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Report to the Ranking Minority Member, Committee on Government Reform, House of Representatives

March 2003

PESTICIDES ON TOBACCO

Federal Activities to Assess Risks and Monitor Residues

GAO-03-485

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Highlights

Highlights of GAO-03-485, a report to the Ranking Minority Member, Committee on Government Reform, House of Representatives

Why GAO Did This Study

Pesticides play a significant role in increasing production of tobacco, food, and other crops by reducing the number of crop-destroying pests. However, if used improperly, pesticides can have significant adverse health effects. GAO was asked to (1) identify the pesticides commonly used on tobacco crops and the potential health risks associated with them, (2) determine how the Environmental Protection Agency (EPA) assesses and mitigates health risks associated with pesticides used on tobacco, and (3) assess the extent to which federal agencies regulate and test for pesticide residues on tobacco.

What GAO Recommends

GAO recommends that the Secretary of the Department of Agriculture direct the Administrators of the Agricultural Marketing Service and the Farm Service Agency to periodically review and update the pesticides on tobacco for which they set residue limits and test imported and domestic tobacco.

Commenting on a draft of this report, EPA officials said GAO accurately characterized the agency's risk assessment process for pesticides used on tobacco, and Department of Agriculture officials agreed with GAO's recommendation to periodically review and update the pesticides for which the department sets residue limits and tests tobacco.

www.gao.gov/cgi-bin/getrpt?GAO-03-485.

To view the full report, including the scope and methodology, click on the link above. For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

What GAO Found

In the 1990s, domestic growers commonly used 37 pesticides approved for use on tobacco by EPA. Most of these pesticides were also used on food crops. When used in ways that deviate from conditions set by EPA, many of these pesticides can cause moderate to severe respiratory and neurological damage—and may result in death. Moreover, animal studies suggest that some of these pesticides may cause birth defects or cancer.

Under its pesticide registration program, EPA evaluates toxicity and other data to assess health risks to workers and the public from exposure to pesticides—and risks to smokers from exposure to residues in smoke. These assessments have identified a range of risks that required such mitigation as limiting where and how the pesticide may be used, prohibiting use in certain states, and requiring workers to wear respirators and chemical-resistant clothing. On the other hand, EPA has concluded that low levels of residues in tobacco smoke do not pose short-term health concerns requiring mitigation. EPA does not assess intermediate or long-term risks to smokers because of the severity of health effects linked to use of tobacco products themselves.

While EPA regulates the specific pesticides that may be used on tobacco and other crops and specifies how the pesticides may be used, it does not otherwise regulate residues of pesticides approved for use on tobacco. USDA, however, is required by the Dairy and Tobacco Adjustment Act to test imported and domestic tobacco for residues of pesticides *not* approved by EPA for use on tobacco that federal officials believe are used in other countries. By helping ensure that other countries do not use highly toxic pesticides that U.S. tobacco growers may not use, federal regulation of pesticide residues on tobacco addresses trade equity as well as health and environmental issues. However, USDA has not reevaluated the list of pesticides for which it tests since 1989, even though EPA has cancelled tobacco use for over 30 pesticides since then.

USDA Inspectors Take a Tobacco Sample for Laboratory Testing

Source: GAO.

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Abbreviations

1,3-D	1,3-dichloropropene
2,4-D	2,4-dichlorophenoxyacetic acid
2,4,5-T	2,4,5-trichlorophenoxyacetic acid
AMS	Agricultural Marketing Service
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco
DBCP	Dibromocloropropane
DDE	Dichlorodiphenyldichloroethylene
DDT	Dichlorodiphenyltrichloroethane
EDB	Ethylene dibromide
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FSA	Farm Service Agency
HCB	Hexachlorobenzene

NCFAP	National Center for Food and Agricultural Policy
NCSU	North Carolina State University
ppm	parts per million
TDE	Tetrachlorodiphenylethane
TTR	total toxic residue
USDA	U.S. Department of Agriculture

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United States General Accounting Office
Washington, DC 20548

March 26, 2003

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives

Dear Mr. Waxman:

As you know, pesticides are used regularly on food and nonfood crops, such as tobacco, to control a range of unwanted animal, plant, and microbial pests.[1] Trace amounts of pesticides, called residues, remain on tobacco and other crops after treatment. Typically, the residue levels on tobacco decline as the leaves are harvested, dried, and further processed into consumer products, and still further when the tobacco is burned. However, varying residue levels may remain. As a result, human exposure to pesticide residues on tobacco may occur when residues remaining in cigarette smoke are inhaled. While much is known about the significant health risks of using tobacco products, limited information exists on the extent to which the use of pesticides on tobacco may increase the considerable health risks associated with tobacco use itself.

By controlling pests that reduce crop yields, pesticides can provide more abundant supplies of fruits, vegetables, and other crops. Nonetheless, pesticides are generally designed to be toxic to living organisms and thus can have significant adverse health effects if used improperly. The Environmental Protection Agency (EPA) determines whether and under what conditions pesticides can be used in the United States without posing an unreasonable risk to human health or the environment. Pesticides that meet EPA's requirements are granted licenses or "registrations," which permit their distribution, sale, and use according to specific directions and requirements identified on the labels. In addition, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) monitor crops for certain pesticide residues.

[1]This report generally uses the term "pesticide" to refer to the toxic compounds, also called active ingredients, that are contained in pesticide products. Pesticide products typically include at least one active ingredient as well as inert ingredients.

In response to your request for information on how the federal government addresses the public health implications of pesticides on tobacco, this report describes (1) the pesticides commonly used on tobacco and the potential health risks associated with them; (2) how EPA assesses and mitigates health risks associated with pesticides used on tobacco; and (3) how, and the extent to which, federal agencies regulate and monitor pesticide residues on tobacco. Several pesticide use surveys conducted or sponsored by the federal government provide information on the types and amounts of pesticides commonly used on tobacco and other crops in the 1990s. These data, available through 1998, estimate average annual agricultural use of pesticides, excluding such uses as pest control in greenhouses. To determine how EPA assesses and mitigates health risks associated with pesticides used on tobacco, we reviewed, among other things, studies and documentation related to 13 pesticides commonly used on tobacco that EPA evaluated under its reregistration program between 1994 and 2002. For more details on our scope and methodology, see appendix I.

Results in Brief

Surveys conducted during the 1990s indicate that tobacco producers in the United States commonly used 37 pesticides approved for such use by EPA, most of which were also approved for use on food crops. When used in ways that deviate from the conditions set by EPA, many of these pesticides can cause moderate to severe respiratory and neurological damage—and may result in death. Further, animal studies suggest that some of these pesticides may cause birth defects and cancer. About half of the pesticides used on tobacco work primarily by preventing the normal flow of nerve impulses to muscles and are among those most often implicated in poisonings, injuries, and illnesses. In humans, symptoms appear within minutes to hours after exposure and range from tightness in the chest, headache, nausea, and dizziness to death from respiratory failure.

EPA bases its assessments of the health risks to both workers and the general population from exposure to the pesticides that are used on tobacco and other crops on its evaluation of a wide range of toxicity, residue, and other data. Workers are exposed through mixing and applying pesticides, and the general population is exposed through pesticide products used in the home and in public places and through pesticide residues in food and water. EPA also assesses the health risks to smokers from exposure to pesticide residues that remain in cigarette smoke by analyzing data on the toxicity of specific pesticides and the residue levels that remain on tobacco and in tobacco smoke. EPA's assessments of risks

to workers and the public from exposure to pesticides that are used on tobacco and other crops have identified a range of potential adverse health effects. To mitigate such effects, EPA has set special limitations on where and how some pesticides may be used, such as requiring workers who use them to wear respirators and chemical-resistant clothing, prohibiting their use in certain states to avoid high pesticide levels in groundwater used for drinking, and not permitting certain uses at all. On the other hand, EPA has generally concluded that the low levels of residues measured in tobacco smoke do not pose short-term health concerns. EPA does not assess the additional risk of either intermediate- or long-term exposure to pesticide residues in smoke because of the severity and quantity of health effects associated with the use of tobacco products themselves. In addition, the agency does not include short-, intermediate-, or long-term exposure to residues on tobacco in its assessments of total exposures to the pesticides. Officials and experts with whom we spoke generally agreed that pesticide residues on tobacco could incrementally increase health risks, though some also said the known harm from using tobacco products dwarfs any potential effect from exposure to pesticide residues in the smoke.

While EPA regulates the *specific pesticides* that may be used on tobacco and other crops and specifies how the pesticides it approves may be used, EPA does not otherwise regulate the *residues of pesticides* approved for use on tobacco and other nonfood crops. USDA, however, is required by the Dairy and Tobacco Adjustment Act, as amended, to test domestic and imported tobacco for pesticides not approved for use on tobacco by EPA. As a result, federal regulation of pesticide residues on tobacco is limited to selected pesticides that are not approved by EPA for such use in the United States. USDA tests most imported tobacco, as well as the portion of domestic tobacco the federal government acquires under the tobacco price support program, for residues of 20 pesticides not approved for use on tobacco that federal officials believe are used in some other countries. Most of these pesticides, such as DDT, are highly toxic, persist in the environment, and accumulate in the bodies of humans and animals.[2] By helping to ensure that other countries do not use pesticides that U.S. tobacco growers are not allowed to use, the federal regulation of pesticide residues on tobacco addresses trade equity as well as health and

[2]Dichlorodiphenyltrichloroethane, known as DDT, was one of the most widely used chemicals for controlling insect pests on crops after 1945. Under the authority of EPA, all registrations of DDT have been cancelled, prohibiting the use of the pesticide in the United States.

environmental issues. USDA has not reevaluated since 1989 the pesticides the department monitors in its tobacco pesticide residue testing program, although EPA has subsequently cancelled tobacco uses for at least 30 pesticides not currently monitored by USDA. Consequently, USDA's testing program excludes some highly toxic pesticides that may still be used in other countries. To better protect the public from residues not approved for use on tobacco, we are recommending that USDA periodically reevaluate the pesticides it includes in its testing program.

Background

Tobacco is a high-value, pesticide-intensive crop. That is, tobacco is the nation's ninth highest valued crop, and in terms of the amount of pesticide applied per acre, tobacco ranks sixth—behind potatoes, tomatoes, citrus, grapes, and apples. In the United States, tobacco is grown in 16 states, 2 of which—Kentucky and North Carolina—produce about two-thirds of all domestic tobacco.[3] Further, it is grown in over 100 countries. Until recently, the United States was the world's leading exporter of unmanufactured tobacco; however, in 2001, it ranked third, behind Brazil and Zimbabwe. The tobacco industry in the United States both exports tobacco to Japan and Western Europe—principally Germany, the Netherlands, Denmark, the United Kingdom, Belgium, Italy, and Spain—and imports tobacco in increasing amounts from countries such as Brazil, Argentina, Malawi, and Thailand. Furthermore, the United States is the second largest producer of cigarettes in the world, following China. More than 90 percent of the tobacco grown in the United States is used to manufacture cigarettes, as is most tobacco produced in the world. The remainder is used for chewing tobacco, snuff, cigars, and pipe tobacco. Tobacco types are often defined by such characteristics as how the tobacco is cured (flue-, air-, or sun-cured), as well as the color, size, and thickness of the leaves. Different types of tobacco are used in the various tobacco products. The tobacco component of cigarettes made in the United States usually consists of flue-cured and burley tobacco blended with imported oriental tobacco and small amounts of specialty tobaccos grown in Maryland and Pennsylvania.[4]

[3]The 14 other states are Connecticut, Florida, Georgia, Indiana, Maryland, Massachusetts, Missouri, Ohio, Pennsylvania, South Carolina, Tennessee, Virginia, West Virginia, and Wisconsin.

[4]In addition to tobacco, cigarettes contain other ingredients (additives) to enhance flavor and other qualities of the product.

Although pesticides play a significant role in increasing production of tobacco, food, and other crops by reducing the number of crop-destroying pests, exposure to pesticides can harm humans. The potential for harm is related to both the amount of a substance a person is exposed to—the dose—and the toxicity of the chemical. For example, small doses of aspirin can be beneficial to people, but at very high doses, this common medicine can be deadly. Furthermore, in some individuals, even at very low doses, aspirin may be lethal. The age and health status of an individual can also affect the potential for harm. Children may be more susceptible to harm because, for example, they eat more food, drink more water, and breathe more air than adults per pound of body weight, resulting in greater exposure. Generally, assessments of dose and response involve considering the dose levels at which adverse effects are observed in test animals and using these dose levels to calculate an equivalent dose in humans.

In many cases, exposure to pesticides is through residues that remain on crops following use of the pesticides. The amount of pesticide residue that remains reflects, among other things, the amount of pesticide applied, the time lapsed since application, and the speed with which the pesticide dissipates in the environment. Residue levels remaining on crops are also affected by where the pesticides are applied, such as in the soil or on the plant, and when they are used in the life cycle of the plant, such as when the plant is a seedling or shortly before the plant is harvested. Typically, residues on tobacco decline as the plant moves from field to finished consumer product.

The primary federal requirements pertaining to the registration, sale, and use of pesticides are in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), both as amended by the Food Quality Protection Act (FQPA). Pesticides must generally be registered with EPA in order to be sold or distributed. EPA will register a pesticide if it determines, among other things, that the pesticide will not generally cause unreasonable adverse effects on human health or the environment when used in accordance with conditions specified on the label. Throughout this report we will focus on EPA's analysis of potentially harmful effects to human health, rather than the environment.

In 1988 FIFRA was amended to require that EPA review pesticides initially registered prior to November 1984—when less toxicity data were available—to consider their health effects and to determine whether and how they might continue to be registered. These reviews are designed to

ensure that older pesticides meet contemporary health and safety standards and that their risks are mitigated. Essentially, manufacturers of the older pesticides must provide EPA with substantially the same toxicity, chemistry, and other data as are now required to register a new pesticide.[5] EPA reviews of the older pesticides are called reregistrations. Most of the pesticides used on tobacco during the 1990s were initially approved before 1984 and therefore are subject to reregistration.

In addition, the FQPA amendments to FIFRA passed in 1996 require EPA to reevaluate the amounts of pesticide residues allowed on or in food—known as tolerances. EPA must ensure that there is a reasonable certainty that no harm will result from all pesticide exposures from food and nonfood uses for which there is reliable information. In doing so, unless another safety factor is determined to be appropriate, EPA is required to apply an additional 10-fold safety factor in setting tolerances to ensure the safety of foods for children. EPA is also required to ensure that there is reasonable certainty that no harm will result to children specifically from "aggregate" exposure to a single pesticide—that is, from all sources, such as lawn treatments, household uses, drinking water, and food. EPA must also consider available information concerning the cumulative effects on children of pesticides that act in a similar harmful way (known as a common mechanism of toxicity). To accomplish this requirement, EPA has recently developed a method to evaluate the cumulative exposure of one class of highly toxic pesticides—the organophosphates—from residues in food and drinking water and from residential uses.

EPA uses risk assessment—the systematic, scientific description of potential adverse effects from exposure to hazardous substances—to evaluate the potential health impacts of a pesticide on humans and determine what measures are needed to mitigate identified risks. The product of a risk assessment is an identification of the various health risks, along with quantitative and/or qualitative statements regarding the probability that an exposed population will be harmed and to what degree. For example, EPA qualitatively classifies pesticides and other toxic substances according to their potential to cause cancer using descriptors such as "likely" or "suggestive evidence but not sufficient to assess human carcinogenic potential." In addition, for many carcinogens, EPA develops a quantitative dose/response health risk assessment that estimates the

[5]Typically, applicants for pesticide registrations are the manufacturers; EPA calls the applicants "registrants."

health risks at varying exposures. For health effects other than cancer, EPA may calculate what it terms a "reference dose" or, in the case of exposure by inhalation, a "reference concentration," which represents a daily level of exposure that is unlikely to result in harm over a lifetime. Alternatively, EPA may calculate a "margin of exposure," which is a ratio that shows how far the actual (or estimated) human exposure to a substance is from levels that are harmful. In essence, evaluating and managing the risk of exposure to a pesticide involves determining the maximum safe level of exposure to the pesticide and assessing whether expected actual exposure is below this maximum level. If expected actual exposure levels exceed the maximum safe amount, EPA must determine the best ways to reduce exposure.

Pesticides Commonly Used on Tobacco Have Potential Short- and Long-Term Adverse Health Effects

According to federally sponsored surveys, during the 1990s tobacco producers in the United States commonly used 37 of the pesticides approved by EPA for such use.[6] As shown in table 1, most of the pesticides used on tobacco were insecticides and herbicides, which control insect and plant pests; others were fungicides, which combat fungal diseases, or plant growth regulators; and a few had more than one use.[7]

[6]The National Center for Food and Agricultural Policy, a private nonprofit, nonadvocacy research organization, conducted two key surveys for USDA covering the periods 1990-93 (called the 1992 survey) and 1994-98 (called the 1997 survey). See appendix I for more detail on these surveys.

[7]In this report, the term "insecticide" includes pesticides used to control insects, spiders, and nematodes (worms).

Table 1: Pesticides Commonly Used on Domestic Tobacco, 1990-98

Primary use(s)	Pesticide
Insecticide	Acephate, aldicarb, *Bacillus thuringiensis*, carbaryl, carbofuran, chlorpyrifos, diazinon, disulfoton, endosulfan, ethoprop, fenamiphos, fonofos, imidacloprid, malathion, methidathion, methomyl, spinosad, trichlorfon
Herbicide	Benefin, clomazone, diphenamid, isopropalin, napropamide, pebulate, pendimethalin, sethoxydim, sulfentrazone
Fungicide	Dimethomorph, mancozeb, mefenoxam, metalaxyl
Plant growth regulator	Ethephon, flumetralin
Plant growth regulator, herbicide	Maleic hydrazide
Fumigant, insecticide	Chloropicrin
Fumigant, insecticide, herbicide	Methyl bromide
Fungicide, insecticide, herbicide	1,3-dichloropropene (1,3-D)

Source: EPA, International Organization for Standardization, National Center for Food and Agricultural Policy, and USDA.

Note: GAO's analysis of EPA, International Organization for Standardization, National Center for Food and Agricultural Policy, and USDA data.

Most of these pesticides were also widely used on food crops. The actual number and amount of pesticides used on tobacco or other crops in any given year vary depending on factors such as the weather and the specific pests that become problematic. For example, the incidence of many plant diseases is closely correlated to the amount of rainfall, resulting in greater use of fungicides in years with high rainfall. In addition, pesticide use tends to change over time as pests develop resistance to the pesticides and as use on tobacco is approved for new pesticides and cancelled for older pesticides.[8] As table 2 shows, 10 pesticides identified in the 1997 survey as commonly used on tobacco were not identified in the earlier survey. Two of these pesticides, dimethomorph and mancozeb, began to be used in response to the appearance of a disease resistant to metalaxyl, which declined in usage during the 1990s. In addition, during the years included in the 1997 survey, tobacco use for 5 of the 7 pesticides no longer reported as being used—diazinon, diphenamid, isopropalin, methidathion, and trichlorfon—was being cancelled.[9] In some cases, pesticide cancellations resulted in the increased use of other pesticides. For example, by 1997 clomazone had replaced diphenamid and isopropalin as the pesticide of

[8]During the 1990s, EPA cancelled tobacco use for approximately 34 pesticides.

[9]When EPA cancels the use of a pesticide, the pesticide is typically phased out over time.

choice for controlling unwanted weeds, and imidacloprid was most commonly used to control insect pests, leading to reduced use of acephate, aldicarb, chlorpyrifos, ethoprop, and carbofuran. Manufacturers may initiate cancellation of some or all uses of a pesticide, often for economic reasons,[10] or EPA may cancel uses when the agency determines that one or more uses pose unreasonable risks to human health or the environment. For example, as required under the Clean Air Act, EPA has been phasing out the use of methyl bromide on tobacco and a wide range of other crops because it depletes the earth's protective layer of ozone.[11] Methyl bromide use on tobacco decreased from about 5.4 million pounds in 1992 to about 0.7 million pounds in 1997 because of EPA's efforts and changes in how tobacco producers raise seedlings. Specifically, producers have begun to grow tobacco seedlings in greenhouses, where methyl bromide is not generally used.

Table 2: Pesticide Use on Tobacco, 1990-98

Pesticide	Pounds used on tobacco 1992 survey (1990-93)	Pounds used on tobacco 1997 survey (1994-98)
1,3-dichloropropene (1,3-D)	11,537,540	13,279,285
Chloropicrin	577,082	6,761,644
Maleic hydrazide	1,789,208	1,790,089
Acephate	1,570,457	871,899
Methyl bromide	5,356,748	685,026
Pendimethalin	321,931	473,718
Chlorpyrifos	685,554	406,822
Fenamiphos	257,142	379,841
Mancozeb	[a]	356,811
Flumetralin	[a]	352,742
Metalaxyl	371,645	271,368
Clomazone	[a]	217,617
Ethoprop	438,274	182,321
Endosulfan	[a]	172,766
Mefenoxam	[a]	139,199
Pebulate	412,000	131,665
Ethephon	113,238	102,130

[10]One reason manufacturers may choose to request cancellation of pesticide registrations is to avoid costs associated with reregistering pesticides for each use, such as the cost of providing EPA with data and studies.

[11]EPA's efforts to phase out the use of methyl bromide in the 1990s were consistent with international efforts to curtail its use under the Montreal Protocol, a treaty signed by over 160 countries to control the production and trade of ozone-depleting substances globally.

Pesticide	Pounds used on tobacco 1992 survey (1990-93)	Pounds used on tobacco 1997 survey (1994-98)
Napropamide	191,840	92,622
Sulfentrazone	[a]	69,073
Imidacloprid	[a]	67,896
Aldicarb	159,044	59,719
Dimethomorph	[a]	36,818
Methomyl	57,137	29,773
Malathion	7,549	15,437
Disulfoton	52,578	13,495
Sethoxydim	[a]	9,579
Spinosad	[a]	2,815
Carbaryl	16,487	2,057
Fonofos	12,798	16
Benefin	56,963	[a]
Bacillus thuringiensis	[b]	[b]
Carbofuran	149,965	[a]
Diazinon	53,670	[a]
Diphenamid	81,624	[a]
Isopropalin	129,287	[a]
Methidathion	68	[a]
Trichlorfon	722	[a]
Total used on tobacco	**24,400,552**	**26,974,241**

Source: National Center for Food and Agricultural Policy.

[a]Not identified as being used in the survey.

[b]Neither survey estimated the use of *Bacillus thuringiensis* in pounds.

EPA determines the amounts and conditions under which a pesticide may be used so that it will not pose unreasonable risks to workers or the general population. Failure to comply with the conditions set by EPA could result in a range of harmful effects. For example, 17 of the 37 pesticides commonly used on tobacco in the 1990s belong to three chemical classes that, at high doses, are known to cause adverse human health effects up to and including death (see table 3).

Table 3: Organochlorine, Organophosphate, and Carbamate Pesticides Commonly Used on Tobacco in the 1990s

Chemical class	Pesticide name
Organochlorine	Endosulfan
Organophosphate	Acephate, chlorpyrifos, diazinon, disulfoton, ethoprop, fenamiphos, fonofos, malathion, methidathion, trichlorfon
Carbamate	Aldicarb, carbaryl, carbofuran, mancozeb, methomyl, pebulate

Source: EPA, National Center for Food and Agricultural Policy, and USDA.

Note: GAO's analysis of EPA, National Center for Food and Agricultural Policy, and USDA data.

Although they do not all produce their toxic effects in the same way, pesticides in these three classes—organochlorines, organophosphates, and carbamates—act on the nervous system to prevent the normal flow of nerve impulses to muscles that control both voluntary movement, such as walking, and involuntary movement, such as breathing and heart beat. Pesticides in all three classes are absorbed to varying degrees through inhalation, ingestion, and skin contact. Exposure to amounts of these pesticides that exceed levels set by EPA could result in immediate and life-threatening effects, such as respiratory failure, or conditions that do not appear immediately, such as cancer. While EPA has concluded that most of these 17 pesticides do not cause birth defects, the agency has also concluded that 5 of them and a by-product of another may cause cancer.[12]

Since the 1970s, EPA has severely restricted its approvals of organochlorine pesticides, which include DDT, aldrin, and chlordane, because of their potential to harm humans and the environment. Organochlorine pesticides persist in the environment—some have remained in soil for over 50 years—and accumulate in body tissue, particularly fat. Organochlorine pesticides are associated with a range of adverse health effects, including cancer and damage to the neurological and reproductive systems. The one organochlorine pesticide still approved for use on tobacco, endosulfan, is highly toxic when ingested or inhaled and slightly toxic through contact with the skin. While EPA has determined that it is unlikely to cause cancer as other members of this class do, endosulfan, like all organochlorine pesticides, primarily affects the nervous system. EPA has requested additional data from the manufacturer to address its concerns that exposure to endosulfan could

[12]EPA will assess the health effects of carbofuran in fiscal year 2003 during its reregistration review.

harm the nervous system of developing fetuses. Organophosphate and carbamate pesticides have largely replaced the organochlorine pesticides in the United States.

While they break down quickly in the environment and do not accumulate in body tissues, organophosphate pesticides are much more acutely toxic to humans and animals than the persistent organochlorine pesticides they have largely replaced. The primary cause of death from organophosphate poisoning is respiratory failure, although cardiovascular symptoms, such as decreased heart rate that progresses to cardiac arrest, usually occur as well. In humans, additional symptoms from exposure to organophosphate pesticides, which can develop during use or within minutes to hours after exposure, include headache, nausea, dizziness, sweating, muscle twitching, anxiety, and depression. Exposure by inhalation causes the most rapid appearance of toxic symptoms. As a result, to minimize the potential for harmful exposure of workers, EPA requires those who mix, use, or apply the pesticides to have special training, use respirators, and wear chemical-resistant clothing. Regarding the potential to cause cancer, EPA has determined that 4 of the 10 organophosphate pesticides used on tobacco—acephate, ethoprop, methidathion, and trichlorfon—may cause cancer. In addition, EPA has concluded that 7 of the 8 organophosphate pesticides it evaluated for their potential to cause birth defects would not cause them but that the eighth—chlorpyrifos—may do so at very high levels that may also harm the pregnant female.[13]

Carbamates, which also affect the central nervous system, produce symptoms similar to those of organophosphate pesticides, although the effects of carbamate poisoning tend to be of shorter duration and somewhat easier to treat. The primary cause of death from carbamate poisoning is respiratory failure. Of the six carbamate pesticides used on tobacco, EPA has determined that one and a by-product always associated with another may cause cancer; two are unlikely to cause cancer; data are insufficient to determine the cancer-causing potential of one; and one will be evaluated in fiscal year 2003. EPA has evaluated four of the carbamates for their potential to cause birth defects: three do not and only minimal evidence exists for the potential of the fourth to cause birth defects. EPA has requested, but not yet received, data from the manufacturer on the

[13]EPA has requested data to assess the potential of trichlorfon, which is no longer approved for use on tobacco, to cause birth defects and has terminated its assessment of fonofos because all uses of the pesticide were cancelled.

potential of one of the two remaining carbamate pesticides to produce birth defects, and the agency will evaluate the health effects of the other in fiscal year 2003.

The potential acute adverse health effects from the remaining 20 pesticides used on tobacco—representing 12 different chemical classes—range from mild to severe.[14] For example, EPA found no known health effects on mammals from exposure to *Bacillus thuringiensis* as it is currently manufactured. Similarly, EPA has found that both maleic hydrazide, a plant growth regulator and herbicide, and metalaxyl, a fungicide, have low acute toxicity, and neither is thought to cause cancer or birth defects. However, EPA has found that serious adverse health effects could occur with high exposures to insecticides, such as chloropicrin, 1,3-dichloropropene (1,3-D), and methyl bromide, which are applied as fumigants and can be severely irritating to the eyes, skin, and lungs. EPA has also found that poisoning from exposure to methyl bromide may result in persistent neurological impairment.

In general, because most of the pesticides used on tobacco are widely used on food and other crops, as well as in residential and other settings, the exposure resulting from residues on tobacco represents a small portion of total exposure to these pesticides. Specifically, 1997 survey data estimate that about 27 million pounds of the 37 pesticides were used on tobacco, while the estimated use of these pesticides nationally on all crops was 175 million pounds. Therefore, most of the exposure to these pesticides stems from their use on other crops and in other products, such as household insecticides. However, for some pesticides—dimethomorph, fenamiphos, flumetralin, maleic hydrazide, mefenoxam, and sulfentrazone—more than 50 percent of their use in 1994 through 1998 was on tobacco. Further, more than 80 percent of maleic hydrazide used and 100 percent of flumetralin and sulfentrazone used were applied to tobacco. Appendix II provides information on the amounts of the 37 pesticides used on (1) tobacco and (2) domestic crops, as estimated in the 1992 and 1997 surveys.

[14]One herbicide, clomazone, has not been classified chemically.

EPA Concludes that Health Risks of Pesticide Residues on Tobacco Are Minimal but Requires Mitigation for Risks from Other Exposures

To determine whether the use of individual pesticides can reasonably be expected not to harm human health, EPA conducts health risk assessments under its pesticide registration program. These risk assessments are based on EPA's evaluations of the results of numerous scientific studies and tests that the agency requires pesticide manufacturers to carry out. EPA also assesses the health risks to smokers from exposure to pesticides used on tobacco by analyzing data on their toxicity and the residue levels that remain on tobacco and in tobacco smoke. Because pesticides are used extensively on crops, including tobacco, and in home pesticide products, the risk assessments focus on exposures of (1) workers who handle the pesticides and (2) the general public, which is exposed to pesticides via residues on food or in drinking water or from pesticide products used in and around the home and in public places. EPA's health risk assessments often identify risks to workers that must be mitigated before EPA will approve the pesticide. The assessments also identify risks to the general population that may also require special limitations on how or where the pesticides may be used. EPA has generally concluded that the low levels of residues measured in tobacco smoke do not pose health concerns that require mitigation. While EPA officials were generally able to provide us with copies of the studies and evaluations we requested during our review, documentation of the agency's evaluation of the validity and reliability of the residue studies was inconsistently available.

EPA Assesses Health Risks of Varied Exposures to Pesticides

Under its pesticide registration program, EPA routinely assesses the health risks of exposure to pesticides from residues in drinking water and food and from pesticide use in the home, in public places, and at work. The Health Effects Division of the Office of Pesticide Programs in EPA develops its health risk assessments on the basis of a substantial body of data, including toxicity, residue chemistry, and other data provided by pesticide manufacturers, as well as other relevant information, such as human and animal studies from the general scientific literature and poisoning incident databases. The risk assessments focus on the potential cancer and noncancer health risks associated with short-term (acute), intermediate-, and long-term (chronic) exposures to pesticides from the primary exposure routes—oral, inhalation, and contact with skin (dermal). Noncancer health risks that EPA assesses include risk of birth defects, reproductive impairments, damage to genetic material, and interference

with the body's endocrine system.[15] EPA's health risk assessments are subject to numerous reviews by a variety of committees, including the agency's Hazard Identification Science Assessment Review Committee, Cancer Science Assessment Review Committee, and Reproductive and Developmental Toxicity Science Assessment Review Committee. The health risk assessments provide critical information to the pesticide registration divisions on the human health component of risk management decisions—such as whether to approve pesticides for use; what amounts may be used; and what special restrictions, if any, may be needed.

To evaluate the levels of pesticides to which cigarette smokers might be exposed from residues on tobacco, EPA reviews plant metabolism and residue studies provided by manufacturers that identify the residues of pesticides, and any harmful by-products[16] they may produce, that remain on the crop after it has been treated. The plant metabolism studies reveal how plants process a pesticide once it is applied and the relative amounts of the pesticide and its by-products that remain after treatment—the total toxic residue (TTR). The residue studies, called field trials, quantify the levels of pesticide and by-product residues that remain on plants grown under actual agricultural conditions that approximate the expected "real life" environment. Such field trial data, which are required for all pesticides that will be used on food, may not always be required for pesticides used on tobacco because EPA uses a "tiered" approach to evaluate residues on tobacco. That is, for tobacco, the agency requires additional residue data after the metabolism study only if it has shown that the combined residue levels of the pesticide itself and any harmful by-products exceed 0.1 parts per million (ppm)—the agency's "threshold of concern" for residues on tobacco. Thus, as figure 1 shows, EPA generally requires plant metabolism studies for green tobacco and may require data from field trials for both green and cured (aged) tobacco,

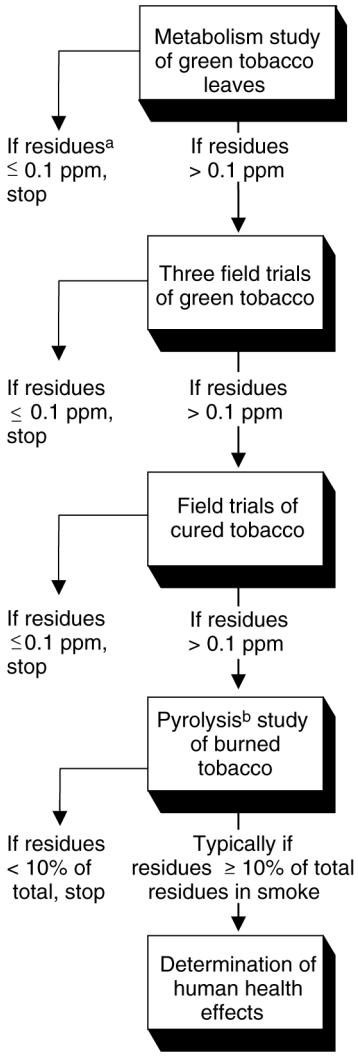
[15]The body's endocrine system produces hormones that help guide the development, growth, reproduction, and behavior of animals, including humans. Some chemicals can interfere with the normal function of this complex system in ways that mimic a natural hormone, thereby fooling the body into overresponding to a hormone or blocking the effects of a hormone. Others may directly stimulate or inhibit the endocrine system, leading to overproduction or underproduction of hormones. Certain drugs are used to intentionally cause some of these effects, such as birth control pills.

[16]EPA requires metabolism studies to identify by-products of pesticides that are of toxicological concern or that account for 10 percent or more of the total radioactive residues. (For metabolism studies, the pesticides have had radioactive atoms attached to their molecular structure to allow tracking of the pesticide through the plant.)

depending upon the amount of residues that are identified.[17] In addition, EPA may require pyrolysis studies that measure the residues in smoke when tobacco treated with a pesticide is burned. Finally, EPA may require additional residue studies to estimate potential exposure, even if the residues are below 0.1 ppm, if it has concerns about the toxicity of a pesticide.

[17]The results of metabolism studies on food crops may be used to determine the identity of the residues of concern.

Figure 1: EPA's Tiered Approach to Assessing Health Risks of Exposure to Residues on Tobacco



Source: GAO and EPA.

[a]Residues are measured as TTR—the sum of the residue from the parent pesticide and its by-products (degradation products, metabolites, and impurities that are of toxicological concern).

[b]Pyrolysis refers to chemical change brought about by the action of heat (burning).

The tiered approach to analyzing residues on tobacco reflects the fact that, typically, pesticide residues on tobacco decline over time, as the tobacco is stored, cured, manufactured into cigarettes, and burned during smoking.[18] EPA uses the tiered approach for tobacco, in part, because the agency has concluded that the potential for harm to human health from pesticide residues on tobacco at or below the 0.1-ppm level is extremely low and unlikely to result in a risk of concern to smokers.[19]

According to EPA officials in the Health Effects Division, since August 1999, EPA's policy for assessing the health risks from using pesticides on tobacco has been to evaluate the risks of short-term exposure to residues on tobacco and to quantify the estimated health risks using a consistent method and set of assumptions.[20] This policy is applied to all newly registered pesticides, as well as to currently registered pesticides as they are periodically reviewed to ensure they meet current human health and environmental safety standards in accordance with the requirements of the 1988 amendments to FIFRA. EPA officials attribute the more structured approach to advances in the science of risk assessment and the 1996 enactment of FQPA, which has spurred the agency to more systematically quantify the exposure to pesticide residues in food and drinking water and from residential uses.

EPA selected the margin of exposure method to quantify the health risks associated with exposure to pesticide residues in smoke. As discussed earlier, a margin of exposure shows how far the actual (or estimated) human exposure to a substance is from levels that have been shown to

[18]EPA does not use the tiered approach to analyze pesticide residues on food and feed crops. Instead, it generally requires data on how the plants metabolize the pesticide and studies of residues that remain at the time of harvest (field trials), and, in some cases, as the food is processed.

[19]EPA's conclusion is based on its analysis, which compared its threshold (0.1 ppm) with residue levels at which inhalation exposure to other pesticide residues produces no harmful effects. Specifically, the 0.1-ppm threshold represents an estimated actual exposure to pesticide residues equivalent to half of the lowest residue level that EPA officials know of for inhalation exposure that does not produce adverse effects.

[20]Prior to 1999, the determination of the methodology and assumptions for assessing the risk to smokers of pesticide residues on tobacco was left to the discretion of individual toxicologists, who made independent determinations for each chemical based on what they considered to be reasonable assumptions. Quantitative risk assessments generally were not performed. This new policy was formalized as guidance in August 2000 and is available electronically to EPA's risk assessors as part of the Health Effects Division's Risk Science Assessment Review Committee Library.

cause no harm in animal studies. To estimate exposure, EPA typically uses (1) the residue levels identified in tobacco field trials or pyrolysis studies and (2) standard assumptions for key variables that affect exposure. Specifically, EPA assumes that people smoke 15 cigarettes a day[21] and that they weigh about 150 pounds, if male, and 130 pounds, if female. Moreover, EPA assumes 100 percent of the pesticide residue on the tobacco is inhaled and absorbed. In practice, some residues will be trapped in cigarette butts, and the amount of smoke inhaled varies widely among people. EPA officials said the assumptions are conservative—that is, they are protective of public health—because they tend to overstate, rather than understate, the extent to which smokers are exposed to the potentially toxic effects of the pesticides.

Also according to EPA officials, the agency does not include exposure to the residues in tobacco smoke in its aggregate health risk assessments of individual pesticides, which are required by FQPA, because the added exposure from residues in smoke is minimal. In addition, EPA has chosen not to assess the risk of either intermediate- or long-term exposure to pesticide residues in smoke because of the severity and quantity of health effects associated with the use of tobacco products themselves. Specifically, exposure to tobacco products—particularly cigarettes—is the single major preventable cause of cancer and heart and lung disease in the United States.

Finally, although experts and public health officials are concerned about the potential for harm, particularly to children, from exposure to pesticides, little is known directly about the chronic effects of pesticide use in general in the United States—for example, in agriculture and in schools.[22] Moreover, studies linking adverse human health effects to exposure to pesticide residues on tobacco are rare, according to public health officials and experts we spoke to. And while a number of federally sponsored studies of the effects of exposure to pesticides are underway, it will be years, if not decades, before conclusive results are known. Officials and experts we spoke with about possible harm from pesticide residues on

[21]Pierce, J.P., et al., 1989. *Tobacco Use in 1986 – Methods and Basic Tabulations from Adult Use of Tobacco Survey.* U.S. Department of Health and Human Services Publication Number OM90-2004. Office on Smoking and Health, Rockville, Maryland.

[22]U.S. General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children*, GAO/RCED-00-40 (Washington, D.C.: Mar. 14, 2000) and *Pesticides: Use, Effects, and Alternatives to Pesticides in Schools*, GAO/RCED-00-17 (Washington, D.C.: Nov. 29, 1999).

tobacco generally agreed that such residues could incrementally add to the risk, and some also believed the known harm from using tobacco products dwarfs any potential effect from exposure to pesticide residues in the smoke.

EPA Concludes That Risks Associated with Pesticide Use Can Be Significant, but Those Associated with Pesticide Residues on Tobacco Appear to Be Minimal

EPA's health risk assessments have identified a number of potential adverse health effects associated with the pesticides used on tobacco and other crops that, in some cases, have led the agency to impose special limitations on the uses of these pesticides. The risks that required mitigation stemmed from (1) potential exposure of workers who apply pesticides or harvest crops and (2) potential exposure of the general population to pesticide residues in food or drinking water or from pesticides used in the home or in public. None of the risks requiring mitigation were associated with exposure to residues on tobacco or in tobacco smoke.

Some of EPA's Risk Assessments Result in Special Mitigation Measures

Our review of studies and other documentation related to EPA's completed reregistration reviews of 13 of the 37 pesticides commonly used on tobacco identified the health risks associated with them and the related mitigation measures the agency required.[23] The following cases illustrate some of the health risks that have required mitigation.

EPA has classified 1,3-D, a widely used fumigant that controls soil-borne pests and diseases, as a probable carcinogen—that is, evidence from human and animal studies suggests that 1,3-D, once ingested or inhaled, is likely to cause cancer. In its risk assessment, EPA determined that 1,3-D could make its way to groundwater and pose a risk of cancer for residents who obtained their drinking water from wells near treated fields. To mitigate the potential cancer risks and as a condition for reregistration, EPA required that wells used for drinking water be located 100 or more feet from treated fields and prohibited the use of 1,3-D altogether in 11 states with porous soil.[24] In addition, vapors from 1,3-D—which is injected as a liquid into soil, where it quickly evaporates—can move into the air. Consequently, EPA also required (1) a 300-foot buffer between occupied

[23]The 13 pesticides are 1,3-D, acephate, chlorpyrifos, diazinon, disulfoton, endosulfan, ethoprop, ethephon, maleic hydrazide, metalaxyl, methidathion, pebulate, and pendimethalin.

[24]The 11 states where 1,3-D cannot be used are Maine, Massachusetts, Minnesota, Montana, New Hampshire, New York, North Dakota, South Dakota, Utah, Vermont, and Wisconsin.

buildings and fields treated with the pesticide and (2) workers who apply the pesticide to wear respirators and protective clothing, among other things. Further, because of 1,3-D's volatility and potential to harm humans, EPA classified it as a "restricted use" pesticide, which means it can only be applied by, or under the supervision of, individuals trained to handle particularly toxic or harmful pesticides. Currently, 1,3-D is registered for use on soils in which all food and feed crops may be planted. Moreover, according to the 1997 survey, an estimated 13 million pounds of 1,3-D were applied to tobacco annually during the survey period—almost twice the amount of chloropicrin, the second most commonly used pesticide on tobacco.[25] Despite the health risks posed by injecting 1,3-D into soil, EPA identified no risks associated with residues on tobacco leaves or in tobacco smoke because 1,3-D metabolizes to nontoxic by-products and is subsequently absorbed by the plant.[26]

Similarly, EPA determined that residues on tobacco of chlorpyrifos—another pesticide frequently used on tobacco and food crops and one of the most widely used organophosphate insecticides in the United States—were below the agency's threshold of concern. But the agency determined that chlorpyrifos presented potential health risks unrelated to its use on tobacco that required strict mitigation measures. Specifically, the agency identified health risks to children from exposure to chlorpyrifos. Before 2000, chlorpyrifos was one of the insecticides used most often in residential and commercial settings—for example, on carpets and in schools, daycare centers, hotels, and restaurants—and on food crops. EPA identified significant risks to children from these many uses and required stringent measures to address them. Between 1997 and 2000, EPA cancelled nearly all indoor and outdoor residential uses and prohibited the use of chlorpyrifos in schools and public parks. In addition, manufacturers agreed to eliminate the use of chlorpyrifos on tomatoes and restrict its use on apples.[27] EPA also identified concerns for some workers who mix, load,

[25]The 1997 survey estimated that, of the 37 pesticides used on tobacco in the 1990s, 12 were applied to tobacco in amounts less than 100,000 pounds and 8 were shown as not used during this survey (1994-98). See appendix II for more detail on the estimated amounts of pesticides used on tobacco.

[26]Although 1,3-D is also widely used on soils where food crops are planted, EPA does not require that food use tolerances be established for this pesticide because no residues remain on plants grown in treated soil.

[27]Chlorpyrifos is currently registered to control foliage-borne and soil-borne pests on food and feed crops; at golf courses; and on nonstructural wood, such as utility poles and fence posts, as well as to kill adult mosquitoes. Structural treatments for termites are also registered uses but are being phased out by the end of 2005.

and apply chlorpyrifos in agricultural and other nonresidential settings. As a result, EPA required that workers wear a respirator and a double layer of clothing, including chemical-resistant gloves, shoes, and headgear. Workers must also use water-soluble packages to mix powdered forms of chlorpyrifos and remain in an enclosed cockpit when aerially spraying a field. EPA also set a time interval between applications of the pesticide and when workers can reenter treated areas, ranging from 24 hours for most crops to 5 days for others. EPA did not, however, identify risks associated with chlorpyrifos used on tobacco because residue levels on green tobacco were below 0.1 ppm.

EPA also identified a range of potential harmful effects from other exposures to the other pesticides we reviewed. For 11 pesticides, including 1,3-D and chlorpyrifos, EPA identified a range of concerns, largely for exposures of workers—particularly those engaged in spraying the pesticides—that required at least some mitigation. Most often the mitigation measures included the use of enclosed mixing systems and tractor cabs, additional protective respirators and clothing, reductions in the rate and frequency of application, and increases in the time between application and reentry to the treated areas. In some cases, such as for acephate, disulfoton, and ethoprop—all of which are organophosphate pesticides—certain uses were cancelled, including use on golf courses and lawns and indoor and outdoor residential uses. Three of these 11 pesticides—disulfoton, endosulfan, and ethoprop—also raised concerns about dietary or drinking water exposure for which EPA required such mitigation as canceling use on some foods, reducing the rate and frequency of application on others, and requiring buffer zones between treated fields and water bodies. EPA placed a number of additional restrictions on the use of endosulfan, a highly toxic and persistent organochlorine pesticide, including restricting use on cotton and tobacco to certain states; eliminating or reducing aerial spray applications on crops such as strawberries, nuts, and tobacco; and requiring buffer zones between treated areas and bodies of water.[28] In addition, EPA required that all products containing endosulfan be labeled as restricted use pesticides, which can only be used by, or under the supervision of, specially trained

[28]EPA determined that endosulfan can be used on tobacco in only 6 of the 16 states where it is grown—Indiana, Kentucky, Ohio, Pennsylvania, Tennessee, and West Virginia—which account for about 40 percent of domestic production.

applicators.[29] EPA also noted that it may require further restrictions on acephate once the agency completes its assessment of the cumulative exposure to organophosphate pesticides because this organophosphate pesticide degrades in plants to another organophosphate pesticide.[30] EPA found that 2 of the 13 pesticides we reviewed presented no concerns that needed changes in existing conditions on how to use and apply the pesticides.[31]

The pesticides we reviewed, including ones no longer approved for use in the United States, are used in many other tobacco-producing countries, according to experts. Researchers and advocacy groups have raised concerns about adverse health effects on tobacco workers in other countries from exposure to pesticides, citing such factors as the absence of cautionary labels on some pesticides and the limited use of protective clothing by agricultural workers. For example, researchers found elevated rates of depression and suicide rates that were twice the national average among tobacco producers in Brazil, a leading tobacco exporter. And although many factors, such as poverty and stress, may play a role in suicide, one group of researchers noted tobacco producers in Brazil routinely used organophosphate pesticides, which have been shown to cause depression. Moreover, these researchers reported that suicides are more likely to occur during planting and harvesting seasons, when organophosphate pesticides are used intensively. To some extent, such harmful exposure may occur because pesticide regulations in other countries may be less stringent than those in the United States or because other countries' enforcement of regulations may be more limited, according to advocacy groups.

Regarding pesticide residues on domestic tobacco, overall, EPA officials did not find associated health risks that required mitigation. Further, the data we reviewed on 13 pesticides were consistent with statements from EPA officials that the residues on tobacco were below the agency's

[29]Of the 13 pesticides we reviewed, all of the currently approved products containing 1,3-D, disulfoton, and ethoprop are restricted use products, and some of the products containing chlorpyrifos are restricted use products.

[30]In June 2002, EPA issued a preliminary cumulative risk assessment for organophosphates for public comment. The agency, in consultation with scientific advisors, will revise the assessment on the basis of comments and data that were submitted. No date has been set to issue the final cumulative risk assessment for organophosphate pesticides.

[31]Maleic hydrazide and metalaxyl.

identified level of concern in 11 cases. EPA did not evaluate the remaining 2 pesticides—diazinon and pendimethalin—for use on tobacco. In the case of diazinon, evaluating residue data was not relevant because the pesticide was no longer approved for use on tobacco at the time EPA conducted its evaluation. In the case of pendimethalin, at the time we conducted this work, EPA had not yet reviewed the relevant data received from the manufacturer. EPA approved the reregistration for this pesticide, but its use on tobacco is subject to the agency's evaluation of this data.

Of the 11 pesticides that EPA evaluated for use on tobacco, 3 left residues on green or cured tobacco that were less than 0.1 ppm—and one left no residues at all. Specifically, the maximum residues of ethoprop on green tobacco were 0.01 ppm, the residues of chlorpyrifos were 0.09 ppm, the residues of pebulate on both green and cured tobacco were less than 0.02 ppm, and the plant metabolism study for 1,3-D showed no residues remaining on the plant. Manufacturers provided pyrolysis studies in two of the four cases in which the residue levels on green tobacco were 0.1 ppm or less. The pyrolysis study for ethoprop identified residues in the smoke that were below the agency's level of concern. The pyrolysis study for a by-product of chlorpyrifos that was initially of concern to the agency identified the by-product in the smoke. However, EPA subsequently concluded that the by-product, which accounted for more than 10 percent of the residue in the smoke, was not of toxicological concern because, unlike its parent compound, it does not act toxically on the nervous system.

Of the seven pesticides that progressed through EPA's tiered risk assessment approach because residues on cured tobacco were greater than 0.1 ppm, pyrolysis studies were conducted on five. No residues were found in the smoke of four of these five pesticides; the residues of the fifth were not of sufficient magnitude to require further study or evaluation. One of the remaining two pesticides with residue levels greater than 0.1 ppm was evaluated using a study of the health effects on rats exposed to residues in smoke,[32] and one was approved subject to EPA's review of requested additional residue data, including a pyrolysis study, to confirm EPA's assessment that residues on tobacco do not pose a risk to human health.

[32]EPA issued the reregistration decision for this pesticide, metalaxyl, in 1994. EPA officials said they would no longer substitute a rat inhalation study for a pyrolysis study. Researchers found no difference between rats exposed to smoke containing metalaxyl residues and those that were not.

The reregistration decisions for 7 of the 13 pesticides we reviewed were issued after EPA implemented guidance in 1999 requiring quantification of the risks of short-term exposure to pesticide residues in tobacco smoke.[33] However, none of the human health risk assessments or other documentation we reviewed contained this information—that is, the margin of exposure estimate—because the health risk assessments supporting these decisions were completed before the policy was implemented. For pesticides with many uses and much data, several years may elapse between the initial scientific assessment of the tobacco use and the issuance of the reregistration decision.

Not including the 13 pesticides mentioned above, we reviewed five additional health risk assessments EPA prepared after it developed the policy requiring the quantification of the risks of short-term exposure to pesticide residues in tobacco smoke that did include estimates of margin of exposure. EPA generally does not have concerns about adverse health effects when a margin of exposure is greater than 100—that is, when the pesticide causes no adverse effects at levels 100 or more times greater than the expected actual exposure to the pesticide. Consequently, a margin of exposure greater than 100 is considered to reflect risk that is below EPA's level of concern. As table 4 shows, EPA's recent health risk assessments of five pesticides approved for use on tobacco—four of which were newly registered and one reregistered—generally indicated that the margins of exposure were substantially greater than 100. Although one margin of exposure was below 100, EPA officials told us that because they used very conservative assumptions to estimate exposure, resulting in an extreme overstatement of actual exposure, EPA was not concerned about the potential for adverse health effects. For these five pesticides, EPA concluded that no mitigation related to the use on tobacco was required. Overall, EPA officials said that potential risks from exposure to residues on tobacco had never been high enough to require mitigation.

[33]The other 6 registration decisions were issued prior to the 1999 guidance.

Table 4: Margins of Exposure for Five Pesticides Approved for Use on Tobacco

Pesticide	Margin of exposure (male)	Margin of exposure (female)
Actigard	518,518	444,444
Carbaryl	104	89
Dimethomorph	1,400	1,200
Pymetrozine	3,333	2,857
Thiamethoxam	3,500	3,000

Source: GAO and EPA.

Note: GAO's analysis of EPA risk assessment documents.

EPA Evaluations of Studies Are Not Always Available

EPA requires that pesticide manufacturers provide most of the studies it considers in assessing the health risks of pesticides, and the agency's evaluations of these studies are critical to the assessment process. EPA officials were generally able to provide us with copies of the studies and evaluations we requested, but documentation of the agency's evaluation of the quality of the residue studies and other data upon which it relied to evaluate the potential for adverse health effects was inconsistent. Specifically, for eight of the pesticides, EPA officials were unable to provide their evaluations of the validity and reliability of residue data used in their assessments of potential health risks. In addition, for chlorpyrifos, EPA officials were unable to provide the residue studies and agency evaluations of them from the early 1980s. As a result, we examined subsequent EPA evaluations that referred to the results of these early studies and the agency's conclusion that the residues were below the level of concern. According to EPA officials, they were unable to locate the documents, in part, because not all records from this time have yet been converted to electronic format, and the paper copies could not be located among the substantial backlog of paper documents. EPA officials noted that each pesticide registration could consist of 100 or more studies from pesticide manufacturers, each of which requires one or more agency evaluations. The officials reported that, as resources permit, contract and agency staff are converting documents to electronic format to make them more readily available for review.

Federal Regulation of Pesticide Residues on Tobacco Is Limited

While EPA is required to regulate residues of pesticides approved for use on human food and animal feed crops, no such requirement applies to pesticides approved for use on tobacco. However, primarily as a matter of trade equity, USDA does (1) regulate residues of selected pesticides that are prohibited in the United States but that may be used on imported tobacco and (2) test certain types of imported and domestic tobacco to

ensure they do not exceed residue limits. USDA has not reevaluated the pesticides it regulates since 1989, although changes in the pesticides used on tobacco have occurred since then. Through its testing programs, USDA has found that a small fraction of imported and domestic tobacco exceeds the residue limits.

Federal Regulation Focuses on Pesticides Not Approved for Use on Tobacco

As discussed previously, EPA regulates pesticides in the United States by granting registrations, which permit the distribution, sale, and use of the pesticides according to directions identified on the label. EPA also regulates the residues of pesticides that are approved for use on human food and animal feed crops by setting tolerances—maximum concentrations of residues that may remain on crops. FDA and USDA test food and feed crops to ensure that residue levels do not exceed the tolerances EPA has set. Because tobacco is not used as food or feed, however, EPA does not set tolerances for residues of pesticides approved for use on tobacco,[34] and FDA and USDA do not test tobacco for maximum concentrations of residues of approved pesticides. Consequently, residues of pesticides approved for use on tobacco in the United States are not federally regulated.

Instead, federal regulation of pesticide residues on tobacco focuses exclusively on pesticides *not approved* for use on tobacco. The Dairy and Tobacco Adjustment Act of 1983, as amended, requires USDA to (1) establish maximum allowable concentrations for residues of selected pesticides that are not approved for use on tobacco in the United States but that are likely used on tobacco in some other countries and (2) test imported and domestic flue-cured and burley tobacco to ensure the residue levels do not exceed the maximum levels allowed.[35] In selecting which pesticide residues to regulate, USDA is to consider pesticides whose use on tobacco has been cancelled, suspended, revoked, or otherwise prohibited under FIFRA. The regulation helps ensure that domestic tobacco producers are not placed at an unfair disadvantage in the market because they are not allowed to use certain pesticides that may

[34]In addition, EPA does not require validation by an independent laboratory of the analytic method used to measure pesticide residues on nonfood crops as it does for methods used to measure pesticide residues on food and feed. The purpose of the external validation is to support enforcement of tolerances by ensuring that competent analysts can apply the method used.

[35]7 U.S.C. 511r.

be used in other countries; it also helps protect the public from exposure to the residues of highly toxic pesticides not approved for use on tobacco in the United States.

While the focus of U.S. regulation of pesticide residues on tobacco is on those pesticides not approved for use on tobacco, some other countries have set limits on residues of pesticides that are used on tobacco. Further, as in the United States, some countries limit the concentration of residues as measured on tobacco leaf. However, at least one country—Germany—limits the pesticide residues as measured in cigarettes and other tobacco products. Appendix III provides information on the limits established by Germany, Italy, and Spain.

USDA Has Not Reevaluated the Pesticides it Regulates Since 1989

USDA has implemented the Dairy and Tobacco Adjustment Act, in part, by setting 15 residue limits (maximum allowable concentrations) covering 20 pesticides currently not approved for use on tobacco in the United States that the agency believed were used in other countries. Most of the pesticides USDA regulates, such as DDT and toxaphene, are organochlorine pesticides. As discussed earlier, organochlorine pesticides persist in the environment and accumulate in the bodies of humans and animals, and many are highly toxic—a number of them have been banned for these reasons. Eleven of the 15 residue limits apply to individual pesticides and 4 apply to 2 or more pesticides in combination.[36] For example, aldrin and dieldrin are summed because dieldrin is the primary degradation product of aldrin. Table 5 lists the residue limits included in USDA's testing program, with the 12 organochlorine pesticides highlighted. As indicated in the table, methoxychlor is the only organochlorine pesticide included in USDA's testing program that is currently approved for other uses in the United States, such as on food crops.

[36]USDA's method of measuring residues is consistent with EPA's and FDA's.

Table 5: USDA's Residue Limits for Pesticides on Tobacco

Pesticide (organochlorine pesticides in bold)	Residue limit (parts per million)	Approved for nontobacco use(s)
1. Chlordane	3.0	No
2. Dibromochloropropane (DBCP)	1.0	No
3. Dicamba	5.0	Yes
4. Endrin	0.1	No
5. Ethylene dibromide (EDB)	0.1	No
6. Formothion	0.5	No
7. Hexachlorobenzene (HCB)	0.1	No
8. Methoxychlor	0.1	Yes
9. Toxaphene	0.3	No
10. 2,4-D	5.0	Yes
11. 2,4,5-T	0.1	Yes
12. Sum of aldrin and dieldrin	0.1	No
13. Sum of cypermethrin and permethrin	3.0	Yes
14. Sum of DDT, TDE, and DDE	0.4	No
15. Sum of heptachlor and heptachlor epoxide	0.1	No

Source: 7 CFR 29.427, USDA, and EPA.

Note: GAO's analysis of EPA data.

USDA's Agricultural Marketing Service (AMS) initially established maximum allowable concentrations of pesticides in August 1986 after determining the countries from which the United States imports tobacco, the pesticides that might reasonably be expected to be used on tobacco in those countries, and the pesticides not approved for use in the United States. In 1989, AMS revised the number of pesticides to its current total of 20 residues.

Although in 1986 USDA stated its intent to periodically reevaluate the pesticides it regulates, the department has not done so since 1989. According to officials at USDA, reevaluating the regulated pesticide residues has not been a priority of the department. However, since USDA selected the pesticides it would test in 1989, tobacco uses have been cancelled for more than 30 pesticides that had been approved for use on tobacco.[37] For example, by 2000, EPA had cancelled all tobacco uses of lindane—a highly persistent, organochlorine pesticide that may cause

[37]Not including the cancelled pesticides, about 100 pesticides had approval for tobacco uses in the 1990s.

cancer and harm the environment. USDA does not currently regulate pesticide residues of lindane because it was still approved for tobacco when USDA last reevaluated the regulated pesticides. Other pesticides, such as trichlorfon and diazinon, are also candidates for regulation—that is, pesticides no longer approved for use on tobacco in the United States but likely to be used in some other countries. As appendix III shows, some countries that set limits for pesticides used on tobacco have established them for trichlorfon and diazinon—one of the leading causes of acute insecticide poisoning for humans. However, because USDA has not revised the regulated pesticide residues it tests for, the department's testing program may not include some pesticides with characteristics similar to those of pesticides currently included in the testing program and that may still be used in other countries. Tobacco and pesticide experts with whom we spoke agreed that periodic reevaluations of the regulated pesticides would be appropriate. Furthermore, two of these experts—a toxicologist who has measured residues on tobacco for many years and a former government official who now represents tobacco producers—told us that many of the pesticides USDA currently regulates, particularly the organochlorine pesticides, warrant continued inclusion in the testing program because they are persistent in the environment, accumulate in the body, and continue to be used on crops overseas.

USDA Tests Imported and Domestic Tobacco for Regulated Pesticides

Also as required by the Dairy and Tobacco Adjustment Act, USDA tests certain imported and domestic tobacco to ensure that residues do not exceed the maximum allowable concentrations the agency established. USDA is required to test samples of two types of tobacco—flue-cured and burley—that are commonly imported from other countries and also produced in the United States to determine whether they conform to the pesticide residue limits. These two types of tobacco are the major components of cigarettes, and imports of them have continued to increase over time. For example, USDA reported that imports of flue-cured tobacco represented about 12 percent of the flue-cured tobacco used in the United States in 1980 and about 36 percent in 2001.[38] USDA is not required to test other types of imported tobacco, such as oriental tobacco, which is added to cigarettes for purposes of flavor and aroma but which is not grown in the United States.

[38]USDA Economic Research Service *U.S. Tobacco Import Update* (TBS-2002-02), Feb. 2003.

Tobacco is imported into the United States in large, sealed shipping containers that hold approximately 40,000 pounds of tobacco in 90 to 96 boxes weighing about 440 pounds each. In 1986, AMS began testing imported flue-cured and burley tobacco, which represented about 60 percent of the tobacco imported into the United States in 2001. Random samples of imported flue-cured and burley tobacco are tested for residues of the 20 regulated pesticides. AMS inspectors use a computer program to randomly select one box of tobacco from each shipping container. The domestic testing program began in 1989 and is administered by the USDA Farm Service Agency (FSA)[39] under a cooperative agreement with AMS. Similar to the AMS program for tobacco imports, FSA tests randomly selected samples of domestic flue-cured and burley tobacco for the 20 regulated pesticides not approved for use in the United States. FSA tests the portion of domestically grown flue-cured and burley tobacco that becomes loan stock (surplus tobacco) under USDA's tobacco price support program.[40] The proportion of domestic tobacco that becomes loan stock varies each year, depending on tobacco quality and demand from manufacturers, and has declined in recent years. Additional information about the domestic loan stock program is provided in appendix IV.

For 1999 through 2001, USDA's testing programs found less than 1 percent of domestically produced or imported flue-cured and burley tobacco with residue levels above the allowable levels.[41] According to agency officials, those results are consistent with results obtained since testing began in 1986. More specifically, for 1999 through 2001, the FSA domestic testing program found a small fraction of a percentage of domestically produced tobacco in excess of the limits. FSA found 4 samples of flue-cured tobacco and 24 samples of burley tobacco—representing more than 12,000 pounds of tobacco—that exceeded the maximum allowable concentrations of 2 of the regulated pesticides—methoxychlor and permethrin. AMS found residues of DDT/TDE/DDE, cypermethrin, and ethylene dibromide in excess of the limits on less than 1 percent of the imported tobacco entering the United States during this time.

[39]FSA was formed in 1994 from programs in several agencies, including tobacco programs from the former Agricultural Stabilization and Conservation Service.

[40]The price support program is administered by stabilization cooperatives—owned by tobacco growers—under agreement with USDA's Commodity Credit Corporation and auction warehouses.

[41]Imported tobacco percentage calculated by weight of imported flue-cured and burley tobacco; domestic percentage calculated by weight of flue-cured and burley loan stock.

If imported tobacco exceeds any of the limits, the importer is notified of the violation and may choose to appeal the result or reexport the tobacco to another country. When an importer appeals, AMS inspectors randomly select three additional samples for testing, and the residue levels for the four samples are averaged. If the average result is below the limits, the tobacco is cleared for entry into the United States. However, if the average exceeds the limits, the container of tobacco is denied entry and is typically reexported. Under the Dairy and Tobacco Adjustment Act, domestically produced flue-cured or burley tobacco not meeting the residue requirements must be destroyed. According to USDA officials, because of restrictions on the disposition of products contaminated by pesticides, boxes of domestic tobacco are typically disposed of in an approved landfill with a permit from EPA.

Conclusions

To ensure that pesticides can be used without posing an unreasonable risk to human health, EPA conducts risk assessments of exposures to the pesticides it evaluates for use in the United States, including exposure to pesticide residues on tobacco. EPA's decision to limit its quantitative assessment of the risks associated with pesticides on tobacco to the effects of short-term exposure, and not include the long-term exposure of smokers, recognizes that the pesticides are used on a crop that itself poses very significant health risks to humans through use in various consumer products—primarily cigarettes. Overall, EPA's health risk assessments show that the pesticides used on tobacco and other crops are probably a greater hazard for those who handle them than for those who inhale tobacco smoke. Nonetheless, while the risks of some exposures, such as acute poisoning, are clear, less is known with certainty about the effects of long-term exposure to small amounts of pesticides, such as residues in food and water, on tobacco, or in the environment.

While historically EPA has required pesticide manufacturers to provide data on the residues remaining on tobacco, its assessments of the health effects associated with exposure to the residues were not identified in risk assessment documents and generally were not quantified. Mirroring the improvements in risk assessment methods in recent years, EPA has adopted a more formal and consistent approach to evaluating the health risks associated with pesticides used on tobacco and has started to document, in its risk assessment documents, its conclusions on the potential for short-term risks from pesticide residues that may remain in tobacco smoke. As a result, interested parties are better informed about the potential risks, and EPA is appropriately more accountable for its assessments.

When used as intended—most commonly in cigarettes—tobacco is generally inhaled into the body. However, because it is not a food, tobacco is regulated as a nonfood crop with regard to pesticide residues. That is, no residue limits are established or monitored for pesticides approved for use on tobacco, as is done for foods. While the regulation of pesticide residues on tobacco is limited because it does not include pesticides approved for use on this crop, USDA tests tobacco for residues of 20 pesticides not approved for domestic use on tobacco, primarily for purposes of trade equity. Because many of the tested pesticides are known to harm humans and the environment, the USDA testing program helps minimize the public's exposure to some highly toxic pesticides. The universe of pesticides not approved for use on tobacco has grown since USDA selected the pesticides it tests, but USDA has not reevaluated the program's coverage in 14 years. The USDA testing program would be improved by assessing the current universe of pesticides not approved for use on tobacco and determining whether an update to its program is warranted.

Recommendation for Executive Action

To better protect the public from exposures to residues of pesticides not approved for use on tobacco in the United States and ensure that domestic tobacco producers are not placed at an unfair disadvantage relative to producers in other countries, we recommend that the Secretary of the Department of Agriculture direct the Administrators of the Agricultural Marketing Service and the Farm Service Agency to periodically review and update the pesticides for which they set residue limits and test imported and domestic tobacco.

Agency Comments

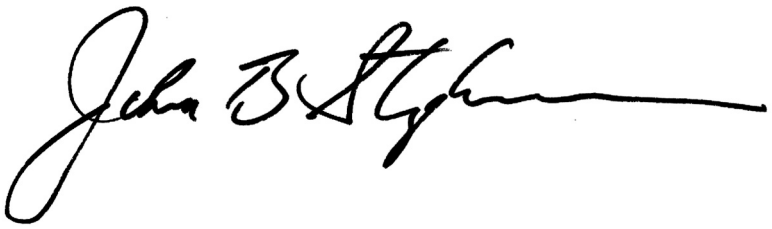
We provided copies of our draft report to EPA and USDA for review and comment. In commenting on the draft, EPA officials said we accurately characterized the agency's risk assessment process for pesticides used on tobacco, and USDA officials agreed with our recommendation to periodically review and update the pesticides for which the department sets residue limits and tests tobacco. USDA officials said they plan to annually review and update the testing program for tobacco.

We conducted our review from May 2002 through March 2003 in accordance with generally accepted government auditing standards. Our scope and methodology are discussed in appendix I.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time we will send copies of this report to the Administrator, EPA; the Secretary of Agriculture; and other interested parties. We will make copies available to others upon request. In addition, the report will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions, please call me at (202) 512-3841. Key contributors to this report are listed in appendix V.

Sincerely yours,



John B. Stephenson
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report provides information on (1) the pesticides commonly used on tobacco and the potential health risks associated with them; (2) how the Environmental Protection Agency (EPA) assesses and mitigates health risks associated with pesticides used on tobacco; and (3) how, and the extent to which, EPA, U.S. Department of Agriculture (USDA), and other federal agencies regulate and monitor pesticide residues on tobacco. In addition, this report provides information on the regulatory residue limits adopted by three countries that are significant importers of tobacco grown in the United States.

To identify the chemicals commonly used on tobacco, we reviewed pesticide-use databases developed by the National Center for Food and Agricultural Policy (NCFAP), a nonprofit research organization, under a cooperative agreement with USDA. These databases summarized national use of 235 pesticides on 87 food and nonfood crops for the period 1990 though 1998. These databases, compiled from more than 130 federal and state surveys and reports, include pesticide use on cropland in the coterminous 48 states and do not include new pesticides approved by EPA since 1997. We also reviewed data from national surveys conducted in the 1990s by the U.S. Geological Survey and USDA and from several tobacco-producing states—Kentucky, North Carolina, Tennessee, and Virginia. In total, 53 pesticides were identified as being used on tobacco in one or more of the surveys. Of these, 37 were identified in one or more of the surveys that included national data, and we refer to this latter group as the pesticides that were commonly used on tobacco in the United States during the 1990s. To identify the adverse health effects associated with these 37 pesticides, we collected and reviewed relevant human health risk assessments prepared by EPA's Office of Pesticide Programs. Where such assessments were not available, we reviewed documents from academic experts who maintain a database on pesticides and other toxic chemicals for USDA, and other programs within EPA. In addition we interviewed, and reviewed reports prepared or recommended by, experts on the human health effects of exposure to pesticides and other toxins at the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Center for Environmental Health, Johns Hopkins Bloomberg School of Public Health, and the Institute for Cancer Prevention (formerly the American Health Foundation).

To determine how EPA assesses and mitigates potential health risks from pesticide residues on tobacco, we reviewed agency policies and procedures on identifying the levels of pesticide residues on tobacco and the related health risks, and we interviewed EPA officials in the Office of Pesticide Programs who perform these tasks. In addition, we examined in

detail how EPA implemented its policies and procedures for 13 of the 37 pesticides commonly used on tobacco. That is, we reviewed pesticide residue studies submitted to EPA and EPA's evaluations of pesticide residues and their potential health effects conducted as part of the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act for 1,3-D, acephate, chlorpyrifos, diazinon, disulfoton, endosulfan, ethoprop, ethephon, maleic hydrazide, metalaxyl, methidathion, pebulate, and pendimethalin. We focused primarily on those pesticides for which EPA had completed registrations between 1994 and 2002. We did not independently evaluate the validity or scientific merit of the studies that EPA relied upon to reach its conclusions.

To determine the extent to which EPA, USDA, and other federal agencies regulate and monitor pesticide residues on tobacco, we met with cognizant officials and reviewed authorizing legislation, regulations, and documentation on how programs related to pesticide residues on tobacco are implemented. In addition, we analyzed USDA data on tobacco production, imports, and residue-testing results. We also interviewed academic and tobacco industry experts and reviewed residue data collected by North Carolina State University.

To provide information on other countries that have adopted regulatory limits on pesticide residues, we reviewed articles by academic experts on the international regulation of pesticides on tobacco. We provide information on three major importers of U.S. tobacco—Germany, Italy, and Spain—as examples of regulatory approaches in other countries, focusing on the residue limits they set. We did not examine how, or the extent to which, these countries monitor or enforce their pesticide residue limits. We updated and clarified the information on the three countries' residue limits provided in the articles with information from the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA), an international tobacco research organization, and officials responsible for oversight of pesticides and tobacco in Germany and Spain. To identify countries that import U.S. tobacco, we extracted data from the United States International Trade Commission's interactive tariff and trade database on the countries that received U.S. flue-cured and burley tobacco from 1996 through 2001.

We conducted our review from May 2002 through March 2003 in accordance with generally accepted government auditing standards.

Appendix II: Pesticide Use on Tobacco and Other Crops

Most of the pesticides used on tobacco are widely used on food and other crops. As shown in table 6, tobacco use of most pesticides represents a small portion of the total use. However, for some pesticides—dimethomorph, fenamiphos, flumetralin, maleic hydrazide, mefenoxam, and sulfentrazone—most of the use in 1994 through 1998 was on tobacco.

Table 6: Pesticide Use on Tobacco and All Crops, 1990-98

	Use in pounds—1992 survey (1990-93)		Use in pounds—1997 survey (1994-98)	
Pesticide	**Tobacco**	**All crops**	**Tobacco**	**All crops**
1,3-dichloropropene (1,3-D)	11,537,540	40,083,611	13,279,285	34,717,237
Chloropicrin	577,082	11,086,567	6,761,644	13,882,188
Maleic hydrazide	1,789,208	2,073,238	1,790,089	2,143,154
Acephate	1,570,457	3,389,865	871,899	2,462,354
Methyl bromide	5,356,748	44,196,554	685,026	32,803,943
Pendimethalin	321,931	20,281,766	473,718	27,284,718
Chlorpyrifos	685,554	14,764,535	406,822	13,463,879
Fenamiphos	257,142	614,937	379,841	726,675
Mancozeb	[a]	8,062,374	356,811	9,585,777
Flumetralin	[a]	[a]	352,742	352,742
Metalaxyl	371,645	855,400	271,368	659,997
Clomazone	[a]	1,801,776	217,617	2,531,160
Ethoprop	438,274	1,449,743	182,321	1,010,807
Endosulfan	[a]	1,796,726	172,766	1,601,195
Mefenoxam	[a]	[a]	139,199	210,101
Pebulate	412,000	673,046	131,665	343,322
Ethephon	113,238	2,701,284	102,130	5,407,986
Napropamide	191,840	500,695	92,622	448,400
Sulfentrazone	[a]	[a]	69,073	69,073
Imidacloprid	[a]	[a]	67,896	272,207
Aldicarb	159,044	4,022,468	59,719	4,277,552
Dimethomorph	[a]	[a]	36,818	51,536
Methomyl	57,137	2,754,907	29,773	1,997,489
Malathion	7,549	3,377,678	15,437	5,809,943
Disulfoton	52,578	1,806,527	13,495	1,196,066
Sethoxydim	[a]	1,350,566	9,579	1,717,271
Spinosad	[a]	[a]	2,815	117,315
Carbaryl	16,487	4,570,414	2,057	4,857,542
Fonofos	12,798	3,233,797	16	417,372
Benefin	56,963	478,205	[a]	161,983
Bacillus thuringiensis	[b]	[b]	[b]	[b]
Carbofuran	149,965	5,101,406	[a]	3,398,067
Diazinon	53,670	1,265,739	[a]	918,087
Diphenamid	81,624	105,009	[a]	[a]

	Use in pounds—1992 survey (1990-93)		Use in pounds—1997 survey (1994-98)	
Pesticide	**Tobacco**	**All crops**	**Tobacco**	**All crops**
Isopropalin	129,287	129,287	[a]	[a]
Methidathion	68	372,953	[a]	314,091
Trichlorfon	722	13,974	[a]	[a]
Grand total	**24,400,552**	**182,915,047**	**26,974,241**	**175,211,229**

Source: National Center for Food and Agricultural Policy.

[a]Not identified as being used in survey.

[b]Neither survey estimated the use of *Bacillus thuringiensis* in pounds.

Appendix III: Germany, Italy, and Spain Have Adopted Regulatory Limits for Pesticide Residues on Tobacco

Several countries that are major importers of U.S. tobacco have adopted regulations for specific pesticide residues on various forms of tobacco. For example, Germany's residue limits (maximum residue levels) apply to finished products, such as cigarettes, whereas limits in Italy and Spain generally apply to tobacco leaf. Although they have somewhat different regulatory approaches to pesticides on tobacco, Germany, Italy, and Spain differ from the United States in that they regulate residues of pesticides approved for use on tobacco in addition to regulating some residues of pesticides not approved for use on tobacco.

According to 2003 data from CORESTA—the Cooperation Centre for Scientific Research Relative to Tobacco—Germany, Italy, and Spain have residue limits on tobacco for 79, 100, and 58 pesticides, respectively.[1] Of the 37 pesticides commonly used on tobacco in the United States during the 1990s, Germany has limits for 20, Italy for 24, and Spain for 21 (see table 7). None of these countries have adopted limits for 7 of the pesticides commonly used on U.S. tobacco during the 1990s.[2]

Table 7: Residue Limits Adopted by Germany, Italy, and Spain for Pesticides Commonly Used on Tobacco in the United States during the 1990s

	Residue limits in ppm (country)		
Pesticide	**Germany[a]**	**Italy[b]**	**Spain[c]**
Acephate	[d]	1.5	[d]
Aldicarb	10.0	0.6 (green) 3.0 (cured)	5.0
Benefin	[d]	0.01	0.02
Carbaryl	3.0	3.0	0.1
Carbofuran	20.0	0.1	10.0
Chlorpyrifos	[d]	0.2	0.05
Diazinon	1.0	[d]	0.02
Dichloropropene	[d]	[d]	0.05
Diphenamid	1.5	0.1	5.0
Disulfoton	1.0	0.4	[d]
Endosulfan	20.0	1.0	[d]

[1]CORESTA is an international research association whose members are companies and research institutes having research and development activities related to tobacco. It has 190 members from 52 countries.

[2]The seven pesticides are *Bacillus thuringiensis*, chloropicrin, clomazone, dimethomorph, mefanoxam, spinosad, and sulfentrazone.

	Residue limits in ppm (country)		
Pesticide	**Germany[a]**	**Italy[b]**	**Spain[c]**
Ethephon	[d]	16.0 (green) 80.0 (cured)	[d]
Ethoprop	3.0	0.02	0.02
Fenamiphos	15.0	0.1	0.02
Flumetralin	20.0	2.0 (green) 10.0 (cured)	5.0
Fonophos	1.0	0.05	[d]
Imidacloprid	[d]	10.0 (green) 50.0 (cured)	5.0
Isopropalin	0.5	0.02	[d]
Malathion	3.0	0.5	0.5
Maleic hydrazide	80.0	80.0[a]	80.0
Mancozeb	50.0[e]	2.0 (green) 10.0[f] (cured)	0.05[g]
Metalaxyl	[d]	1.0	3.0
Methidathion	1.0	[d]	[d]
Methomyl	2.0	[d]	[d]
Methyl bromide	[d]	[d]	20.0
Napropamide	0.1	0.1	0.05
Pebulate	0.5	[d]	0.05
Pendimethalin	[d]	0.05	0.05
Sethoxydim	[d]	0.5	[d]
Trichlorfon	1.0	0.1	0.1
Number of limits for commonly used pesticides	**20**	**24**	**21**

Source: CORESTA and European Court of Auditors.

Note: GAO's analysis of CORESTA and European Court of Auditors data.

[a]Residue limit on finished products.

[b]Residue limit on green tobacco if not otherwise specified.

[c]Residue limit on dried tobacco.

[d]Country has not adopted limits for this pesticide.

[e]Residue limit established for the entire class of dithiocarbamates except metam.

[f]Residue limit established for the entire class of dithiocarbamates except thiram.

[g]Residue limit established for the entire class of dithiocarbamates except metam and thiram.

In addition to residue limits for approved pesticides, Germany and Italy collectively have residue limits on tobacco that apply to 15 of the 20 pesticides not approved for use in the United States that USDA monitors in its tobacco testing programs. The 15 pesticides are aldrin, dieldrin, chlordane, cypermethrin, DDT, DDE, endrin, ethylene dibromide, formothion, heptachlor, heptachlor epoxide, hexachlorobenzene,

methoxychlor, permethrin, and TDE. Further, where no specific pesticide limits are set for tobacco products in Germany, residues of pesticides not approved for use on tobacco in Germany may be present in amounts that are not likely to pose a risk to human health. In Italy and Spain, residues of pesticides not approved for use on tobacco in those countries must not exceed the limit of detection, generally between 0.01 ppm and 0.05 ppm. We did not examine how, or the extent to which, these countries monitor or enforce their pesticide residue limits.

From 1971 to 2000, researchers at the North Carolina State University (NCSU) collected limited data on the residues of various pesticides on some domestically grown tobacco. NCSU data for the 1990s included six pesticides for which Germany, Italy, or Spain have residue limits. The domestic tobacco tested by NCSU identified residue levels that were (1) consistently below the lowest limit for endosulfan, flumetralin, and metalaxyl; (2) generally above the limit for maleic hydrazide;[3] and (3) more varied for fenamiphos and the dithiocarbamates—a class of fungicides that includes mancozeb. For example, in 1995 residue levels on flue-cured tobacco were below the lowest limit for fenamiphos—0.02 ppm adopted by Spain—but exceeded this limit in 1992 and 1994. Also, in 1991 and 1997 residue levels of dithiocarbamates were generally lower on burley tobacco than limits in Germany and Italy—50 ppm and 10 ppm, respectively—but exceeded Spain's limit of 0.05 ppm.

[3]According to tobacco experts with whom we spoke, tobacco with high levels of maleic hydrazide may be blended with tobacco from other sources to reduce overall maleic hydrazide levels.

Appendix IV: USDA Tests Domestic Tobacco in the Loan Stock Program

The USDA Farm Service Agency (FSA)[1] tests the portion of domestically grown flue-cured and burley tobacco that becomes loan stock (surplus tobacco) under USDA's tobacco price support program for the 20 regulated pesticides.[2] To receive price supports, tobacco must be sold in USDA-approved auction warehouses and inspected by USDA graders. At the auction warehouse, each individual lot of tobacco is sold to the highest bidder. If the highest bid is below the government's loan (support) price, or no bid is received, the stabilization cooperative makes loans to growers whose tobacco does not bring the minimum price at auction with funds borrowed from USDA's Commodity Credit Corporation. The growers' tobacco, which is consigned to the cooperative as loan stock, is pledged as collateral to the credit corporation for the money borrowed. The cooperative receives, processes, stores, and later sells the loan stock tobacco when demand increases, with the proceeds used to repay the credit corporation loan, plus interest. An alternative to traditional auction marketing—growers contracting to sell their tobacco directly to manufacturers—also reduces the amount of tobacco going to auction and thus potentially to loan stock. For the most recently completed marketing season—growing year 2001—20 percent of domestic tobacco was sold at auction, and 2.4 percent became loan stock.

After auction, the tobacco is processed in distinct "runs" of approximately 100,000 pounds, when the tobacco is stemmed, redried, finely chopped, and placed into boxes holding approximately 440 pounds. The tobacco cooperative randomly selects one box from each run and draws a one-pound sample of tobacco for pesticide testing at USDA's laboratory. If the sample exceeds any of the residue limits, the box of tobacco from which it came is destroyed. The adjacent boxes, processed before and after the original box, are also sampled. The testing continues with adjacent boxes of tobacco until the samples are found to be below the residue limits. Because the samples are drawn by the tobacco cooperatives, FSA resamples 5 percent of the tested inventory (or 25 samples, whichever is less) for oversight purposes each year.

[1]FSA was formed in 1994 from programs in several agencies, including tobacco programs from the former Agricultural Stabilization and Conservation Service.

[2]The price support program is administered by stabilization cooperatives—owned by tobacco growers—under agreement with USDA's Commodity Credit Corporation and auction warehouses.

Historically a substantial portion of domestic tobacco was sold at auctions in conjunction with the tobacco price support program, but in recent years most domestic tobacco has been sold under contract directly to cigarette manufacturers—approximately 80 percent in 2001. Officials from USDA and tobacco associations told us the market has changed because manufacturers asserted that auction markets were not providing quality tobacco with the characteristics they required. The recent, dramatic shift in the way tobacco is marketed—with a 60 to 80 percent reduction in the amount of tobacco at auction—has decreased the amount of domestic tobacco that potentially becomes loan stock and thus is tested. Although the amount of domestically produced tobacco that becomes loan stock has varied greatly, an average of 13 percent became loan stock over the past decade. In 2001, only about 2 percent of domestically produced tobacco has become loan stock, reducing the amount of domestic tobacco subjected to pesticide testing. The officials with whom we spoke said that this change is not likely to be reversed.

Appendix V: GAO Contacts and Staff Acknowledgments

GAO Contacts

John B. Stephenson, (202) 512-3841
Christine Fishkin, (202) 512-6895

Acknowledgments

In addition to those named above, Nancy Crothers, Laura Gatz, Terrance Horner, Richard Johnson, Ilga Semeiks, Tina Smith, and Cheryl Williams made key contributions to this report.

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