded in 1953 by the two leading professional medical organizations in the United States devoted to the allergy/immunology specialty, is the oldest asthma and allergy patient group in the world. AAFA is an independent not-for-profit association dedicated to improving the quality of life for people with these chronic conditions through education, advocacy and research. To achieve its mission, AAFA conducts national campaigns, disseminates education programs and tools, articulates policy positions and works with state and regional AAFA chapters, Educational Support Groups, governments, coalitions, corporate sponsors, health professional groups and volunteers.

Mr. BURGESS. I thank the gentleman for his testimony.

Dr. Kerwin, you are recognized for 5 minutes for an opening statement.

STATEMENT OF EDWARD M. KERWIN

Mr. KERWIN. Thank you very much to the committee and the subcommittee for inviting me to testify.

As Congressman Walden explained, I am an allergy researcher, asthma researcher. I have conducted over 300 clinical trials with over 200 new state-of-the-art medicines for asthma and I care for 10,000 asthma patients. And I trained with Monica. I will say that I am a member of the American Thoracic Society, a fellow of the American College of Allergy, and the American Academy of Allergy and never once have those organizations polled me or any of their general membership on the issue of Primatene.

Now, my comments today briefly——

Mr. BURGESS. I am sorry, sir. Your microphone popped. Could you make that statement again? I missed it.

Mr. KERWIN. I thought the microphone was on. I wanted to just state that I am a member of the American Thoracic Society for the last 10 years, a fellow of the American College of Allergy, and the American Academy of Allergy and never once have those organizations polled myself or any others of the general membership on the issue of Primatene and the safety of Primatene. So what I will tell you is these organizations are speaking on behalf of the administrative doctors working there but not on behalf of the general membership.

Now, what I want to say is that I think we live in a difficult era in science and culture. There are major scientific advances happening all the time, and I will just say that that is how I spend 90 percent of my time, doing clinical research with some of the latest, most advanced medicines for asthma. Science tells us CFCs can be harmful to the ozone layer and they do need to be removed gradually over time and that has happened with hairsprays and air conditioners and refrigerators. And I am happy to say that there are many new HFA medications that are available for asthma. So science is moving forward. We hope that there will be an HFA Primatene perhaps within a year.

But I have to say that there are also many issues of practicalities that critically need to be considered when any new law is implemented. And science cannot just be implemented as a blanket process. It has to be implemented in a rational way.

Asthma, as you have heard, is a disease that strikes in the middle of the night, and I don't know many private practice doctors who are going to be available 24/7 if you suddenly need a prescription medicine. Asthma occurs at your 4th of July picnic and it is going to occur when you visit your least favorite relatives who have five cats at home. Asthma may affect your college daughter when she moves into a basement apartment that has mold in it. It may occur when you get out and run a 5K or a 10K running race, and it will hit you when you come to visit me in Oregon where we have horse farms and hay farms.

What I need to make clear is that despite all of the science, which I am happy to discuss endlessly, Primatene Mist is a first

aid situation kind of medicine. The reason it is over-the-counter is that there need to be immediate access, immediate use medicines available to children, poverty-stricken patients, elderly people who have acute airway disease. It is similar to choking where a Heimlich maneuver is needed. It is similar to a bee sting where Benadryl can be picked up at any convenience store. We need regular access to emergency medicines.

Now, the American Thoracic Society and others may say you can get albuterol HFA but I challenge them that is simply not true. There are many, many Americans who have no insurance, they have no doctor, they have no prescriptions. They cannot simply get albuterol HFA.

The best analogy that comes to my mind is basically a life vest or a life raft on a ship. We have all seen the Titanic movie. We know what happens if there are not enough life vests or life rafts. Now, we have seen the Costa Concordia ship. The question is should all the life vests be locked up where only the ship's doctor or the ship's captain has the key? That simply does not make sense for a medicine that can be lifesaving for poor people in inner cities.

I am going to end by reading a brief poem. This is a little over the top but this is the poem engraved on the bottom of the Statute of Liberty, a little excerpt that says, "Give me your tired, your poor, your huddled masses yearning to breathe free, The wretched refuse of your teeming shore. Send these, the homeless, tempest-tost to me, I lift my lamp beside the golden door!" Now, what that means really is that we live in a country where there are many people who don't have opportunities to see fine and wonderful doctors. They need some temporary relief medicines. Scientifically, we are all in favor of HFA over-the-counter medicines, but there are none.

So I would ask the committee to consider extending the use of Primatene. It is the only available rescue medicine for up to 30 million Americans who don't have healthcare.

Thank you.

[The prepared statement of Mr. Kerwin follows:]

Points of Testimony

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1. Edward Kerwin, MD is an Allergy Asthma and Clinical Research Physician specializing in the treatment of Asthma and COPD patients. Dr. Kerwin has acted as a principal investigator on over 300 clinical trials of new inhaled medications for Asthma and COPD, including some 50 trials studying new HFA (Hydrofluoroalkane) inhalers used to replace older CFC (Chlorofluorocarbon) inhalers. Dr. Kerwin is an independent physician, and is not an employee of any pharmaceutical company, but performs research for many pharmaceutical companies.
2. Asthma is a common condition affecting up to 10% of children and 6% of adults in the U.S. COPD affects up to 10% of U.S. adults and elderly patients. Acute Bronchitis is an acute lung infection of the airways (medical term "Bronchioles") caused by viral or bacterial infections. All of these conditions cause episodes of airway muscle spasm and mucous plugging leading to acute, sometimes severe narrowing or obstruction of airways and inability to breathe. Acute exacerbations of asthma, COPD and bronchitis are common, occurring as frequently as daily in susceptible patients. Patients with "bronchospasm" require quick or immediate treatment with "rescue bronchodilator" medicines, generally given as inhalers, designed to provide near immediate relief to the airway blockages and obstruction typical of asthma, COPD and acute bronchitis.

3. Asthma, COPD and Acute Bronchitis can occur in the middle of the night, on weekends, during hikes, picnics, excursions, or camps far from cities. Severe Asthma flare-ups and COPD/ Bronchitis flare-ups can cause critical, sometimes progressive shortness of breath that can lead to death and very severe distress if untreated. Asthma especially is allergy and exercise triggered. Picnicking near a hay field, visiting relatives with cats, cleaning a moldy basement or dusty carpet can trigger severe life-threatening asthma flare-ups. Exercise also triggers flares. These generally require immediate treatment, usually with 2-4 puffs of a rescue bronchodilator given within minutes of the onset of airway obstruction. Death from asthma can occur within as little as 20 minutes (due to hypoxia, or starving for air) if asthma and bronchospasm are not rapidly treated.
4. Every patient with Asthma and COPD should carry with them a rescue bronchodilator (such as albuterol HFA inhaler or epinephrine CFC inhaler) per Guidelines of U.S. and Global Asthma and COPD organizations.
5. Since Acute Asthma, Acute COPD and Acute Bronchitis are potential medical emergencies requiring immediate treatment, *over-the-counter therapies can play a key life-saving role* when patients have a flare-up.
6. Another similar emergency condition is acute bee sting anaphylaxis, or food, shrimp or peanut anaphylaxis, or acute allergy to penicillin or another drug. In all these cases there are readily available over-the-counter medicines, Benadryl (dephenhydramine), other antihistamines, (cetirizine, loratidine, fexofenadine), decongestants like Sudafed (pseudoephedrine available OTC in some states), and other rescue-relief medicines that patients can give themselves within minutes in an emergency.

7. This is a key point. Patients have a fundamental right to self-treatment, to try to heal or treat themselves in whatever ways they can, before they resort to the expense and inconvenience of seeing a doctor. This is a fundamental part of American values and American self-reliance, what we might call the Pioneer American Spirit; Americans have a right to treat themselves first and foremost with whatever remedies are available. We would never have settled the Midwestern, Southern, or Western U.S. without this spirit. Many Americans today in Montana, Colorado, California, Idaho, Arizona, Michigan, Wisconsin, Alabama, Georgia, Oregon, etc., live on rural ranches and farms miles from any doctor or hospital. Americans have a fundamental right to treat ourselves, at least with initial emergency first aid treatments. This is who we are.
8. Historically 60-100 years ago asthma was fortunately rare, and was notoriously difficult to treat. Patients smoked asthma cigarettes with anti-cholinergic medicines. They downed theophylline pills and teas, breathed in steam and struggled to take showers, trying to ease their breathing. These were truly the "dark ages" of asthma care. And many Americans died if their severe asthma did not resolve.
9. For 49 years, through four generations, over-the-counter rescue breathing medicines have been readily available OTC to Americans with Asthma or COPD or Bronchitis flare-ups. Primatene Mist (CFC) was released in about 1963. Other brands of inhalers and pills containing epinephrine have also been available over-the-counter to any person without a doctor's appointment for nearly 50 years.
10. Only now as of December 31, 2011, has the U.S. EPA and FDA banned pharmacies in the U.S. from selling Primatene Mist (CFC) or any other inhaled epinephrine products.

11. Let me make this clear. As of January 1, 2012, there are no OTC rescue asthma medicines in U.S. pharmacies whatsoever. There are none.
12. So if you have an acute bee sting allergy in the forest, or at night, or in the inner city, or as an elderly person in your home, you can still get Benadryl, Zyrtec, Claritin or Allegra at any local 7-11 store or gas station.
13. But if you get an acute asthma flare-up on a hike in rural America, in the inner city, at night or on a weekend, you are out of luck. Maybe you can get an immediate doctor's appointment within 20 minutes…. As my teenage son would say, good luck with that. Maybe you are super organized and already have a prescription asthma/COPD rescue medicine like prescription albuterol HFA with you. But we all know that up to half of Americans are not so organized with their healthcare. Maybe you can treat yourself with "dark ages" treatments (see item 8 above). But even though for 50 years rescue epinephrine has been available OTC to every American, now there is no rescue inhaler that you can get in rural America, in the West, South, Midwest, or Northeast, in inner cities, or for poor or elderly patients with poor mobility.
14. You can think of an OTC rescue inhaler like epinephrine inhaler (Primatene Mist) as *a life preserver* for patients with severe flare-ups of asthma, COPD or acute bronchitis.
15. Just as on the *Titanic* or the *Costa Concordia*, people don't think about life preservers until they are drowning. Is it really right to lock up all the life preservers and give the only keys to a ship's doctor or a ship's Captain? As my teenage son says, good luck with that.

16. Rescue inhalers like Epinephrine (inhaled CFC or eventually HFA) should continue to be available over-the-counter to Americans without a requirement for a doctor's visit or a prescription or an ER visit. This is basically a "First Aid" medicine, like a band-aid for a cut, or Benadryl for a bee sting, or a Heimlich maneuver for a choking person. There need to continue to be over-the-counter, fast acting rescue bronchodilators available to Americans in need. They have had these continuously available since 1963. Only in January 2012 did the EPA and FDA prematurely withdraw CFC Primatene Mist inhaler without ensuring that there were alternative OTC rescue inhalers for patients with acute Asthma, COPD and Bronchitis.
17. The EPA and FDA have raided your "First Aid Kit," and removed a key rescue inhaler therapy. An extension on the withdrawal of Primatene Mist (CFC) for two years or 18 months is needed to allow an alternative HFA Epinephrine inhaler to be developed and to be approved for over-the-counter use by all Americans.

Thank you for your attention.

Edward M. Kerwin, MD

Summary

Testimony of Edward Kerwin, MD
Senior Medical Director, Allergy & Asthma Center of Southern Oregon, PC

- Asthma, COPD and Acute Bronchitis effect more than 30 million Americans. They cause episodic severe breathlessness requiring the use of rescue bronchodilator inhalers.
- For 49 years Americans have had an over-the-counter (OTC) rescue inhaler alternative, called Primatene Mist (epinephrine) with a chlorofluorocarbon (CFC) propellant. CFC Primatene Mist has been available for four generations of Americans, since 1963.
- The first principal of medicine is that patients have a right to treat themselves, to render first aid, to try to heal their own health before they go to any doctor or ER. This is a fundamentally American value, and how our rural frontiers were settled. Americans have a right to treat themselves through first aid in emergencies.
- OTC Inhaled Epinephrine (CFC) is a lifesaving rescue medicine for acute asthma, COPD, albuterol. This is similar to the role Benadryl plays for bee sting, peanut, or penicillin anaphylactic reactions. Such rescue medicines need to be available over-the-counter. There should be no "locking up" of these life preserving medicines in pharmacies and doctors' offices. They are needed promptly within minutes, in the middle of the night, in rural areas, in inner cities, by the poor and infirm, by Americans who may have no rapid medical access to a doctor or hospital.
- An 18 month to two year extension of the licensing of OTC Primatene Mist (CFC) inhaler in the U.S. will allow time for a suitable HFA (hydrofluoroalkane) replacement to be developed as an OTC rescue inhaler for Asthma, COPD, and bronchitis patients, available to all Americans.

Mr. BURGESS. The gentleman's time is expired.

We thank all witnesses for their testimony. I am going to start with myself.

If I was sitting down there, I would complain to the chairman that we don't have the EPA here and we don't have the Food and Drug Administration here because really that is who needs to be at this hearing. And I do want to thank all of you. I mean this has been difficult for me because I just simply did not understand what in the hell was going on. You have got the EPA saying the Montreal Protocol says we have got to take this stuff off the market. The FDA is saying, yes, yes, we are working on a replacement; we are going to get to it. But it just wasn't happening and I couldn't get anyone to answer my questions. Lisa Jackson, Gina McCarthy were not only dismissive, they were derisive. Dr. Hamburg at the EPA just simply evaded the question but now I understand. There is a contingent of people who do not think that epinephrine belongs as part of the armamentarium for treating asthma. OK.

Dr. Kraft, have you talked to the FDA about the withdrawal of epinephrine as an asthma therapy? I mean it has been around for 50 years. Presumably it was approved at some point. So have you provided testimony or documentation to the FDA on this subject?

Mr. KRAFT. What I have done is we have been involved as a society in looking at——

Mr. BURGESS. So the answer to the question is no, you have not——

Mr. KRAFT. No, I have not talked to them directly other than offline. So you won't find any documented testimony. One thing I would like to put forth, however——

Mr. BURGESS. Well, could you provide us those things that you have sent to them offline? You have communications?

Mr. KRAFT. And I am just being told the ATS other than myself personally has commented on the transition process.

Mr. BURGESS. OK, so you will——

Mr. KRAFT. We can provide that.

Mr. BURGESS. On the transition process, but I mean look, if you want a drug withdrawn from the market—and this happens all the time—I mean you go to the FDA and say we have post-market surveillance. This stuff is as bad as key tech. This stuff is as bad as—I forgot what the anti-inflammatory was——

Mr. KRAFT. VIOXX.

Mr. BURGESS. VIOXX. And things happen.

Mr. KRAFT. Sure.

Mr. BURGESS. Have you done that?

Mr. KRAFT. We can provide you with—absolutely. We have been to the FDA. We have two issues actually if you permit me to——

Mr. BURGESS. Well, what did the FDA tell you?

Mr. KRAFT [continuing]. Speak. We have issues on—there is a CFC issue. To be honest, I am here today as a physician caring for patients. I am really here for the patients' safety piece because we have been calling for the removal of inhaled epinephrine well before Montreal Protocol really became an issue.

Mr. BURGESS. Right. So that is the issue that you are coming to discuss today, but the hearing is on the Montreal Protocol and the CFC prohibition preventing asthmatic patients——

Mr. KRAFT. Right.

Mr. BURGESS [continuing]. From having a rescue inhaler.

Mr. KRAFT. Absolutely. So——

Mr. BURGESS. And I am speaking to you not just as a Member of Congress. I am also a physician. I am also an asthma patient——

Mr. KRAFT. Right.

Mr. BURGESS [continuing]. And I use over-the-counter epinephrine metered-dose inhalers and I have for some time. I use them as part of the rescue phenomenon that we have all heard talked about, and yes, OK. I am a doctor. I can go down to the all-night pharmacy and write my own prescription for albuterol. But if I get trapped in a situation without an inhaler, it happened to me in Chicago at an NRCC fundraiser a few years ago. The hotel put me in a room where somebody had been smoking. So at 2:00 in the morning, guess what? I can't breathe. So I got two options. I can stay up the rest of the night holding onto the chair using the accessory muscles of respiration and have a sleepless night or I can go down to the front desk clerk and say where is your nearest 24-hour pharmacy? He says one block over, two blocks up. I say thank you very much, take my life in my hands, walk across the streets of Chicago at 2:00 in the morning, but a rescue inhaler is available to me.

Mr. KRAFT. Right.

Mr. BURGESS. And I could do this without being a physician, just being a regular Joe you can go and get that but not anymore. And this is the difficulty that I have is you have the product in the warehouses. If you are really concerned about CFCs, if this is really about the hole in the ozone, what is going to happen to those canisters? I mean at some point they degrade to the point where they blow up I guess. I mean I don't know. I don't know what the lifecycle is of one of those things. But the CFC is going to go into the environment. So what are we preventing here? Are we going to go put them in Yucca Mountain and entomb them in concrete so that they don't ever get out? I mean I don't even know how much CFC we are talking about here.

But it is just preposterous that we are having this argument around CFC, around the propellant under the Montreal Protocol when really your beef is with epinephrine and we should have the FDA here and you should be asking them——

Mr. KRAFT. I agree.

Mr. BURGESS [continuing]. To explain what studies have you done? Why do you still allow this stuff to be sold? And I would have some questions for them about that as well. But no one would answer my questions. Can you understand the frustration? I have had Lisa Jackson here at this table and she just looks at me like I am nuts. I have had Gina McCarthy and she laughs that I am even concerned about this.

Mr. KRAFT. Um-hum.

Mr. BURGESS. Margaret Hamburg won't even answer the question. Can you understand why there is such frustration with this?

Mr. KRAFT. I do.

Mr. BURGESS. And at the same time I am getting these same letters from constituents, Doc, how come I can't go buy this stuff any-

more? How come you took it away from me? How come you know better than I do about what is best to treat my asthma? It is not just breathing through a straw; it is breathing through a straw that is packed full of cotton. I mean this——

Mr. KRAFT. Absolutely.

Mr. BURGESS [continuing]. You know, Mr. Ward. I mean this is a dreadful set of symptoms to have visited upon someone. You have got a rescue inhaler. If the issue is that it is not a satisfactory pharmacologic agent, let us work on getting albuterol over-the-counter——

Mr. KRAFT. I agree.

Mr. BURGESS [continuing]. And I will just share with you my personal preference is CFC is a much better propellant——

Mr. KRAFT. Right.

Mr. BURGESS [continuing]. Than HFA. HFA is for wimps. CFC delivers the right dose at the right time.

I am going to yield to the ranking member of the subcommittee.

Mr. KRAFT. Would I be permitted to answer?

Mr. BURGESS. Oh, please.

Mr. KRAFT. Thank you. So I agree with your frustration. I can understand that. If I were your doc, I would make sure you had three separate albuterol inhalers. I would have you put one in your briefcase, I would have you put on in the glove box of your car, and I would have you put one in your wife's purse to make sure that you always have albuterol with you. So that is the first part.

Mr. BURGESS. I do that, but the best-laid plans don't always work out. And sorry that I wasn't prepared that night but it happens. It happened on a flight into Dulles where, you know, I didn't have an inhaler. I had a long cab ride back. Oh, my lands, I am really in trouble. I asked the cabdriver, would you stop at a pharmacy and let me pick up a rescue inhaler so I am not sitting here in the backseat of your cab suffocating——

Mr. KRAFT. Right.

Mr. BURGESS [continuing]. And he was happy to accommodate me. I mean those are real-world situations and they happen all the time. My wife will likely not carry one in her purse for me, but I do have one in my glove box. I do have one in my backpack. I don't carry a briefcase but, yes, I have got them scattered all over my life——

Mr. KRAFT. OK.

Mr. BURGESS [continuing]. But sometimes I wander away from them. I will let you respond.

Mr. KRAFT. OK, thank you. The other issue is regard over-the-counter. There actually is a movement going on to start talking about over-the-counter bronchodilators that are safe. It is still in the very early stages. It is somewhat controversial because we are still on the same issue where we want to make sure that practitioners interact with their patients to be able to educate them on the principles of asthma and know what combinations of medications work best for them.

So I don't know if you are aware of that or not. So I wanted to just put that forth as something that is in the works. If we are really focusing on this over-the-counter piece, I think there is a

thoughtful way to consider over-the-counter medications for asthma that aren't necessarily Primatene Mist per se.

I am also a critical care physician and I have seen more patients coming into my intensive care unit with their Primatene Mist inhaler clutched to their chest with a severe asthma exacerbation on a ventilator. And I don't see that when they are on proper therapy. We have seen a much lower incidence of really severe asthma exacerbations because of people getting in with their docs, getting on anti-inflammatory inhalers. Because I worry this reliance on going down to the drugstore and getting Primatene Mist and not being on something daily for asthma—because it is about redness and swelling of the airways is a problem.

Mr. BURGESS. We need to go to Mr. Rush. I don't want you to be concerned for my health and safety. I do have an ADVAIR inhaler and I do use it——

Mr. KRAFT. Well, I am.

Mr. BURGESS [continuing]. Regularly. But there are times when you need that extra boost.

And I will yield to Mr. Rush, 5 minutes for questions.

Mr. RUSH. Well, thank you, Mr. Chairman. Mr. Chairman, I was headed along the same path. I think you might have inadvertently—didn't mean any harm—mentioned the fact that you took your life in your hands by walking outside of a hotel in Chicago and I really take offense to that. But I have been working on this issue of asthma for quite a while and it is a real acute concern of mine and it has been and always will be because it disproportionately impacts my community. In the year 2000, Congress passed the Asthma Reduction Act, which incorporated aspects of a bill that I sponsored into the Children's Health Act of 2000. And it came along and I still am very much concerned about the issue of asthma. And I have to say I am somewhat torn but I have to come down on the side of my constituents.

Mr. Chairman, a month and a half ago I had a pastor at a church and the person who is one of my—not my key person at the church—had asthma and I think you might recall I had to go and bury him. And he was a member of my church and he was an asthmatic patient and he died of congestive heart failure. But he was an asthmatic patient also. And his memory keeps overpowering me and overwhelming me even now. And he was under a doctor's care. But now, many, many people who are my constituents, I have one of my long-time staff members is an asthmatic patient. Every Tuesday she takes half a day off and this has been going on for years. She goes to the doctor to get the shots that I have seen her go into crisis situation on more than one occasion.

And I know that the science and the goodhearted folks—but I just have to say to Dr. Burgess, I think that this legislation that you come up with, I don't like the fact that we have to do this, but I just don't see, given the absence of any other approach that this Congress can make, I don't see how we can avoid it. I for one just find that there are too many of my constituents who don't have access to healthcare, who don't have a doctor, and who even think it would take too much time right now if they would be able to do—they just don't have the wherewithal. They are missing so many elements keeping them from living productive lives, and asthma is

becoming more and more of an issue. It is probably one of the leading health issues in my community.

And I hear the arguments but I think that this Primatene should be allowed back on a temporary basis, understanding what the problems are with it, what the short-term solution might mean to other long-term issues—I haven't addressed the long-term issues. But I don't see the solution to these issues. I don't see that being eminent and overnight, reality, because it has to do with access to healthcare. And this Congress, we have tried to address it but we can't agree on what access to healthcare really means to the American people. I know my time is expired. I had some questions but I just had to get out what I had to say about this particular issue.

I yield back.

Mr. WHITFIELD. Well, thank you, Mr. Rush.

At this time, I recognize the gentleman from Texas, Mr. Barton, for 5 minutes.

Mr. BARTON. Thank you, Mr. Chairman.

When I go to Chicago, which I don't do very often, I just carry around Bobby Rush-is-my-friend cards and I have never had a problem on the streets of Chicago. I just show them that card and they say what can we do for you? They just couldn't be friendlier.

So when Dr. Burgess indicated he was going to introduce this bill, I was encouraging of him introducing the bill. You know, but this goes under the heading of no good deed goes unpunished because apparently a lot of the people in the asthmatic community are fairly opposed to his bill.

My first question would be to the panel. Each of you indicate you support the bill, oppose the bill, or are neutral on the bill. Just start and go right down the line.

Mr. SHANDELL. Yes, I definitely support the bill. I find it ironic that these third parties are now raising safety issues when this really was an environmental issue. Primatene Mist has been around for half a century.

Mr. BARTON. So you support the bill?

Mr. SHANDELL. I support the bill.

Mr. BARTON. I don't need the editorial right now.

Mr. SHANDELL. I support the bill.

Mr. BARTON. OK. Dr. Kraft?

Mr. KRAFT. I oppose the bill. Am I allowed to say anything?

Mr. BARTON. Well, in a minute.

Mr. KRAFT. OK.

Mr. BARTON. Right now, we have got one for and one against.

Mr. KRAFT. All right.

Mr. BARTON. Mr. Ward?

Mr. WARD. As a patient, I think I would oppose the bill——

Mr. BARTON. Oppose the——

Mr. WARD [continuing]. As it is currently constructed.

Mr. BARTON. As it is currently constructed, OK.

And Dr. Kerwin?

Mr. KERWIN. And I definitely support the bill——

Mr. BARTON. Support the bill.

Mr. KERWIN [continuing]. Only alternative out there for people who don't have a doctor right next to——

Mr. BARTON. So we are two to two. We have two for and two against. That is not bad. I mean, you know, that is a tie. In this committee, the tie goes to the sponsor of the bill.

So my next question, Primatene Mist, if it were allowed to be sold over-the-counter, the existing stocks, what would that cost an individual who just walked in and purchased it? What would it——

Mr. SHANDELL. I can answer that. So we sell to the retailers who then mark up, but we will not raise the price of Primatene. As I said, we will donate all the profits. So based on the past sales, we are looking at about $20 at the retail——

Mr. BARTON. If it were allowed to be sold, it would be around $20?

Mr. SHANDELL. Correct.

Mr. BARTON. Now, if I don't have it and I have to go to a doctor and get a prescription, what does that prescription cost for the equivalent amount of dosages?

Mr. SHANDELL. Well, the prescription itself let us not forget the doctor's bill but the actual inhaler is $110.

Mr. BARTON. OK, Dr. Kraft, you have got——

Ms. KRAFT. I would like to respectfully disagree. Yes, there are places where in fact it is $120. If you look, which I just did today, not in Canada, $30——

Mr. BARTON. Thirty dollars.

Ms. KRAFT [continuing]. You can find——

Mr. BARTON. You can get——

Mr. KERWIN. Well, I will just have to say that having practiced allergy and asthma care for 20 years, there is nowhere in my State of Oregon where you can get albuterol inhaler HFA for less than $60 to $70 a canister.

Mr. BARTON. All right. So——

Mr. KERWIN. So that is the fact——

Mr. BARTON. We are——

Ms. KRAFT. Well, I guess I practice in a part of the country that is a little less——

Mr. BARTON. We are all in agreement that the prescription is going to be somewhat more expensive. If you are an informed consumer like Dr. Kraft, you can get it much less expensively, but there is nowhere you can get it for the same price. That is fair?

Now, the next question—which of you a medical doctor, which of the two doctors? So we have two medical doctors. This is great because you are on each side of the issue. What is wrong with allowing the sale of the existing stocks and use that as an emergency but also have your prescription where you get the treatment regime that actually seems to be more effective? What is wrong with that, Dr. Kerwin?

Mr. KERWIN. Well, thank you for making that point. That is exactly the kind of care we think Americans should get. Like Dr. Burgess does, they should see a doctor, they should get educated about their asthma, they should reduce their allergy exposures, they should get anti-inflammatory inhalers, and they should have access to Primatene just for emergencies. I live in a rural State. Many patients in southern Oregon live 50 miles from the nearest doctor. That is quite common. Certainly, 100 miles from an emergency room. We believe there is a role for Primatene or epinephrine or

any over-the-counter inhaler. I would support over-the-counter albuterol but it is not——

Mr. BARTON. My time is about to expire.

Dr. Kraft, my friends at the Allergy and Asthma Network Mothers of Asthmatics point out that there is a product manufactured by Nephron Pharmaceutical that is a handheld bulb nebulizer. What does that cost? And is that effective?

Ms. KRAFT. That is epinephrine also is my understanding and so I do not know the cost of that. But I would like to comment on your first statement——

Mr. BARTON. I mean that would take care of the Montreal Protocol issue I think because it is a handheld. It doesn't use a CFC.

Ms. KRAFT. Right. The issue I see is that Primatene has been around for 50 years, so that is one issue that people like to bring up. I would argue that 50 years ago we didn't have a lot of particularly effective asthma therapies. So that is all there was. Now, we do.

Now, I am also in favor of over-the-counter options for asthma and that is actually, as I was mentioning earlier, that is in the works at the FDA.

Mr. BARTON. Well, it has been in the works for——

Ms. KRAFT. Well——

Mr. BARTON [continuing]. A number of years.

Ms. KRAFT [continuing]. Actually, I think there have been hearings. It is actually heating up quite vigorously and we are right in there part of it as supportive with thought.

Mr. BARTON. Well, my time is expired and I appreciate the chairman's courtesy.

Ms. KRAFT. OK.

Mr. WHITFIELD. The gentleman's time is expired.

Mr. BARTON. I do think Dr. Burgess has a good idea here. If we can work with the community so it is not two to two, we may have a bill that actually goes somewhere.

Mr. WHITFIELD. At this time, I will recognize the gentleman from California, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman.

Obviously, if you have two on each side, it doesn't produce a tie; it just means it is a balanced presentation and that is always a good idea so we hear both sides of the issue.

But I am going to ask about the health effects of all of this. Dr. Kraft, you are the president of the American Thoracic Society and a recognized expert on asthma. And there is a long list of medical and public health organizations who have raised concern about the over-the-counter epinephrine inhalers. In your testimony, you said epinephrine inhalers like Primatene Mist are not a safe treatment for asthma and are not recommended by expert guidelines. Why is that?

Ms. KRAFT. You are absolutely right. That is true. The reason is it is the compound itself, the chemical epinephrine. It is nonselective. So yes, it can bronchodilate, so that is the good news, but it has effects on other organs. And the major concern is cardiac, excessive cardiac stimulation and can lead to myocardial infarction, heart attack in patients who have heart disease. And that is really the concern. I am not against over-the-counter medications for

asthma necessarily if done in a thoughtful way. I think that this particular medication is concerning. And there have been voices for many years calling for the removal of this particular agent because of the dangers and the side effect profile. That is really where we are sort of coming from today.

Mr. WAXMAN. But it is not easy for FDA to take a drug off the market. Do you know what the standard of proof is? I assume it is pretty tough.

Ms. KRAFT. I am sorry. Repeat that question, please.

Mr. WAXMAN. Has FDA tried to take it off the market? Is it something that FDA should take off the market?

Ms. KRAFT. You mean Primatene?

Mr. WAXMAN. Yes.

Ms. KRAFT. Well, it has been off the market for 6 months because of——

Mr. WAXMAN. But did they ever move to take it off the market?

Ms. KRAFT. There have been calls from the American Medical Association——

Mr. WAXMAN. Um-hum.

Ms. KRAFT [continuing]. To the FDA to consider it. But I think it is a difficult situation because the question is can we look at alternatives and can we improve access to care for patients——

Mr. WAXMAN. Um-hum.

Ms. KRAFT [continuing]. So that they can actually get the right medications. So I like the idea of having something available for patients but I would argue let us make it the best medication and a safe medication.

Mr. WAXMAN. Well, Dr. Kerwin argues in his testimony that Primatene Mist is necessary for an emergency situation where someone suffering from asthma does not have a prescription medication. He says people would die or could die without it. What do you think in a potentially life-threatening situation, should asthmatics use Primatene Mist?

Ms. KRAFT. I have actually seen the ramifications of using it in an emergency situation and relying upon it to improve asthma symptoms. And the issues—it is very short-term in terms of its action and the excessive additional side effects of the cardiac piece actually, in my opinion, is not a safe alternative. So I would actually recommend—and we have done this in the community that I practice—we have the ability for patients to get albuterol very easily and to have access to emergency departments and follow up with us so they can get the medications they need. And we have a big community program in Durham for this purpose exactly to help the underserved because I think that is who we are talking about today, those patients who don't have the access that perhaps the rest of us do.

Mr. WAXMAN. Well, I take seriously when the health professionals take a point of view that something is not safe, particularly if it is—this bill would go to extraordinary lengths to put it back on the market. It is not on the market now. If I were convinced, however, that it is necessary, then I would say fine. Let us keep it out there. But I don't think we have got to push legislation to put a product back on the market in the face of such strong opposition by public health and physician organizations.

Am I correct that public health and physician organizations take the same point of view you do?

Ms. KRAFT. Yes, many.

Mr. WAXMAN. Now, I want to go into the question of how fair this is to the company. The company obviously wants to sell the product that they still have and they are not going to pursue it after that. The initial proposal by FDA was to phase out the drug and it was agreed upon it would be December 31, 2010. Armstrong submitted comments to FDA requesting it be extended 1 year, and FDA granted Armstrong's request for a 1-year extension. Isn't that right, Mr. Shandell?

Mr. SHANDELL. Yes. I would like to address that because——

Mr. WAXMAN. Well, I just want your answer because——

Mr. SHANDELL. Yes, that is correct.

Mr. WAXMAN. No, my understanding is that about a dozen other types of inhalers containing CFCs were phased out before Primatene Mist. That includes the albuterol phase-out in 2008 which involved moving millions of asthmatics to new treatments——

Mr. SHANDELL. Which was our product as well.

Mr. WAXMAN [continuing]. Only two CFC-based inhalers remain to be phased out, and both are scheduled to be taken off the market at the end of 2013. So Primatene Mist was actually phased out several years later than many other types of inhalers. Would it be fair to them to have you come back on the market when they——

Mr. SHANDELL. Well, that is what I would like to address because, you know, this is an environmental issue regarding CFC. It is not a safety issue because otherwise——

Mr. WAXMAN. Well, this is not a safety question that I am asking. I am just asking you in basic fairness——

Mr. SHANDELL. Well, yes, the——

Mr. WAXMAN [continuing]. If other companies follow the rules——

Mr. SHANDELL [continuing]. Fairness question is that we have been working with FDA since 2007 for HFA Primatene. So obviously the FDA believes in Primatene because we have spent tens of millions of dollars on clinical trials and we are looking to get an approval next year. So obviously——

Mr. WAXMAN. No other company——

Mr. SHANDELL [continuing]. New drug applications——

Mr. WAXMAN [continuing]. Came back and said we are not——

Mr. SHANDELL. And the only reason we are——

Mr. WAXMAN. Excuse me, sir.

Mr. SHANDELL. Yes.

Mr. WAXMAN. I have already exceeded my time but I get to ask the questions.

Mr. SHANDELL. Sure.

Mr. WAXMAN. And other companies phased out—not other company was allowed to come back and sell off its remaining inventory after the phase-out date. Isn't that right?

Mr. SHANDELL. That is correct. No other company is over-the-counter so there is no——

Mr. WAXMAN. What difference does it makes if it is over-the-counter or prescription?

Mr. SHANDELL. Because if you don't have a prescription, you can't afford insurance, you have no choice.

Mr. WAXMAN. That is a different issue but a drug to be extended and allowed to come back and sell off the——

Mr. SHANDELL. We have a million units remaining——

Mr. WAXMAN [continuing]. Inventory.

Mr. SHANDELL. We don't need to sell the inventory. We are advocating on behalf of our customers who have been complaining saying that people have died actually. So we are just coming out not for money. We are saying, look, let the million be sold. We are really interested in getting HFA approved so there is an over-the-counter. In terms of fairness, there are two prescriptions that are still not the market with CFC and nobody has answered why those are allowed to stay if it is an environmental issue and not a safety issue.

Mr. WHITFIELD. Gentleman's time is expired.

I will recognize myself for 5 minutes of questions now.

We have a situation here where we have in storage some Primatene Mist. This legislation relates only to that. This is a product that has been used 40, 50 years, was accepted by people who used it and obviously people benefitted from it or they wouldn't continue to buy it. We have a lot of letters or emails here from people—"I just spent my last $200 on my son at a doctor's appointment for asthma medicine and will no longer be able to go to the doctor's" because Primatene Mist is gone. We have a lot to that effect. I understand a genuine concern about, oh, this is not safe for people, and Dr. Kraft, you have said that this is not a safe treatment. There are side effects. There are cardiac problems with it. And now, Dr. Kerwin, would you reply to that comment that Dr. Kraft made?

Mr. KERWIN. Yes, I would be delighted to reply to that. You know, Primatene was released and approved by the FDA either in 1957 or 1963, and at that time, the approval process was less rigorous than it is now. So Primatene has been what we would call a grandfathered medicine that has been out for many, many years. Every drug company is required to collect safety reports if there is any episode where a drug fails a patient or where they die for any reason that could be related to the drug. And my understanding is Amphastar has received no complaints of patients who have had life-threatening cardiac problems or other what we call serious adverse events with this medicine. It is truly unfair to say that it is not a safe drug. That is 100 percent speculative. The way safety is assessed is through a clinical trial process, and epinephrine in the HFA form is going through a very careful and rigorous FDA-authorized safety process.

Mr. WHITFIELD. Thank you. I might——

Mr. KERWIN. Safety is roughly parallel. It is slightly more cardiac stimulating.

Mr. WHITFIELD. I mean I can understand in Durham that there may be a program developed that really addresses this emergency need, but there are lots of places in the country that do not have programs like that. And from my personal perspective, I don't see what is wrong with giving patients a choice. If it is available and they want it for a period of time, why not?

But I would like to yield the balance of my time to Dr. Burgess.

Mr. BURGESS. Well, Mr. Chairman, I would just reiterate the observation that we are here today having this hearing. The legislation has been introduced essentially because two Federal agencies decline to be truthful with the committee. And that is the real tragedy here. Yes, we should have the EPA here. They should be answering the question why are there two prescription products that are continuing to use CFCs still sold, not affected under the ban? We should hear from the FDA. Have you had post-market surveillance data on inhaled epinephrine products that lead you to believe that it is unsafe?

But instead, we have got this mishmash, this backdoor banning of a product that has been approved for 50 years on which people depend under the Montreal Protocol. I mean this really makes no sense. If we are really frightened of the CFC in those remaining canisters that Mr. Shandell has secreted away somewhere, I submit that we ought to reopen Yucca Mountain and take them deep into the Earth and entomb them in cement like we would radioactive waste.

But those canisters are eventually going to degrade, pop open, and the CFC floats over the Antarctic and widens the hole in the ozone. At least that is what we are led to believe that this small amount of CFC is going to lead to all sorts of global calamities.

Dr. Kerwin, look, I have been in the ICU when a young patient has died from an aspirin overdose. I mean that is tragic, the acidosis that accompanies like 24, 36 hours later. Everybody thinks the kid is out of the woods and then he dies. So we know people can die from over-the-counter products. Yet, people take aspirin all the time for headaches. Would it make sense that we told people if you have a headache, you really shouldn't take aspirin anymore. Come to the emergency room, let us give a CAT scan to make sure you are not dying of a brain tumor and then we will get you something. I mean that is kind of what we are saying here, isn't it?

Mr. KERWIN. I would say that the principle of having medicines available over-the-counter is sort of a twofold principle. One is America was settled by frontiers people who came out to many of the big States and they didn't have a doctor on their Oregon Trail wagon train. So we live in a country where people have a fundamental right to try to treat themselves first before they take the radical step of seeing a doctor. The second thing I would say is medicines over-the-counter are designed in order to help the many even if overuse of the medicine or misuse might harm a few. And I think Tylenol, 20 pills of that can hurt your liver. Benadryl, 20 pills of that could put you in a car crash, and yes, 20 puffs of epinephrine might make your heart race. But these medicines are consistent with the values that patients should have a right to treat themselves initially and they should then seek better medical care.

Mr. BURGESS. Well, Mr. Chairman, I will just close with the observation that we should require the two Federal agencies involved—Environmental Protection Agency and the Food and Drug Administration—to come before this committee and be honest with us for a change, none of this hide-the-ball, oh, it is a Montreal Protocol thing. If there is a danger to inhaled epinephrine, then why the hell has the FDA not prevented it? We have been through this

round and round with the FDA where they say, oh, we know that something is dangerous but we can't prevent it being sold. That is nonsense. That is their job. That is what they are there to do. If they have post-market surveillance that says inhaled epinephrine multi-dose inhalers are damaging to people's health, they owe it to this committee to come here and share that with us.

Mr. WHITFIELD. At this time, I would like to recognize the gentleman from Michigan, Mr. Dingell, for 5 minutes.

Mr. DINGELL. I thank you for your courtesy. And I would like to ask these questions of Mr. Shandell, yes or no.

It is my understanding that there are 1.2 million units of Primatene Mist remaining in inventory, is that correct?

Mr. SHANDELL. Yes, approximately.

Mr. DINGELL. Now, is this remaining inventory being stored under safe and proper conditions?

Mr. SHANDELL. Yes, it is.

Mr. DINGELL. You are sure of that?

Mr. SHANDELL. Yes.

Mr. DINGELL. When will the remaining inventory expire?

Mr. SHANDELL. It expires at varying times, mostly in August of 2013.

Mr. DINGELL. OK.

Mr. SHANDELL. Starting in January.

Mr. DINGELL. The remaining inventory has been stored properly and has not yet expired. Do you know the reason or do you have reason to believe then that any of the remaining inventory is unsafe for use by patients?

Mr. SHANDELL. No, we do not. It should be very safe for patients——

Mr. DINGELL. Does anybody at the table have any reason to believe that the storage of the remaining inventory of Primatene Mist is creating an unsafe product? Yes or no?

Ms. KRAFT. I just had a question on the expiration. It is January to August of '13, right?

Mr. DINGELL. Well, is anybody down there going to sit there and tell me that this Primatene Mist is going to be unsafe when it is put on the market if it is so?

Ms. KRAFT. Based on the way it is stored, sir?

Mr. DINGELL. Based on any fact. Yes or no. It is a yes-or-no question. You should have no trouble doing it.

Ms. KRAFT. Yes. Then I would say yes.

Mr. DINGELL. You believe it is unsafe?

Ms. KRAFT. Yes.

Mr. DINGELL. Why?

Ms. KRAFT. For the reasons that I stated previously. It has nothing to do with storage. I think they have been storing their product——

Mr. DINGELL. Do you have knowledge of this or is this supposition?

Ms. KRAFT. That it is unsafe? I have had personal experience with patients who have taken it and had severe asthma—I am talking about safety from a mechanism perspective.

Mr. DINGELL. Thank you very much for that unhelpful response.

Now, according to your testimony, Mr. Shandell, there have been between 2 and 3 million Primatene Mist users. If Amphastar is allowed to distribute and sell the remaining inventory of Primatene Mist, how would your company do so equitably?

Mr. SHANDELL. Yes, we will do it equitably. We will not raise the price from what it was previously. We also, as I have stated, this is for the goodwill of our customers. We are not looking to make any profit here, so we will actually donate all the net profits to charity. And I really want to go back to people are saying that this is an unsafe drug, then why has the FDA been working with us since 2007 for an HFA version?

Mr. DINGELL. May I persist in my questions?

Mr. SHANDELL. Yes, sure.

Mr. DINGELL. Is there any reason to fear that pharmacies may not be willing to restock Primatene Mist for any reason?

Mr. SHANDELL. There is some concern to that but if it is as sought after as we believe by our customers, they can always get it online by CVS.com. There are——

Mr. DINGELL. So there is the fear that they would refuse to stock it?

Mr. SHANDELL. No. Well, there is some fear on the shelf life stocking——

Mr. DINGELL. Yes or no?

Mr. SHANDELL. Yes. Yes.

Mr. DINGELL. You have no reason?

Mr. SHANDELL. I have no——

Mr. DINGELL. You have no fear that the customers would refuse to stock this if it is put back on the market?

Mr. SHANDELL. I believe that there is a strong demand for it.

Mr. DINGELL. All right. Now, in order to assure the proper education of patients regarding the phase-out of Primatene Mist, these inhalers were packaged with labeling noting that Primatene Mist would no longer be available after December 31, 2011, and encouraged patients to talk to your doctor or pharmacist about other asthma medicines. How is your company going to address potential confusion that will be caused among your patient population when these inhalers become again available?

Mr. SHANDELL. Yes. This message is on the box. If we are allowed to sell the remaining inventory, such units will be moved to our subsidiary. They will be relabeled to eliminate this statement and then released by quality assurance.

Mr. DINGELL. All right. Now, I have another question. There are two remaining prescription products containing CFCs that are not being phased out until 2013. These products are Combivent CFC, which contains albuterol and ipratropium bromide in combination; and Maxair, which contains pirbuterol. These two drugs are subject of the separate rulemaking that was financed on April 14, 2010. It seems to me that this tells me that FDA and EPA didn't feel that there was a significant problem with regard to the carrying medium that they have in your product. Is that right?

Mr. SHANDELL. Yes. I have never received clarity as to why the prescriptions are still out——

Mr. DINGELL. All right. Thank you. My time has expired.

Mr. Chairman, your courtesy is much appreciated. I would ask that the chair would be supportive of me. I am going to send a letter down to FDA asking a number of questions. And I am going to ask that the FDA would respond, and if they are slow, I am going to look to you for your assistance in seeing to it that they are properly responsive.

Mr. WHITFIELD. Thank you.

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. WHITFIELD. We would be happy to assist in any way possible.

At this time, I would like to recognize the gentleman from New York, Mr. Engel, for 5 minutes.

Mr. ENGEL. Thank you, Mr. Chairman. And I don't think I will take 5 minutes because I think we have a vote on the floor, and a lot of the questions have been asked.

But there are a lot of swirling issues here. I am co-chair of the Asthma and Allergy Caucus and I have worked with the asthma and allergy advocacy community for many years, and I have been surprised by their strong opposition to allowing Primatene Mist to continue to be sold. I signed a letter in January asking Commissioner Hamburg to allow the remaining units of Primatene Mist to be sold past the December 31, 2011, deadline.

I mean I think there have been good points on both sides, but I really want to ask Mr. Shandell. What is in it for you? Tell me what is in it for you. You are not going to make a profit on it because you are going to donate everything to charity. You mentioned your company offered to distribute all the remaining units as a donation to public health clinics and the offer was rejected. So if you are not going to make a profit, why are you fighting so hard to get another exception——

Mr. SHANDELL. Yes.

Mr. ENGEL [continuing]. From FDA and EPA?

Mr. SHANDELL. It is a good question because it is rare to see corporations not doing something for profit, but we are a private company in California. We are founded in science and this is a discontinued product. It is not in our sales forecast and we could walk away. However, we have received thousands of complaints from our customers who just don't understand why they cannot access this. So we really are advocating on behalf of our customers.

Mr. ENGEL. I think I am going to leave it there, Mr. Chairman. I do have a bunch of questions but I am concerned about, you know, the vote. I mean the bottom line is is epinephrine safe? That is also a question. What do you say to people like Dr. Kraft who say it is not?

Mr. SHANDELL. Well, see I would love to answer that because as a company, we receive all of the adverse events, and if something is significant, we are required to report it to FDA within 15 days. So I have talked to the departments that receive these adverse events and people talk about heart problems. We have never had any adverse event related to heart. All we have is glass sometimes breaks.

Mr. ENGEL. Let me ask Dr. Kraft because she said before in her testimony that she feels it is not safe.

Ms. KRAFT. Right. I would argue that the mechanism to get the reports depending on when the patient has taken the medication and what their status is may or may not actually be filed. And so I worry that there is some underreporting.

Mr. SHANDELL. After 50 years, nothing?

Ms. KRAFT. Also, I would like to make another statement. The company has done two trials to look at the HFA preparation, which is good. But I was interested that they didn't have a comparison armed with albuterol. They had a placebo armed with—do the patients use albuterol in the placebo arm presumably? Because I thought that would be a perfect situation to compare albuterol HFA with Primatene.

Mr. SHANDELL. Thank you. Actually, we have submitted data to the FDA, and as I indicated, we will be submitting the new drug application in the fourth quarter, and we actually have evidence that show that albuterol actually causes more adverse events than our product.

Ms. KRAFT. And the question is is these are mild patients. I can tell from clinicaltrials.gov——

Mr. SHANDELL. Correct.

Ms. KRAFT [continuing]. They are mild patients?

Mr. SHANDELL. Correct.

Ms. KRAFT. So that was one of the concerns I wanted to bring up. I think in mild asthma a lot of things may work but what I worry about with having this drug available and looking at my more severe patients, they are often the ones who will go and get this medication in lieu of——

Mr. SHANDELL. But it has been available for 50——

Ms. KRAFT [continuing]. Medical care.

Mr. SHANDELL [continuing]. Years, and, you know, to this day people get good medical care but there are people that don't. There are people who can't afford it.

Mr. ENGEL. Mr. Ward, let me ask you quickly. If Primatene Mist is on the market for 13 months and then it is not, what is the harm? Is there going to be people who are going to die in 13 months if they——

Ms. KRAFT. Well, I think it is sort of an ethical issue. I am not against over-the-counter medication for asthma, nor is my society. I would like to have a safe and effective one out there for patients. And so I would actually think that this work being done at the FDA to put medications out there over the counter such as albuterol, it should continue.

Mr. SHANDELL. But the work at FDA, they are working with us on Primatene for 5 years now.

Ms. KRAFT. But it is not approved yet.

Mr. SHANDELL. It is not approved yet but we have great phase three trial data.

Mr. ENGEL. I would love to stay longer but we are going to miss a vote, Mr. Chairman. So thank you and——

Mr. WHITFIELD. Well, thank you. And that would conclude today's——

Mr. RUSH. Mr. Chairman, I just want to reiterate and restate my call that rather than us moving so quickly to markup, especially in light of this discussion, that we take time to invite the FDA and

the EPA here so that we can get to the bottom of some of these outstanding questions that we have and get some real answers to these questions. And I want to reiterate my request.

Mr. WHITFIELD. And Mr. Rush has asked unanimous consent to enter into the record various testimonies from the International Pharmaceutical Aerosol Consortium, various health groups, Alliance for Responsible Atmospheric Policy, and a letter from Teva Pharmaceuticals. And then we also have letters from the National Association of Chain Drugstores, the National Community Pharmacists Association, EPA, et cetera. So without objection, they will be entered.

[The information appears at the conclusion of the hearing.]

Mr. WHITFIELD. I want to thank all of you for being with us today. We appreciate your testimony very much and your concern about this important issue.

And with that, this hearing is adjourned.

[Whereupon, at 1:45 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

[DISCUSSION DRAFT]

112TH CONGRESS
2D SESSION

H. R. _____

To ensure the viability and competitiveness of the United States agricultural sector.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To ensure the viability and competitiveness of the United States agricultural sector.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "U.S. Agricultural Sector Relief Act of 2012".

SEC. 2. ENSURING THE AVAILABILITY OF METHYL BROMIDE FOR CRITICAL USES.

(a) CRITICAL USE EXEMPTIONS AND EMERGENCY EVENTS.—Subsection (h) of section 604 of the Clean Air Act (42 U.S.C. 7671c(h)) is amended—

(1) by striking "Notwithstanding" and inserting the following:

"(1) IN GENERAL.—Notwithstanding"; and

(2) by adding at the end the following new paragraphs:

"(2) CRITICAL USE EXEMPTIONS AND EMERGENCY EVENTS.—

"(A) CRITICAL USE EXEMPTIONS.—

"(i) IN GENERAL.—For each calendar year, beginning with 2013, the Administrator, pursuant to an application submitted by any person, shall take all appropriate actions within the authority of the Environmental Protection Agency to seek a critical use exemption under the Montreal Protocol in order to allow the production, importation, and consumption of methyl bromide—

"(I) for any use of methyl bromide that—

"(aa) is an approved critical use; and

"(bb) is determined by the Administrator to be a critical use for the applicant; and

"(II) in the amount necessary for the use described in subclause (I).

"(ii) APPLICATIONS.—The Administrator shall not deny any application referred to in clause (i), or reduce the amount requested under any such application, unless the Administrator—

"(I) has substantial evidence to establish that there is a technically and economically feasible alternative available to the applicant for the use of methyl bromide for which the application was submitted; and

"(II) provides such evidence to the applicant in writing.

"(iii) ALTERNATIVES.—The Administrator, when evaluating the technical and economic feasibility of any alternative pursuant to clause (ii), shall consider—

"(I) cost and commercial availability of the alternative to the applicant;

"(II) demonstrated effectiveness of the alternative for the applicant's specific intended use;

"(III) demonstrated effectiveness of the alternative in the geographic region of the applicant's intended use; and

"(IV) State or local regulations that may restrict use of the alternative for the applicant's intended use.

"(B) EMERGENCY EVENTS.—

"(i) IN GENERAL.—For each calendar year, beginning with 2013, the Administrator, pursuant to an application submitted by any person, shall allow the production, importation, and consumption in the United States of methyl bromide—

"(I) for any use described in subparagraph (A)(i)(I) in response to an emergency event; and

"(II) in an amount necessary for such use.

"(ii) LIMITS ON USE PER EMERGENCY EVENT.—The amount of methyl bromide allowed pursuant to clause (i) for use per emergency event at a specific location shall not exceed 20 metric tons.

"(iii) LIMIT ON AGGREGATE AMOUNT.—The aggregate amount of methyl bromide allowed pursuant to clause (i) for use in the United States in a calendar year shall not exceed the total amount authorized by the parties to the Montreal Protocol pursuant to the Montreal Protocol process for critical uses in the United States in calendar year 2011.

"(C) INTERNATIONAL OBLIGATIONS.—The Administrator shall take such actions as may be necessary to carry out this paragraph in accordance with the Montreal Protocol.

"(D) DEFINITIONS.—In this paragraph:

"(i) The term 'approved critical use' means a use that was an approved critical use in appendix L to subpart A of part 82

of title 40, Code of Federal Regulations, as in effect on January 1, 2005.

"(ii) The term 'critical use' means a circumstance in which—

"(I) there are no technically and economically feasible alternatives or substitutes for methyl bromide available that are acceptable from the standpoint of environment and health and are suitable to the crops and circumstances involved; and

"(II) the lack of availability of methyl bromide for a particular use would result in significant market disruption.

"(iii) The term 'emergency event' means a situation—

"(I) that occurs at a farm, nursery, food processing facility, or commodities storage facility;

"(II) for which there is no critical use exemption in effect for such site, or for which there are not sufficient quantities of methyl bromide available under an existing critical use

exemption for such site, as described in subparagraph (A); and

"(III) that requires the use of methyl bromide to control a pest or disease because there is no technically and economically feasible alternative to methyl bromide available for such use.".

(b) REGULATIONS.—Not later that 180 days after the date of enactment of this Act, the Administrator of the Environmental Protection Agency, acting through the Director of the Office of Pesticide Programs, and in consultation with the Secretary of Agriculture, shall—

(1) issue such final regulations as may be necessary to implement the amendment made by subsection (a); and

(2) include in such regulations—

(A) criteria for identifying an emergency event, as defined in section 604(h)(2)(D)(iii) of the Clean Air Act, as added by such amendment; and

(B) provisions to ensure that each application for use of methyl bromide in response to an emergency event under section 604(h)(2)(B) of the Clean Air Act, as added by such amend-

ment, is approved or disapproved in a timely manner.

[DISCUSSION DRAFT]

112TH CONGRESS
2D SESSION

H. R. _____

To direct the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To direct the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Asthma Inhalers Relief Act of 2012".

SEC. 2. DISTRIBUTION, SALE, AND CONSUMPTION OF REMAINING INVENTORIES OF OVER-THE-COUNTER CFC EPINEPHRINE INHALERS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency—

(1) shall allow for the distribution, sale, and consumption in the United States of remaining inventories of CFC epinephrine inhalers manufactured pursuant to the exception for medical devices under section 604(d)(2) of the Clean Air Act (42 U.S.C. 7671c(d)(2));

(2) shall not take any enforcement action or otherwise seek to restrict the distribution, sale, or consumption of such inhalers on the basis of any Federal law implementing the Montreal Protocol; and

(3) shall, in response to any request of any distributor or seller of such inhalers, including any such request pending on the date of the enactment of this Act, issue a No Action Assurance Letter to the requesting party stating that the Environmental Protection Agency will not initiate an enforcement action relating to the distribution or sale of any such inhaler occurring prior to August 1, 2013.

(b) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to limit or otherwise affect the authority

of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to ensure the safety and effectiveness of CFC epinephrine inhalers to be distributed, sold, or consumed pursuant to this Act.

(c) DEFINITIONS.—In this Act:

(1) The term "CFC epinephrine inhaler" means any epinephrine inhaler containing chlorofluorocarbons that was manufactured and classified as over-the-counter before January 1, 2012.

(2) The phrase "Federal law implementing the Montreal Protocol"—

(A) means any provision of title VI of the Clean Air Act (42 U.S.C. 7671 et seq.) or other Federal law implementing the Montreal Protocol; and

(B) includes the final rule published by the Food and Drug Administration entitled "Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine)" published in the Federal Register at 73 Federal Register 69532 (November 19, 2008).

(3) The term "Montreal Protocol" has the meaning given such term in section 601 of the Clean Air Act (42 U.S.C. 7671).

(4) The term "over-the-counter" means not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) or otherwise required pursuant to Federal law to be dispensed only upon issuance of a prescription.

(d) SUNSET.—This section ceases to be effective August 1, 2013.

October 28, 2011

Honorable Pat Roberts
109 Hart Senate Office Building
Washington, DC 20510-1605
RE: S. 1752 Freedom to Breathe Act of 2011

Honorable Jim DeMint
167 Russell Senate Office Building
Washington, DC 20510
RE: Amendment OTC Epinephrine inhalers

Dear Senator Roberts and Senator DeMint:

Thank you for your interest and concern for patients living with asthma.

Allergy & Asthma Network Mothers of Asthmatics, Alpha-1 Foundation/COPD Foundation, American Association of Respiratory Care, American Latex Allergy Association and Asthma Allies do not support the Freedom to Breathe Act of 2011 or the amendment as both would continue access to an Over The Counter (OTC) bronchodilator, Primatene Mist, developed over 50 years ago that is no longer recommended for use by patients with asthma. Twenty years ago, National Guidelines for the Diagnosis and Management of Asthma were developed by the National Institutes of Health and since then have been updated three times as a result of new evidence-based science about the disease of asthma. Neither NIH guidelines nor the Global Initiative for Asthma (GINA) recommend epinephrine inhalers for the treatment of asthma.

On December 31, 2011, after nearly 20 years' warning, epinephrine inhalers (Primatene Mist and its generic copies made by Armstrong Pharmaceuticals) will no longer be sold in the United States because they contain CFCs and do not meet the criteria for an essential use exemption from US and international treaties signed by Congress to eliminate ozone-depleting CFC propellants.

Of the 20 different brands and types of prescription-only inhalers currently sold in the US, 19 are now CFC-free. Pharmaceutical manufacturers were required to comply with laws and change their products or have them removed them from the market. More than

24 million asthma and COPD patients and their medical care providers were required by law to change treatment plans, pay for additional office visits, and pay higher co-pays and out of pocket costs for newly approved medications.

Badrul Chowdhury MD, director of FDA's Division of Pulmonary, Allergy and Rheumatology Products stated, "There is no technical barrier preventing a non-CFC version of inhaled epinephrine." The manufacturer failed to develop a non-CFC alternative even though they were granted a three-year extension beyond the 2008 deadline other manufacturers met for their bronchodilators, albuterol and levalbuterol.

Inhaled epinephrine, the only nonprescription drug inhaler available, is **not** recommended for the treatment of asthma. It is one of the grandfathered vestiges predating FDA, but it is still subject to the same laws, regulations and treaty that banned every available prescription CFC-containing inhaler for asthma and COPD.

It is stated in your press release that millions of patients will be affected if OTC epinephrine goes away; however, no one really knows if that is true. Armstrong, at several FDA meetings, reported they didn't know how many actual patients use their canisters or how many canisters each patient buys, much less the age, income, or regional locations of epinephrine inhaler users.

Armstrong's customers, as they refer to them, are the wholesalers and retailers — not patients. The numbers of 1.7 to 2.3 million stated in the press release are numbers the manufacturer provided FDA at a meeting. Nobody really knows how many people use this product and the company can only make a guess based on numbers of canisters sold divided by how many canisters they "think" each patient buys.

Two inhalations of epinephrine provide breathing relief and serious side effects for approximately 15-30 minutes, whereas two inhalations of prescription bronchodilators, which is the recommended medication by NIH, last 3-6 hours with less unwanted cardiac stimulation. Primatene Mist is not a cheaper alternative.

Assertions that Medicaid families and thus states will be hard hit should OTC epinephrine evaporate are highly suspect. Inhaled epinephrine is not the drug of choice or last resort for Medicaid patients. Medicaid patients have prescription coverage and access to medical care. Prescription bronchodilators and inhaled corticosteroids recommended by NIH for asthma are covered under Medicaid.

The real problem Medicaid families face is that pharmacies do not always dispense the medication or inhalation devices their doctors prescribe. Patients also tell us that they don't always receive referrals to allergists and pulmonologists, as recommended in NIH guidelines. We would love your help to ensure that NIH Asthma Guidelines-based, cost-effective and patient-centered care is available to every patient — while saving state and federal government funds currently wasted on chronically urgent care, as shown at AANMA's congressional briefing (http://www.aanma.org/advocacy/congressional-asthma-and-allergy-caucus/) earlier this month.

Fifty years ago, epinephrine inhalers were all we had to treat asthma. But like most older medications, it has been replaced with far safer and more effective medications

that treat both the noisy obvious symptom of asthma, bronchospasm, as well as the underlying, smoldering silent cause of symptoms, airway inflammation. Knowledge of the disease of asthma has drastically changed the way it is treated, and 1950s treatments are no longer considered safe.

Today's treatment plans also are not based solely on one or more inhaled or oral medications. They require identifying the cause(s) of symptoms, removing environmental or occupational exposures, repairing airway inflammation using anti-inflammatories and restoring the patient to full and healthy function.

Asthma is not a disease for do-it-yourselfers. Asthma is a serious, potentially life-threatening disease that kills 11 people every day and it deserves serious attention.

Rather than defend a manufacturer's right to continue making an outdated, inferior CFC-propelled drug no longer recommended for the treatment of asthma, AANMA urges Congress to issue vouchers through physicians, clinics and hospitals to offset patient expenses associated with purchasing NIH guideline-recommended medications for asthma.

The Freedom to Breathe Act of 2011 does nothing to address and solve the problem of patients' access to NIH guideline-level care, but rather grants special favors to a manufacturer — the only one who will benefit from the Freedom to Breathe Act of 2011.

AANMA is prepared to help in any way to ensure patients with asthma receive NIH guideline-level care and appropriate medical treatment.

Thank you for your time and attention to our concerns. We look forward to discussing this most important issue with you. Please feel free to contact AANMA at 703-641-9595 or Sandra Fusco-Walker, AANMA's Director of Patient Advocacy, at 703-641-9595 x1524.

Sincerely,

Nancy Sander

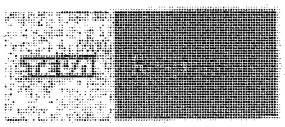
Nancy Sander, President and Founder
Allergy & Asthma Network Mothers of Asthmatics

John W. Walsh, President and CEO
Alpha-1 Foundation
COPD Foundation

Karen J. Stewart, President
American Association of Respiratory Care

Sue Lockwood, Executive Director and Co-Founder
American Latex Allergy Association

Gerri Dawnielle Rivers, Co-Founder
Asthma Allies



November 28, 2011

The Honorable Lisa Jackson
Administrator
Environmental Protection Agency
Ariel Rios Federal Building
1200 Pennsylvania Avenue, NW
Room 3000
Washington, DC 20460

Dear Administrator Jackson:

I am writing on behalf of Teva Respiratory, a brand division of Teva Pharmaceuticals, to provide a profile of Primatene Mist CFC users. As you know, concerns have been raised about the impact on patients of the regulation that would prohibit the selling of over-the-counter epinephrine inhalers, primarily Primatene Mist, after December 31, 2011. Regretfully, there seems to be a lot of misperceptions and faulty assumptions about who the Primatene Mist CFC customer is and his/her access to appropriate medication alternatives.

In order to prepare for the transition, Teva Respiratory conducted a market research survey to better understand how to best educate patients and health care providers of the transition from Primatene Mist CFC to albuterol HFA. While this information is proprietary, I did want to share some of the top line findings in order to provide a better understanding of the current Primatene Mist user.

We surveyed consumers between the ages of 20 and 75 who have purchased and used Primatene Mist CFC within the past two years. The findings included:

- Primatene Mist CFC users are well educated, well above the general population
  - 28% had graduated college compared to 19% of the U.S. population
  - 21% had done post graduate work compared to 10% of the U.S. population;
- The median number of Primatene Mist CFC inhalers used in the past 18 months is 2;
- 84% of Primatene Mist CFC users are insured;
- 80% of Primatene Mist CFC users have prescription drug coverage;
- 83% of Primatene Mist CFC users have a personal physician and 72% have seen their physician in the past year;

425 Privet Road, Horsham, PA 19044 Phone: 215.591.3000 Fax: 215.293.6538 www.tevapharm-na.com

- Tier 2 copays for insured patients average $20-$25 (similar to retail costs of Primatene Mist CFC inhalers)
  - For the 16% of those not insured, low income patients (200% or less of the Federal Poverty Level) would qualify for The Teva Assistance Program for free albuterol HFA inhalers;

- 88% of Primatene Mist CFC users have a respiratory diagnosis and nearly 40% are already taking a prescription inhaler;

- Only 11% of Primatene Mist CFC users cited cost as a factor when citing reasons for using the product over a prescription inhaler.

The data clearly suggests that the majority of Primatene Mist CFC users are already in the health care system have access to a physician and visit their physician on a regular basis.

Many of the concerns raised about this transition are similar to those raised during the 2008 "CFC to HFA" albuterol switch. Due to the hard work and efforts of all the stakeholders – the federal government, patient groups, medical societies, pharmacies and drug manufacturers – it was extremely successful with virtually no disruption in access or harm to patients. Teva Respiratory, and indeed all of our competitors, initiated numerous programs to educate patients and health care providers. Although the scale was much greater for the 2008 transition – 50 million albuterol units compared to 2-3 million Primatene Mist CFC units – the effort has been similar. Significant resources were invested to drive awareness of the albuterol CFC-HFA transition, just as they have been in this switch, with the goal of ensuring that all were prepared. Patients and health care providers were ready for the transition in 2008 and they are ready for the switch this year.

I hope you find this information helpful. Please do not hesitate to contact me should you have additional questions.

Sincerely,

Mark Salyer

Mark Salyer
Executive Vice President and General Manager

cc: Margaret Hamburg, MD
Commissioner
Food and Drug Administration

Cynthia Giles
Assistant Administrator, Office of Enforcement and Compliance Assurance
Environmental Protection Agency

Regina McCarthy
Assistant Administrator, Office of Air and Radiation
Environmental Protection Agency

425 Privet Road, Horsham, PA 19044 Phone: 215.591.3000 Fax: 215.293.6538 www.tevapharm-na.com

The Alliance
for Responsible Atmospheric Policy
30 1980-2010

December 12, 2011

Commissioner Margaret A. Hamburg
U.S. Food and Drug Administration
Office of the Commissioner
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

On behalf of the Alliance for Responsible Atmospheric Policy (Alliance), an industry coalition addressing issues related to fluorocarbons, I am writing in support of the attached letter from the International Pharmaceutical Aerosol Consortium (IPAC) expressing strong support for the FDA's Final Rule establishing 31 December 2011 as the deadline for transition of CFC-based epinephrine metered-dose inhalers (MDIs). A list of Alliance members is attached.

The Alliance was organized in 1980 to address the issue of stratospheric ozone depletion. It is presently composed of fluorocarbon producers and manufacturers and businesses that rely on compounds such as HCFCs and HFCs. Today, the Alliance is a leading industry voice that coordinates industry participation in the development of reasonable international and U.S. government policies regarding ozone protection and climate change.

The Alliance has become an effective voice in influencing policy on the ozone protection issue and has succeeded in ensuring an appropriate global approach to the issue through the Montreal Protocol while minimizing costly and ineffective regulations on industries. The Alliance's role of bringing diverse industries together to form a consensus on policy development proved successful. As a result the Alliance provided a credible voice in encouraging a responsible phaseout of CFCs and other ozone-depleting compounds.

Overall, the Alliance has advocated the benefits of alternatives to CFCs, educated policymakers as to the feasibility of laws and regulations, and assisted in removing barriers to the use of many alternatives. We urge the responsible phaseout of CFCs in MDIs, and support the efforts of FDA and EPA in this transition. We look forward to the continuation of a productive working relationship with FDA and EPA on these issues.

Regards,

Dave Stirpe
Executive Director

cc: Badrul Chowdhury, Office of New Drugs, CDER
Lisa P. Jackson, EPA Administrator
Gina A. McCarthy, Assistant Administrator for Office of Air and Radiation, US EPA
Sarah Dunham, Director of the Office of Atmospheric Programs
Drusilla Hufford, Director, Stratospheric Protection Division, US EPA
Dan Reifsnyder, Deputy Assistant Secretary for Environment and Sustainable Development, US Department of State
John Thompson, Foreign Affairs Officer, Office of Environmental Policy, US Department of State

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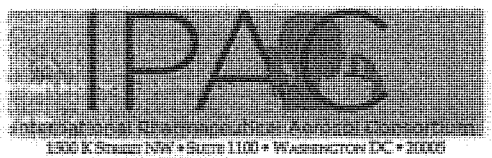
Phone: 703-243-0344 • Fax: 703-243-2874 • E-mail: alliance98@aol.com

MEMBERSHIP LIST

Alliance for Responsible Atmospheric Policy

AGC Chemicals Americas
Air Conditioning, Heating & Refrigeration Institute
Airgas
American Pacific Corp.
Arkema
Bard Manufacturing Co.
BASF
Brooks Automation, Inc.
Cap & Seal Company
Carrier Corporation
Center for the Polyurethanes Industry
Coolgas
Danfoss
DuPont
Dynatemp International
Emerson Climate Technologies
E.V. Dunbar Co.
Falcon Safety Products
FP International
Golden Refrigerant
Halotron
Heating, Airconditioning & Refrigeration Distributors International
Honeywell
Hudson Technologies
ICOR International
IDQ Holdings
Ingersoll-Rand
International Pharmaceutical Aerosol Consortium
Johnson Controls
Lennox International
McQuay International
Metl-Span Corporation
Mexichem Fluor Inc.
Midwest Refrigerants
National Refrigerants
Owens Corning Specialty & Foam Products Center
Polar Technology
RemTec International
Rheem Manufacturing Company
Ritchie Engineering
Solvay
Trane Company
Worthington Cylinder



1300 K Street NW • Suite 1100 • Washington DC • 20005
Telephone +1 202 230 5130 • Facsimile +1 202 842 8465
Internet: http://www.ipacmfg.com

November 4, 2011

Via Email

Commissioner Margaret A. Hamburg
U.S. Food and Drug Administration
Office of the Commissioner
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

This letter is submitted on behalf of the International Pharmaceutical Aerosol Consortium (IPAC) to express strong support for FDA's Final Rule establishing 31 December 2011 as the deadline for the transition of CFC-based epinephrine metered-dose inhalers (MDIs) (*brand name: Primatene Mist*). IPAC is an association of companies that manufacture medicines for the treatment of respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD). IPAC was formed more than two decades ago in response to the mandates of the *Montreal Protocol on Substances that Deplete the Ozone Layer*. IPAC is firmly committed to the transition from CFC MDIs to CFC-free alternatives, pursuant to the Montreal Protocol, and has actively engaged in the transition process in the United States. IPAC's member companies have invested substantial resources to develop CFC-free alternatives in order to accomplish the phase-out of CFC-based MDIs in furtherance of the United States' international commitments under the Protocol.

IPAC is extremely concerned about recent efforts within the US Congress to delay or suspend the phase out of epinephrine CFC MDIs and believes that such proposals would have negative implications for patient health. IPAC is encouraged that the amendment proposed by Senator DeMint and considered last week by the Senate was defeated, but wishes to share some perspectives on this issue in case similar delays are introduced.

IPAC notes that FDA undertook a careful, deliberative, and thoughtful open public rulemaking process that included input from patient and physician stakeholders and other key experts to establish the transition deadline for Primatene Mist. This deadline has provided three full years to transition patients to one of the several CFC-free alternatives available. Since the Final Rule was issued in 2008, FDA has worked hard – in collaboration with patients, physicians, and other interested stakeholders – to prepare for a smooth transition for Primatene Mist users. In

addition, available patient assistance programs (and product samples) will help many users of Primatene Mist successfully transition to safe and effective CFC-free alternatives.

Even if Congress were to override FDA's well-considered deadline on Primatene Mist, it would only briefly forestall the inevitable. Due to a global ban on CFC production, safe and adequate supplies of pharmaceutical-grade CFCs do not exist for the continued manufacture of Primatene Mist. It is therefore important for users to transition now pursuant to the deadline established by FDA. Even a small shift of the end 2011 deadline (e.g. 3 to 6 months) could be quite counterproductive for the following reasons: (i) it would introduce confusion and uncertainty for, most importantly, patients, and also for the supply chain; and (ii) it could hamper EPA efforts to enforce the transition when it actually occurs.

In the past, EPA and FDA have firmly denied MDI companies' requests for any extension to transition deadlines (e.g., to use up existing already-produced stockpiles of CRC MDIs), and there is no reason that there should be a different result in the case of Primatene Mist. FDA has made a significant effort to raise awareness of the 31 December 2011 deadline and changing that now would send very mixed signals to patients, consumers, health care providers and other stakeholders.

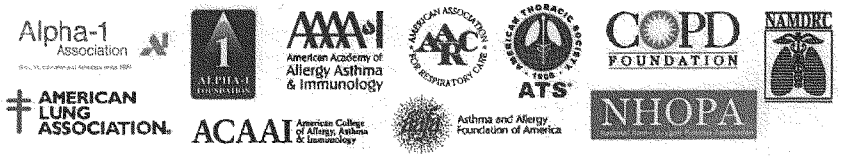
The phase-out of Primatene Mist and other ozone-depleting MDIs was initiated more than two decades ago. The "essential use" process established under the Montreal Protocol has provided the MDI industry ample time to reformulate and seek approvals of CFC-free alternatives. After long ago "seeing the writing on the wall", MDI manufacturers worked diligently to research and develop CFC-free products. Most companies (including all IPAC members) have invested hundreds of millions of dollars to accomplish this important objective. Introducing even a brief delay at this late stage would send a very negative signal to the manufacturers that responded to the US Government's call to be a partner in meeting the Montreal Protocol commitments.

For the sake of the environment, compliant manufacturers and, most importantly for the patients, FDA must not waiver in their commitment on this matter merely for the economic interests of a few.

Sincerely,

Maureen Donahue Hardwick
IPAC Secretariat and Legal Counsel

cc: Badrul Chowdhury, *Office of New Drugs, CDER*
Lisa P. Jackson, *EPA Administrator*
Gina A. McCarthy, *Assistant Administrator for Office of Air and Radiation, US EPA*
Sarah Dunham, *Director of the Office of Atmospheric Programs*
Drusilla Hufford, *Director, Stratospheric Protection Division, US EPA*
Dan Reifsnyder, *Deputy Assistant Secretary for Environment and Sustainable Development, US Department of State*
John Thompson, *Foreign Affairs Officer, Office of Environmental Policy, US Department of State*



July 17, 2012

The Honorable Ed Whitfield
Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
Washington, DC 20515

The Honorable Bobby Rush
Ranking Member
Subcommittee on Energy and Power
Committee on Energy and Commerce
Washington, DC 20515

Dear Chairman Whitfield and Ranking Member Rush:

On behalf of the undersigned medical and public health organizations, we are writing to express our strong opposition to allowing CFC-propelled over¬ the-counter epinephrine (Primatene Mist CFC) to return to the U.S. market. Our organizations strongly believe that allowing this product to return to the marketplace is not in the best interests of patients with asthma or the public health.

Over 25 million Americans – including 7 million children – have asthma. Asthma is the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences from chronic disease – accounting for over 10.5 million lost school days in 2008. Asthma costs our healthcare system over $50.1 billion annually and indirect costs from lost productivity add another $5.9 billion, for a total of $56 billion dollars annually. Asthma claims the lives of more than 3,300 Americans each year, or approximately nine people per day.

Fortunately, based in part on guidelines and recommendations from several expert panels, there are effective treatment protocols that include the use of medication that people living with asthma can use to successfully manage their disease. None of the expert guidelines recommend the use of over-the-counter medications--like Primatene Mist--to treat asthma. The National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, has issued treatment guidelines for management of asthma. NAEPP recommends against the use of epinephrine for treating asthma exacerbations recognizing that it has the potential for "excessive cardiac stimulation."

Our organizations strongly encourage any patient who uses over the counter medications – like Primatene Mist CFC – to treat his/her asthma to seek a healthcare provider who can help the patient develop an asthma management plan and recommend more effective and safer medications to manage the asthma – including products that help prevent asthma episodes.

All pharmaceutical manufacturers have been on notice since 1990 that products containing CFCs would be phased out. Armstrong Pharmaceuticals, the manufacturer of Primatene Mist CFC, has known since 2008 that their product – like others made with CFCs – would also be phased out.

Armstrong Pharmaceuticals already received a one year extension of the transition date from the U.S. Environmental Protection Agency to allow its product to be sold until December 31, 2011.

While other companies and products have successfully transitioned their products, providing for safe and effective medications for people with asthma, the maker of Primatene Mist CFC instead has repeatedly sought to be exempted. Congress should not make an exception for one product – especially one that is not recommended for the treatment of asthma. Moreover, reintroducing this product into the marketplace would only further confuse patients and undermine efforts to transition patients to guidelines-based care for managing their disease.

Our organizations strongly believe Armstrong has had sufficient time to prepare for a final transition date of December 31, 2011. In 2008, the decision was made the CFC propelled inhaled epinephrine should be phased out and our organizations have been working with providers and patients to ensure a smooth and orderly transition process. Congress should not create an exemption for Primatene Mist CFC, but instead work to ensure that all people with asthma are receiving guidelines-based treatment for their disease.

Sincerely,

Alpha-1 Association
Alpha-1 Foundation
American Academy of Allergy Asthma and Immunology
American Association for Respiratory Care
American College of Allergy Asthma and Immunology
American Lung Association
American Thoracic Society
Asthma and Allergy Foundation of America
COPD Foundation
National Association for the Medical Direction of Respiratory Care
National Home Oxygen Patients Association

Cc: The Honorable Fred Upton, Chairman, Energy and Commerce Committee
The Honorable Henry Waxman, Ranking Member, Energy and Commerce Committee

Written Testimony Submitted for the Record (July 18, 2012) to the House Energy and Power Subcommittee Regarding the "Asthma Inhalers Relief Act of 2012"

On behalf of the International Pharmaceutical Aerosol Consortium
Maureen Hardwick, Secretariat
1500 K Street, NW, Suite 1100, Washington, DC 20005
Maureen.Hardwick@dbr.com | 202-230-5133

The International Pharmaceutical Aerosol Consortium (IPAC)–an association of companies that manufacture medicines for the treatment of respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD)–appreciates the opportunity to submit written testimony to the House Energy and Power Subcommittee.

IPAC's members are: AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, GlaxoSmithKline, Sunovion and Teva. For more than 20 years, IPAC has been firmly committed to the transition from Chlorofluorocarbon (CFC) metered-dose inhalers (MDIs) to CFC-free alternatives, pursuant to the mandates of the Montreal Protocol, and actively engaged in the transition process in the United States. IPAC's member companies invested substantial resources to develop CFC-free alternatives in order to accomplish the phase-out of CFC-based MDIs. The United States has achieved significant progress during the last five years toward successfully completing the CFC MDI transition.

IPAC strongly opposes recent efforts within the US Congress to lift the December 31, 2011 ban on the sale of CFC-based epinephrine (*brand name: Primatene Mist*) metered dose inhalers (MDIs) and the proposed legislation, the "Asthma Inhalers Relief Act of 2012." Such a drastic reversal in settled law would be (i) unnecessary to protect the health of asthma patients and (ii) contrary to the United States' important and longstanding commitment to international treaties.

We wish to share the following perspectives on this important issue:

- The phase-out of *Primatene Mist* and other ozone-depleting MDIs was initiated more than two decades ago in response to the mandates of the Montreal Protocol which was signed by President Ronald Reagan in 1987. The "essential use" process under the Montreal Protocol and Clean Air Act provided the MDI industry ample time to reformulate and seek approvals of CFC-free alternatives. MDI manufacturers long ago began working diligently to research and develop CFC-free products in order to meet Montreal Protocol requirements. Most companies (including all IPAC members) invested hundreds of millions of dollars to accomplish this important objective. The

attached timeline summarizes the extensive history of the essential use process and the careful, deliberative steps undertaken to promote a smooth and seamless transition to CFC-free alternatives.

- The December 31, 2011 phase-out date for CFC-based *Primatene Mist* was established by FDA in 2008 (under the prior Administration), and was based upon an extensive administrative record that included input from key stakeholders, including patient and physician groups. This deadline provided three full years to transition patients to one of the several CFC-free alternatives available. It is noteworthy that the manufacturer of Primatene Mist specifically sought the December 31, 2011 deadline after an earlier deadline was initially proposed by FDA.

- There is no evidence that patient health will benefit from briefly re-introducing Primatene Mist onto the market, now more than six months after the ban became effective. Rather, the clear consensus of the major physician and patient groups is that such an action would be extremely confusing and disruptive for patients and would not contribute to improved health outcomes. Tens of millions of asthma and COPD patients in the US have successfully transitioned to CFC-free MDIs over the past 15 years.

- It has been suggested that re-introducing *Primatene Mist* would be cost-effective for patients. A group of respected patient advocates directly disputes this assertion and they note that "two inhalations of epinephrine provide breathing relief ... for 15-30 minutes, whereas two inhalations of prescription bronchodilators, which is the recommended medication by NIH, last 3-6 hours with less unwanted cardiac stimulation. Primatene Mist is not a cheaper alternative." (*Allergy & Asthma Network Mothers of Asthmatics, et al, letter to Senators Pat Roberts and Jim DeMint October 28, 2011).* In addition, patient assistance programs (and product samples) continue to be available to assist many users of *Primatene Mist* to successfully transition to safe and effective CFC-free alternatives.

- The only possible beneficiary of a reversal of the ban on Primatene Mist would be its manufacturer, which stands to garner a financial windfall if its limited stocks are sold. And, any patient buying these MDIs will be forced to switch therapy a second time once the stocks are depleted (which is likely to be within a matter of months).

- Granting extraordinary, unwarranted and special treatment to a single company would send an extremely negative signal to the manufacturers that responded to the US Government's call many years ago to be a partner in meeting the Montreal Protocol commitments. Similar, prior requests for deadline relief (including requests to sell small stockpiles of CFC MDIs) have been firmly denied by the relevant regulatory authorities.

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM
1500 K STREET, NW • SUITE 1100 • WASHINGTON, DC 20005-1209
TEL: +1.202.230.5133 • EMAIL: MAUREEN.HARDWICK@DBR.COM

IPAC
International Pharmaceutical Aerosol Consortium

- Finally, significant practical questions exist as to whether the stockpiled Primatene Mist is nearing the end of its shelf life (assumed to be 18-24 months based on public data) and would, therefore, expire very soon after being sold to patients. According to a recent Congressional letter to FDA, Armstrong ceased producing Primatene Mist in August 2011 - almost a full year ago. Any remaining units sitting in a warehouse somewhere are likely rapidly nearing the end of their useful life.

IPAC respectfully urges the Congress to ensure that the phase-out of CFC-based MDIs remains in effect so that patients and consumers are not subjected to unnecessary risks or uncertainty. We appreciate the opportunity to share our views in our testimony, and please be assured that IPAC stands ready to serve as a resource on this issue.

INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM
1500 K STREET, NW ▪ SUITE 1100 ▪ WASHINGTON, DC 20005-1209
TEL: +1.202.230.5133 ▪ EMAIL: MAUREEN.HARDWICK@DBR.COM

Key Milestones

Phase-Out of CFC-Based Epinephrine Metered-Dose Inhalers (MDIs)

• 1987	President Reagan signs the Montreal Protocol and transmits it to the United States Senate for ratification
• March 14, 1988	US Senate unanimously ratifies Montreal Protocol
• January 1, 1990	Montreal Protocol enters into force
• 1990/1991	Several MDI manufacturers commence joint toxicological testing programs of alternative medical propellants
• January 1, 1996	Ban on CFC production and imports takes effect (but allows for proven "essential uses" under an annual process)
• August 16, 1996	First CFC-free MDI approved in the US (Proventil HFA)
• January 24, 2006	Joint Meeting of FDA's Nonprescription Drug Advisory Committee (NPAC) and Pulmonary-Allergy Drugs Advisory Committee (PADAC) on essential-use status of OTC MDIs containing epinephrine
• September 20, 2007	FDA issues Proposed Rule on removal of "essential use" designation for epinephrine (with an effective date of December 31, 2010)
	○ November 21, 2007 Armstrong Pharmaceuticals, Inc. submits comments requesting FDA to extend effective date to December 31, 2011 (from December 31, 2010)
• December 5, 2007	FDA holds public meeting on removal of essential use designation for epinephrine
• November 18, 2008	FDA issues Final Rule on removal of "essential use" designation for epinephrine with extended effective date of December 31, 2011
• December 31, 2008	FDA deadline for phase out of albuterol CFC MDIs
• September 25, 2009	FDA public workshop on removal of essential use designation for epinephrine
• September 8, 2011	EPA/FDA/State Department host stakeholder meeting on the US transition to ozone-safe MDIs, with focus on ensuring smooth transition of patients relying on over-the-counter CFC-based epinephrine MDIs (i.e., Primatene Mist)
• September 22, 2011	FDA hosts a stakeholder teleconference on the phase-out of CFC-based epinephrine MDIs (Primatene Mist)
• December 31, 2011	Removal of epinephrine's "essential use" status takes effect. Primatene Mist therefore cannot be sold (or otherwise introduced into interstate commerce) after this date

November 17, 2011

Cynthia Giles
Assistant Administrator
Office of Enforcement and Compliance Assurance
Environmental Protection Agency
1200 Pennsylvania Ave NW (6205)
Washington, DC 20460

Re: Primatene Mist Sunset December 31, 2011

Dear Administrator Giles:

On behalf of our customers who rely on Primatene Mist as their over-the-counter ("OTC") emergency asthma rescue medication, we are requesting that our retail stores be allowed to sell Primatene Mist inhalers after December 31, 2011. The Primatene Mist offered for sale would be from our current stock, ordered and received before December 31, 2011.

Our company and our patient population understand that the current chlorofluorocarbon ("CFC") version of Primatene Mist is no longer being manufactured and produced here in the United States. Because Primatene Mist uses CFC as a propellant, it is subject to regulation by the Environmental Protection Agency (EPA) under the Clean Air Act. We further understand that a Final Rule was adopted on November 18, 2008 by the Food and Drug Administration ("FDA") in consultation with the EPA that removes Primatene Mist multi dose inhalers from the "essential use" category for CFC as of December 31, 2011 (the "Final Rule"). As you are aware, this Final Rule was issued pursuant to the Clean Air Act. Enforcement of the Clean Air Act's prohibition against sale of non-essential CFC products resides with EPA.

Currently, there are no other FDA-approved OTC epinephrine inhalation products being marketed within the United States. This means that the removal of Primatene Mist from the market by EPA would eliminate OTC access to this important drug which is needed by millions of Americans for instant relief from sometimes life-threatening asthma attacks. We believe that this marketing ban would impose extreme hardships on asthmatic patients, their families and the overall healthcare system in this country. In light of this information, we urge the EPA to exercise enforcement discretion to ensure that asthma patients have OTC access to Primatene Mist until the 2011 retail supplies (including stocks ordered and received prior to December 31, 2011) are exhausted.

6333 State Route 298, Suite 305, East Syracuse, NY 13057
Office: (315) 451-2873 Fax: (315) 451-2706 www.KinneyDrugs.com

In summation, we are asking the EPA to exercise enforcement discretion in a manner that will allow our retail stores to sell the remaining units of Primatene Mist in their possession after December 31, 2011 and until our retail supply is exhausted. In no case shall this extension exceed June 30, 2012.

We further understand that if our retail stores continue to sell a Primatene CFC inhalation product beyond the June 30, 2012 date, that activity may result in legal action without further notice, including, without limitation, seizure and injunction as set forth in the Clean Air Act.
We respectfully request your prompt consideration in exercising EPA enforcement discretion as it pertains to Primatene Mist.

Sincerely,

Bob Corcuera
Category Manager – Health Care

6333 State Route 298, Suite 305, East Syracuse, NY 13057
Office: (315) 451-2873 Fax: (315) 451-2706 www.KinneyDrugs.com

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

November 22, 2011

Cynthia Giles
Assistant Administrator
Office of Enforcement and Compliance Assurance
Environmental Protection Agency
1200 Pennsylvania Ave NW (6205)
Washington, DC 20460

Dear Administrator Giles:

Re: Primatene Mist Sunset December 31, 2011

On behalf of our patients who rely on Primatene Mist as their over-the-counter ("OTC") emergency asthma rescue medication, we are requesting that our member retail pharmacies be allowed to sell Primatene Mist inhalers after December 31, 2011. The Primatene Mist offered for sale would be from their current stock, ordered and received before December 31, 2011.

The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their $900 billion in annual sales. Every $1 spent in these stores creates a ripple effect of $1.81 in other industries, for a total economic impact of $1.76 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

Our member pharmacies and their patient population understand that the current chlorofluorocarbon ("CFC") version of Primatene Mist is no longer being manufactured and produced here in the United States. Because Primatene Mist uses CFC as a propellant, it is subject to regulation by the Environmental Protection Agency (EPA) under the Clean Air Act. We further understand that a Final Rule was adopted on November 18, 2008 by the Food and Drug Administration ("FDA") in consultation with EPA that removes Primatene Mist multi dose inhalers from the "essential use" category for CFC as of December 31, 2011 (the "Final Rule"). As you are aware, this Final Rule was issued pursuant to the Clean Air Act. Enforcement of the Clean Air Act's prohibition against sale of non-essential CFC products resides with EPA.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

Currently, there are no other FDA-approved OTC epinephrine inhalation products being marketed within the United States. This means that the removal of Primatene Mist from the market by EPA would eliminate OTC access to this important drug which is needed by millions of Americans for instant relief from sometimes life-threatening asthma

attacks. We believe that this marketing ban would impose extreme hardships on asthma patients, their families and the overall healthcare system in this country. Consequently, we urge EPA to exercise enforcement discretion to ensure that asthma patients have OTC access to Primatene Mist until the 2011 retail supplies (including stocks ordered and received prior to December 31, 2011) are exhausted.

In summation, we are asking EPA to exercise enforcement discretion in a manner that will allow retail pharmacy companies to sell the remaining units of Primatene Mist in their possession after December 31, 2011 and until this supply is exhausted. In no case shall this extension exceed June 30, 2012.

We further understand that if our retail pharmacy stores continue to sell a Primatene CFC inhalation product beyond the June 30, 2012 date, that activity may result in legal action without further notice, including, without limitation, seizure and injunction as set forth in the Clean Air Act.

We respectfully request your prompt consideration in exercising EPA enforcement discretion as it pertains to Primatene Mist.

Sincerely,

Kevin N. Nicholson, R.Ph., Esq.
Vice President
Government Affairs and Public Policy

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
WWW.NCPANET.ORG

December 8, 2011

Cynthia Giles
Assistant Administrator
Office of Enforcement and Compliance Assurance
Environmental Protection Agency
1200 Pennsylvania Ave NW (6205)
Washington, DC 20460

Re: Removal of Over-The-Counter Epinephrine Metered-Dose Inhalers; Sunset Date Extension

Dear Administrator Giles,

The National Community Pharmacists Association (NCPA) is sharing concerns regarding the impending removal of Primatene Mist, the only over-the-counter (OTC) inhaler for temporary relief of asthma. On behalf of our patients who utilize Primatene Mist as their over-the-counter asthma rescue medication, we respectfully request that our member community pharmacies be permitted to sell Primatene Mist inhalers after December 31, 2011 until supplies of the CFC-formulation are depleted .

NCPA represents the pharmacist owners, managers, and employees of more than 23,000 independent community pharmacies, pharmacy franchises, and chains, which dispense over 41% of all retail prescriptions. Health care providers, often community pharmacists, are the first line of defense for proper screening and treatment of asthma patients. With the expansion of pharmacist-provided patient care services, there has been a steady increase in community pharmacists who provide asthma management programs. Therefore, the availability and access of asthma products is of great interest to our membership and the patients they serve.

It is our understanding that FDA's decision in consultation with the Environmental Protection Agency (EPA) to remove Primatene Mist is due to environmental compliance with the Montreal Protocol, which

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aims to eliminate ozone-depleting substances (ODS). The chlorofluorocarbons (CFCs) contained in the propellant of the metered dose inhalers (MDI) have been identified as an ODS and according to the phase out plan, will no longer be available for sale after December 31, 2011. Because the propellant within the current formulation of Primatene Mist contains CFC, it is subject to regulation by the EPA under the Clean Air Act, and as such oversight of the Clean Air Act's prohibition against sale of non-essential CFC products resides with EPA. While we fully respect the EPA's enforcement authority on this issue, we urge the EPA to consider a balanced approach between environmental safety and patient access to care while supplies remain on store shelves.

In previous comments to the FDA on this issue, our recommendation was for the Administration to consider extending the sunset date of the current OTC metered-dose inhalers until supplies of the CFC-formulation are depleted to keep asthma medications affordable and accessible to patients that may be seeking rescue therapy and ask for those same considerations with the EPA. Currently Primatene Mist is the only OTC inhaler available and costs significantly less than inhalers which require a prescription. As the sole remaining product available, Primatene Mist may be the most affordable option during a potentially life-threatening asthma attack for some patients. We requested the FDA to allow for the availability of OTC CFC MDIs as a bridge supply to protect patient health.

Similarly, we urge EPA to exercise enforcement discretion to ensure that asthma patients have OTC access to Primatene Mist until the existing supply (including units ordered and received prior to December 31, 2011) are exhausted. This will allow community pharmacies to provide the remaining units of Primatene Mist in stock beyond December 31, 2011 and until the supply is exhausted. Under no circumstance shall this extension exceed June 30, 2012. We further understand that if independent community pharmacies continue to sell a Primatene CFC inhalation product beyond June 30, 2012, that activity may result in legal action without further notice.

We appreciate EPA's prompt attention to this serious health and environmental issue and consideration in exercising enforcement discretion as it pertains to Primatene Mist containing CFC.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Regulatory Affairs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 30 2011

ASSISTANT ADMINISTRATOR
FOR ENFORCEMENT AND
COMPLIANCE ASSURANCE

The Honorable Bart Stupak
Attorney for Amphastar and Armstrong Pharmaceuticals
Venable LLP
575 Seventh Street NW
Washington, DC 20004

Dear Mr. Stupak:

I am writing in response to your letter of December 21, 2011, requesting that the United States Environmental Protection Agency (EPA) allow for the retail sale of Primatene Mist units beyond the date authorized by current law.

We have reviewed the information in your letter as well as the information you provided on December 26 and, as we said we would, we have discussed this matter with our colleagues at the U.S. Food and Drug Administration (FDA). The issues set out in your letter, including the need for access to appropriate care for underserved populations, have been previously addressed by the FDA during the extensive and public rulemaking process that began in 2007 and ended in 2008, that established the December 31, 2011, phase-out date. After consultation with and careful consideration of comments from the EPA, the Department of State, industry, health care professionals, public health and patient advocacy groups, and other stakeholders, the FDA concluded that epinephrine inhalers containing chlorofluorocarbons (CFCs), most commonly marketed as Primatene Mist, are no longer essential uses of CFCs and should be phased out over a three-year period ending December 31, 2011. As the FDA stated in its final rule, it does not believe that continued use of over-the-counter (OTC) epinephrine metered dose inhalers (MDIs) is necessary to save lives, to reduce or prevent asthma morbidity, or to significantly increase patient quality of life. The FDA cited the availability of albuterol MDIs as therapeutic alternatives, and the possibility that, in the absence of the OTC drug product, additional patients may seek assessment and treatment for their asthma conditions from health care professionals and reduce the health threats associated with asthma morbidity as a result. It is not the EPA's province to second guess the informed judgment of the medical experts who previously considered these questions.

We appreciate the concerns expressed in your letter about ensuring that low income patients receive the most appropriate and affordable care. It is important to note that there are a number of patient assistance programs that make asthma relief products available for free or at a reduced cost to low income patients.[1]

[1] *See, e.g.*, Teva Pharmaceuticals offers a patient assistance program (1-877-254-1039) (http://www.proairhfa.com/eib-copd-asthma-resources/assistance-program.aspx) that is a long standing national income-based program which provides free or reduced cost access to asthma relief products. Merck (parent company of Schering-Plough) (http://www.merck.com/merckhelps/patientassistance/home.html) and GlaxoSmithKline (http://www.gskforyou.com) similarly have patient assistance programs that provide medications at a reduced cost or free of charge to individuals meeting

For these reasons, we do not see grounds to invoke the extraordinary relief of a no action assurance. As we explained in our prior letter, a statement by the EPA that we will not enforce the law is one that should be made sparingly, and only when it is clearly necessary to serve the public interest.[2] Accordingly, your and related requests for a no action assurance in this case cannot be approved.

Thank you for your letter.

Sincerely,

for Cynthia Giles

Enclosure

cc: Commissioner Margaret A. Hamburg, U.S. Food and Drug Administration
Kevin N. Nicholson, R. Ph, Esq., Vice President, Government Affairs and Public Policy, National Association of Chain Drug Stores

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certain criteria (e.g., low income and uninsured). The Partnership for Prescription Assistance assists patients without prescription drug coverage get access to medications. (1-888-477-2669) (http://www.pparx.org/).

[2] The EPA has a policy that disfavors "No Action Assurances" except: (1) "where expressly provided by applicable statute or regulation," or (2) "in extremely unusual cases in which a no action assurance is clearly necessary to serve the public interest." See Policy Against "No Action" Assurances, Courtney M. Price, Assistant Administrator for Enforcement and Compliance Monitoring (Nov. 16, 1984). "Public interest" encompasses well-documented health concerns.

Statement for the Record of Regina McCarthy
Assistant Administrator for the Office of Air and Radiation
U.S. Environmental Protection Agency

Hearing on the "U.S. Agricultural Relief Act of 2012" and the "Asthma Inhalers Relief Act of 2012"

Subcommittee on Energy and Power
Committee on Energy and Commerce
July 18, 2012

Chairman Whitfield, Ranking Member Rush, and members of the Committee, I appreciate the opportunity to provide a written statement for the record on the draft bills entitled the "U.S. Agricultural Relief Act of 2012" and the "Asthma Inhalers Relief Act of 2012," which are presently before the Committee. These bills address the treatment of methyl bromide and Primatene Mist, respectively, which are or contain ozone-depleting substances that the United States has agreed to phase out of domestic consumption and production under the Montreal Protocol, subject to specified critical and essential use exemptions.

Although the Administration does not yet have a formal position on these draft bills, the bills could have a number of unintended adverse consequences. Since each legislative draft deals with a very different exemption process and has differing potential consequences, I will provide background and address each separately.

Background on the Montreal Protocol

The Montreal Protocol on Substances that Deplete the Ozone Layer was signed by the United States in 1987, with the personal support of President Ronald Reagan, and ratified in 1988. The Protocol, which has undergone multiple revisions over successive years, phases out the consumption and production of ozone depleting substances. Because the stratospheric ozone layer absorbs ultraviolet-B radiation that would otherwise reach the surface of the planet,

emission of ozone depleting substances results in increased exposure to UV-B radiation which may cause increased incidence of skin cancer and other health and environmental impacts. The Montreal Protocol has been ratified by the United States and 196 other countries and is widely recognized as one of the world's most successful multilateral international conventions in force.

As part of the 1990 amendments to the Clean Air Act, Congress enacted Title VI of the Act, which directs EPA to work with other federal agencies to carry out U.S. Montreal Protocol commitments for phasing out ozone depleting substances. Title VI specifies mechanisms to complement this phase-out, including a ban on nonessential products. It also provides flexibility to allow continued production of ozone depleting substances in areas where additional time might be required to identify effective alternatives.

The "U.S. Agricultural Sector Relief Act of 2012"

Methyl bromide is an odorless, colorless gas that has been used as a soil fumigant and structural fumigant to control pests across a wide range of agricultural and other sectors. Because methyl bromide depletes the stratospheric ozone layer, the amount of methyl bromide produced and imported in the United States was reduced incrementally until it was phased out on January 1, 2005, pursuant to our obligations under the Montreal Protocol and Title VI of the Clean Air Act.

Under the Protocol, the Parties to the Protocol have authority to permit exemptions from the phaseout for "critical" uses of methyl bromide that are nominated by a given country. The Parties to the Protocol have agreed to Decision IX/6 governing such exemptions, which states that:

"use of methyl bromide should qualify as 'critical' only if the nominating Party determines that:

(i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption; and

(ii) There are no technically and economically feasible alternatives or substitutes available to the user that are acceptable from the standpoint of environment and health and are suitable to the crops and circumstances of the nomination;"

The decision also establishes criteria and a process for the Parties to the Protocol to assess the quantity of production and consumption, if any, of methyl bromide that should be permitted for nominated critical uses.

EPA, in 2003, established the Critical Use Exemption process for methyl bromide in anticipation of the 2005 phaseout, to provide for growers with critical needs for continued use of the fumigant beyond the phaseout. The U.S. Government develops each annual critical use nomination for methyl bromide through a rigorous technical process involving the careful efforts of several agencies, and in close collaboration with the grower community.

Each year, EPA solicits applications from growers and grower groups. Staff of the EPA Office of Pesticide Programs and the U.S. Department of Agriculture (USDA) Office of Pest Management Policy review applications and work with growers to compile the best available information on current critical uses. EPA recognizes the vital importance of extensive interaction with the user community. Accordingly, EPA, USDA, and Department of State conducted meetings this winter with user groups to further ensure that federal agencies are able to work actively with applicants to identify information gaps. Calls and meetings were held to discuss specific crop, production, and use conditions, to enhance supporting information. EPA also provides support to, and attends, the annual Methyl Bromide Alternatives Outreach Conference.

In addition, between 1995 and 2012, USDA – through the Agricultural Research Service, the National Institute of Food and Agriculture (formerly, the Cooperative State Research Education and Extension Service), and the Interregional Research Project 4 (IR-4) programs – has provided substantial support for research and outreach related to alternatives for crops that used methyl bromide. These actions demonstrate, on the part of the U.S. Government, an understanding of the important needs of the agriculture and user community and an ongoing commitment to work effectively to help meet those needs.

All these efforts have the common goal of allowing the U.S. Government to develop technically supportable estimates for U.S. critical needs for methyl bromide. The value of this careful process has been demonstrated in the success to date in Montreal Protocol negotiations. The U.S. Government has successfully supported its nominations for critical uses of methyl bromide, securing approval of an average of 88 percent of our nominated amount for each year from 2005 through 2013.

While the current critical use exemption process has been effective and successful, the draft bill could disrupt that process in a number of respects. Most notably, the bill calls for EPA to take all appropriate action within its authority to seek a critical use exemption under the Protocol – for each and every applicant in the full amount requested by the applicant for an approved critical use – unless EPA has substantial evidence that there is a technically and economically feasible alternative available for that use. The bill appears intended to shift the burden of proof for justifying a critical use exemption from the applicant to EPA. This shift may have the unintended result of producing U.S. nominations that are less likely to secure international agreement because they are not as fully technically supported and may be viewed by other Parties as less rigorous than nominations developed under the current process. It may

also undermine the value of EPA's analysis in the interagency process to prepare and submit a critical use exemption nomination to the Montreal Protocol Parties every year. Furthermore, by requiring that the Administrator "shall" seek a critical use exemption under the Montreal Protocol, the bill would interfere with the Executive's constitutional authority to determine the time, scope, and objectives of international negotiations.Another concern raised by the bill is that, by referring to the list of critical uses set forth in the Code of Federal Regulations on January 1, 2005, it applies to an outdated universe of potential critical uses. In so doing, it excludes an array of critical users that were identified after that date. The bill also would add back some uses that need not be on the list, as many once-critical users since 2005 have adopted effective alternatives and no longer rely on methyl bromide.

The draft bill further articulates a separate "emergency events" process for methyl bromide, which we believe would be counterproductive and would ultimately undermine our ability to secure future exemptions for critical uses. In particular, the bill raises three key potential concerns. At present, the Parties have not fully defined what may qualify as an emergency event; if the United States enacts legislation defining the term expansively, this may encourage the Parties to the Protocol to pursue greater specificity with regard to allowable emergency uses, potentially limiting important existing flexibility. In addition, this bill may call into question whether the United States is attempting to create an independent exemption for critical uses that operates outside the agreed critical use exemption process. This could undermine our efforts to have our critical use exemption nomination approved through the Montreal Protocol. Further, the bill's list excludes certain very high value national security applications that are most directly applicable to the emergency uses exemption – for example,

homeland security uses that may be needed, such as use of methyl bromide to decontaminate a building after Anthrax exposure.

Finally, it is important to note that there are two substantial issues associated with the use of methyl bromide that the draft bill does not address and that, if the legislation were enacted, could very well prove to be problematic. First the availability of methyl bromide is regulated by EPA directly under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires the registration of pesticides sold or distributed in the United States. As part of the registration process, EPA approves the labeling of the pesticide product, including enforceable directions for its use. Any uses of methyl bromide as provided for under the provisions of this draft legislation would still be required to meet the FIFRA standards before they could be legally allowed. Thus EPA would still have the responsibility to regulate the use of methyl bromide under FIFRA in meeting its responsibilities for protecting public health and the environment in addition to meeting its Clean Air Act responsibilities.

Just as important, the decision to approve a critical use rests with the Parties to the Montreal Protocol in accordance with the terms of the Protocol. As such, any U.S. nominations for exemptions would still be subject to and dependent on approval under the Protocol before EPA could implement the exemptions domestically.

The "Asthma Inhaler Relief Act of 2012"

Epinephrine is a short-acting beta-adrenergic bronchodilator used for temporary relief of shortness of breath, tightness of chest, and wheezing due to asthma. Marketed as Primatene Mist, epinephrine metered-dose inhalers (MDIs) that contain chlorofluorocarbons (CFCs) are over-the-counter inhalation aerosol products used to treat the symptoms of asthma. CFCs are

ozone-depleting substances that, pursuant to the Montreal Protocol, were banned from domestic consumption and production in the United States in 1996.

Both the Montreal Protocol and Title VI allow for continued production of CFC-based metered dose inhalers through an essential use exemption provision. The Parties to the Montreal Protocol approved Decision IV/25, which provides the following criteria for assessing a proposed essential use:

> "It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and
>
> There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;"

Congress, through Title VI of the Clean Air Act, effectively established a partnership between EPA and the U.S. Food and Drug Administration (FDA) to guide a gradual, patient-safe phase-out of CFC propelled inhalation aerosols, and transition to non-CFC propellant alternate inhalation aerosols for asthma treatments when such an alternate is developed. Since the prior CFC propellants were banned in 1996, EPA has managed the essential use exemption process for these products. Under this process, EPA solicited information from pharmaceutical makers about annual CFC needs, developed essential use exemption requests in close consultation with FDA, and worked with FDA and the Department of State to secure approval of U.S. nomination amounts by the Parties to the Montreal Protocol. EPA then completed rulemakings to allow for additional production of otherwise banned CFCs in amounts authorized by the Parties to the Montreal Protocol. These amounts were determined by careful review and coordination with FDA, the agency with the responsibility for determining the medical necessity for continued essential use status for each individual active agent used to treat asthma.

This interagency partnership has been highly successful. Since the CFC phaseout in 1996, FDA has phased out nearly all CFC-propelled inhalation aerosols from the U.S. market, and has approved 19 safe and effective alternative asthma treatments. In the case of Primatene Mist, FDA conducted a thorough public process involving stakeholders, pharmaceutical manufacturers, and medical and patient advocacy groups. A 2008 FDA rule set a date for removing epinephrine from the list of essential CFC uses, stating that continued availability of epinephrine CFC inhalers are not necessary to save lives, to reduce or prevent asthma morbidity, or to significantly increase patient quality of life. Based on information gathered during the rulemaking process, FDA revised the rule's effective date from the proposed date of December 31, 2010 to December 31, 2011. Delaying the phase-out of epinephrine CFC MDIs by one year provided patients with additional time to transition to non-CFC alternatives and provided the manufacturer of Primatene Mist with the additional time it requested at a public meeting to reformulate Primatene Mist without CFCs. On January 1, 2012, Primatene Mist became subject to the Clean Air Act ban on the sale and distribution of nonessential products.

The certainty and transparency of this process allowed pharmaceutical manufacturers ample time – 20 years in the case of epinephrine – to research, develop and secure regulatory approval for patient-friendly effective alternatives. We are concerned that a bill that would require EPA to allow for the sale of remaining stocks of epinephrine inhalers would confuse patients, reduce confidence in the transition process, and send a strong signal to other pharmaceutical manufacturers that orderly engagement in public policy processes may not be rewarded. Further, the bill's language is directed at restricting EPA enforcement authority. Although Congress has the authority to legalize the sale of Primatene Mist, the proposed legislation would set an unacceptable precedent. The proposed legislation specifically directs the

Executive branch to exercise its discretion in a specific way by requiring the issuance of a No Action Assurance.

Conclusion

In summary, existing flexibilities under the Montreal Protocol and the Clean Air Act have proven adequate to address critical and essential use issues associated with ozone-depleting substances. Using these flexibilities, EPA and its federal agency partners have worked cooperatively with stakeholders to safely and effectively address issues associated with methyl bromide and Primatene Mist. EPA does not believe that the draft bills before the Committee are necessary and is concerned that their enactment could lead to a number of unintended and adverse consequences. Accordingly, I respectfully urge the Committee to carefully consider these issues as it proceeds.

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