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*Understandably, this is a big issue for NACA.
They are not interested in restricting the export
of agricultural chemicals.*

INFORMATIONAL MEMORANDUM FOR THE SECRETARY

THROUGH: Jack C. Parnell
Deputy Secretary

Jo Ann R. Smith
Assistant Secretary
Marketing and Inspection Services

FROM: Daniel D. Haley
Administrator

SUBJECT: Pesticide Export Reform Act

ISSUE:

The Pesticide Export Reform Act and related amendments deal with modifications to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, concerning the export of pesticides to other countries.

BACKGROUND:

Current law permits the export of pesticides to other countries with some restrictions. Unregistered pesticides exported shall be properly labeled, i.e., shall be prepared and packaged according to a foreign purchaser's instruction so labels on exported pesticides are able to be read and understood by users. Also, the purchaser must acknowledge (by signed statement) that it is understood that a pesticide is not registered for use in the United States. A copy of such a signed statement is transmitted to an appropriate official of the government of the importing country. Current law permits the exportation of both registered and unregistered pesticides.

Both the House and Senate versions, which are very similar, of export pesticide reform provisions of the Farm Bill attempt to increase the regulation of all pesticides, whether registered or unregistered in this country, when destined for export. These versions attempt to protect other countries from harmful pesticides, and in turn ensure U.S. consumers that foreign-produced foods do not contain these same harmful pesticides when these foods are brought back into this country.

The Secretary

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Our concerns regarding these provisions of the proposed Farm Bill are based on a number of premises. First, controlling the export of pesticide products from our country alone will not completely resolve the problems associated with pesticide misuse in other countries. The United States is not the only country from which pesticide products are exported. Many countries, including those in the developing world, have manufacturing capabilities to produce and export the same pesticide products that have been banned or severely restricted in the United States or other industrialized countries. Second, Environmental Protection Agency (EPA) regulatory decisions are based upon risk benefit criteria for the United States, which may differ in other countries. Third, USDA believes that it may be more effective for foreign countries to concentrate on controlling the use of pesticide products, and assuring the availability of quality products to those wishing to use them, rather than categorically banning certain classes of U.S. pesticides from international trade. Current FIFRA regulations require the warning of foreign purchasers and their governments of any actions taken against a pesticide product not registered for use in the United States.

In addition, the public has expressed concern about the possibility of importing foods which may contain illegal residues of pesticides that can no longer be used for domestic producers. This threat has been characterized as a "circle of poison." The data from the Food and Drug Administration (FDA) and USDA regulatory residue monitoring programs have shown that residues levels are infrequently encountered in imported food products. For fiscal year 1988, more than 99 percent of the 10,475 imported food samples tested by FDA were at or below the accepted tolerance levels or residues were not detected in any amount.

Existing law already bars the import of foods containing residues not allowed under U.S. tolerance regulations. The House and Senate provisions impose a number of burdensome new information demands on foreign producers not required of domestic producers of pesticides, and would likely be challenged under the General Agreement on Tariffs and Trade rules. These international trade concerns should be evaluated and resolved before a bill moves through the Congress.

RECOMMENDATION:

The Administration's position has been to develop new or enhanced authority through an amendment to FIFRA which will allow the EPA to implement the international system of prior informed consent under the auspices of the Food and Agriculture Organization and the United Nations Environment Programme, developed with the

The Secretary

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support and leadership of the U.S. This approach would require EPA to block the export of a banned or severely restricted pesticide to a country which objects to receiving it, provided that the importing country certifies that it will not buy the pesticide from another country or manufacture it for its own use. This system would allow other nations to make their own decisions on pesticide use, based on all relevant health and safety information. The Secretary of Agriculture and the Administrator of EPA strongly support such an amendment as well as other changes to our pesticide and food safety laws contained in the Administration's food safety proposal transmitted to Congress in March.

Some alternative provisions to consider are the following:

- o Countries that receive unregistered pesticide products from U.S. manufacturers could be required to establish a system of self-certification that any food exported to the U.S. will not contain detectable concentrations of these compounds. These self-certifications would be subject to verification testing at ports of entry in the U.S.
- o Countries that do not wish to import unregistered pesticide products from the U.S. could be required to certify that they will not produce the pesticide or a similar product with the same active ingredient for export purposes only.

Reviewed by: _____

AMS/CSSD/WJFranks/jc/447-3075/8/22/90



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

Honorable E (Kika) de la Garza
Chairman, Committee on Agriculture
U.S. House of Representatives
1301 Longworth House Office Building
Washington, D.C. 20515

Dear Kika:

We appreciate the opportunity to respond to your request for a report on H.R. 3850, a bill entitled "The Federal-State Pesticide Regulation Partnership Act of 1991" which amends various sections of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to make it clear that the Act pre-empts the regulation of pesticides by local governmental units.

The Department of Agriculture supports the enactment of H.R. 3850 to amend FIFRA and provide clear authority to Federal and State governments in the area of pesticide regulation.

The issues surrounding pesticide regulation are complex and diverse and require sound decisions based on science and facts. Local governments rarely have the scientific and technical expertise to make such decisions on these complex issues. Agriculture production and economic viability could be greatly reduced by unsound regulations imposed by local governmental units. Agriculture opportunities and jobs could be reduced in the many sectors of agriculture production and services due to the inability to work across local jurisdictions. We feel strongly that the authority for pesticide regulation must be maintained on a Federal and State level and that local governmental units be pre-empted.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Edward Madigan
Secretary

This has information on the President's Food Safety Plan, which NACA supports for the most part. They are opposed to more restrictive Congressional proposals.

Statement of Daniel D. Haley, Administrator
Agricultural Marketing Service
United States Department of Agriculture
before the
Subcommittee on Department Operations, Research, and
Foreign Agriculture, Committee on Agriculture
United States House of Representatives
on H.R. 3742

"Pesticide Safety Improvement Act of 1991"
November 19, 1991

Mr. Chairman, Members of the Committee:

I am pleased to be here today to discuss H.R. 3742,
"Pesticide Safety Improvement Act of 1991." Accompanying me
today is Dr. Craig Reed, Director of the Science Division of the
Agricultural Marketing Service.

We can all agree that we need to improve the Federal
Government's ability to protect American consumers and the
environment from potential dangers posed by the use of pesticide
chemicals. In order to do this, we need to make major revisions
to the Federal Insecticide, Fungicide, and Rodenticide Act
(FIFRA) and to the Federal Food, Drug, and Cosmetic Act (FFDCA).

In considering the changes to these laws, four fundamental
principles must be taken into consideration:

1. Protect the Public's Health. Prevent harmful exposure
of the public to pesticides in the food supply.
2. Strengthen the oversight of pesticides and their use.
Assure that unsafe pesticides are not used and develop safe
alternatives.
3. Simplify the regulation of pesticides to assist farmers
and the chemical industry in the application of food safety laws.

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4. Build public confidence. Assure that the American food supply will remain safe.

We commend the Committee for holding these hearings and are hopeful that through the collective efforts of the Congress, the Executive Branch, the agricultural sector, the chemical industry, and public interest groups, we will be able to achieve comprehensive reform to our food safety laws concerning pesticides. My testimony will focus on certain key provisions of H.R. 3742 which are consistent with the Administration's position on food safety reforms, those areas of H.R. 3742 which we believe need further clarification, and those provisions of H.R. 3742 on which we have concerns.

Mr. Chairman, we recognize your efforts to seek legislative reform that is both sensitive to the needs of the environmental and agricultural communities, and enhance the safety of our food supply. Several of the components in H.R. 3742 were endorsed by the President's comprehensive food safety plan.

The President's package of food safety reforms marks a major step forward to enhance public health and protect the environment. Enactment of the plan will allow EPA to act more promptly and effectively to deal with problem chemicals and improve the agency's ability to act on the basis of sound science.

The President's plan calls for:

1. Establishing "negligible risk" tolerance levels which

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would be applicable to raw commodities as well as processed foods, moving away from what has been characterized by some as the "zero" risk standard of the Delaney clause;

2. Establishing a system that would provide national uniform pesticide tolerance standards;

3. Requiring periodic review of pesticide registrations to ensure that pesticides meet contemporary standards for health and safety;

4. Improving EPA's flexibility in exercising its suspension authority;

5. Revising the cancellation process, replacing the adjudicatory hearing with notice-and-comment procedures;

6. Enhancing the enforcement provisions of FIFRA, providing for improved authorities and increased penalties for violations; and

7. Providing for appropriate coordination and consultation among Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), and Health and Human Services (HHS) in the pesticide cancellation and suspension process.

KEY PROVISIONS

Single Pesticide Tolerance Standard. USDA supports legislation that would make the same safety standard applicable to pesticide residues in both raw agricultural commodities and

processed food.

Under current law, there are two different legal standards for pesticide residues in food. Tolerances for pesticide residues in raw agricultural commodities are subject to risk/benefit determinations under Section 408 of FFDCA. Tolerances for pesticide residues that concentrate in, or are applied to, processed food are issued under Section 409 of the FFDCA, which contains the Delaney clause which if literally interpreted would mean a "zero risk" standard.

In 1987, the National Academy of Sciences (NAS) recommended that pesticide residues in raw and processed food should be regulated on the basis of consistent standards and that a negligible risk standard should apply to all pesticide residues in food. Consistent with the NAS recommendations, this Administration supports elimination of application of the Section 409 "Delaney clause" to pesticide residues in processed food and supports a uniform negligible risk standard for all pesticide residues in food. Accordingly, we support inclusion of the provision in H.R. 3742 to rectify problems associated with the "zero risk" standard of the Delaney clause.

Negligible Risk Standard. USDA supports a negligible risk standard that would require EPA to set pesticide tolerances at a level adequate to protect the public health. We support legislation that would implement the NAS recommendation for a uniform negligible risk standard for pesticide residues in food

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and, in addition, clearly establish a risk/benefit standard. This would give EPA explicit statutory authority to ignore de minimis or insignificant dietary risks and permit EPA to focus attention on the highest risk pesticides.

The definition of "negligible risk", as proposed by H.R. 3742, should not identify a specific level of risk that would be considered negligible or a numerical expression of that level. Because science and the degree of knowledge and confidence in risk assessment is constantly evolving and improving, it is important to preserve EPA's ability to keep pace with scientific progress in assessing risks.

It is important that EPA continue to have the flexibility to calculate dietary exposure on the basis of the (1) percent of raw agricultural commodities or processed food actually treated with a pesticide, and (2) other data to more closely approximate actual exposure, including information on actual residue levels detected in the treated commodities and the processed food produced from those commodities. This would help avoid unrealistic exposure assessments and would assist in developing more accurate risk projections.

The prescriptive nature of the negligible risk standard in H.R. 3742, coupled with the use of the 90th percentile of consumption, could have the effect of further reducing the amount of pesticide use available for any crop.

We would also note that H.R. 3742 is silent with respect to consultation with USDA and FDA with respect to implementing and

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enforcing "negligible risk" standards. We feel strongly that such consultation is necessary to ensure proper implementation and enforcement of the negligible risk standards.

Consideration of Pesticide Benefits. The process should provide for consideration of benefits, not let benefits drive the process. It should be made clear that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that the risk is reasonable in light of both risks and societal benefits, and that reasonable efforts are made to develop alternatives.

This would assure that pesticide tolerance decisions are not made in isolation, and that EPA may fully consider all relevant factors.

USDA provides information to EPA on the necessity of the use of the chemical for the production of an adequate, wholesome, and economical food supply. EPA then considers this information in making tolerance decisions for pesticide residues on raw agricultural commodities. The President's plan would extend that authority to tolerance decisions for pesticide residues on processed food.

Pesticides provide important societal benefits, including valuable health, nutritional and economic advantages to consumers. The loss of important food use pesticides can result in heightened risk of disease causing organisms in food, food price increases, adverse effects on food quality, and reduction

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in the availability of nutritional food choices. The impact on consumers and their diet can cause particular hardship on the low income sector of our society. In view of the broad range of benefits of food use pesticides, it is important that EPA be allowed to balance benefits against risks in all pesticide tolerance decisions. Let me reiterate, H.R. 3742 does not provide for the consideration of direct producer benefits.

In short, Mr. Chairman, we are opposed to any benefits considerations short of those proposed in the President's food safety package.

National Uniformity. Under current law, States may set tolerances for pesticide residues in foods that are lower than those established by EPA. In recent years, a number of States have set lower tolerances for certain pesticides (including EDB and Alar), thus creating the potential for significant burdens on interstate commerce. We support legislation that sets national uniformity of tolerances for pesticides registered or reregistered under the comprehensive safety data requirements. This uniformity would avoid the consumer confusion and substantial burdens on interstate commerce caused by special tolerance requirements set by States and political subdivisions that may not be warranted by any public health or food safety consideration.

We also support a mechanism for States to petition the EPA for a waiver from a uniform Federal tolerance where the State

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could establish adequate justification. Waivers should be authorized where EPA has concluded that a more stringent State tolerance is justified by special local circumstances, such as unusual food consumption patterns.

As to tolerance setting under FFDCA, the provisions of H.R. 3742 for waivers for special local circumstances are very similar to the President's Plan. With respect to pesticide regulation under FIFRA, however, we defer at this time, pending further discussion and review within the Administration.

Suspension. H.R. 3742 retains the current definition of "imminent hazard" in FIFRA which requires EPA to take into account environmental, economic, and social impacts before it can suspend a pesticide. (We note that suspension, cancellation and tolerance setting entails consideration of benefits that are included in the President's plan.) It further provides that where a suspension is reinstated following a court decision overturning a cancellation order, such suspension order shall terminate 45 days after such reinstatement.

We question whether the "45 days" timeframe for termination of the suspension order and if this is an appropriate timeperiod to correct what appears to be a technical problem. We urge the Committee to clarify this provision.

Cancellation. We strongly support a more streamlined approach in the cancellation process as outlined in the

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President's Plan and frequent, meaningful, and early consultation in all cancellation matters as well as due process to producers, the public, and companies affected by such decisions.

Minor Use. Mr. Chairman, we commend you for addressing the minor use issue. As you are aware, pesticide registrations have already been canceled for numerous fruit and vegetable crops. Many more uses are expected to be dropped in the near future. USDA and EPA have recognized that much needs to be done if agricultural producers are to deal successfully with the consequences of reregistration. We are working aggressively with the chemical companies and producer groups to respond to current and anticipated problems so that we may better identify and meet the needs of minor use producers.

H.R. 3742 attempts to improve the minor use pesticide issue by amending voluntary cancellation provisions. However, preventing a registrant from dropping a labeled use if anyone objects to the deletion, could result in total pesticide use that exceeds negligible risk, and could result in forcing registrants to list uses on their labels that they do not wish to support for a variety of reasons.

The Department strongly supports minor pesticide uses and believes that approaches such as third party registrations, the Interregional Research Project No. 4 (IR-4) program, development of alternative pesticides, actual residue data where available and alternative funding for data production are

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preferable to the legislative remedy proposed by H.R. 3742. Let me assure you, however, that we are open to legislation to address minor use and look forward to working with you on this very important issue.

Pesticide Use and Dietary Exposure Information. H.R. 3742 adds a section directing the Secretary of Agriculture to gather and furnish information to the Administrator of EPA on food consumption patterns, use of pesticides, and actual levels of pesticide residues on food items.

Current Department surveys are conducted as a part of the National Nutrition Monitoring System. They provide on an ongoing basis, information on food consumption patterns of the total population and large subpopulations, such as adult women and school-age children. The Department is working with EPA and FDA on these surveys and they are currently being expanded to improve coverage of subgroups at nutritional risk, such as low-income groups. The surveys will require further expansion to enable them to provide up-to-date information on smaller subgroups such as infants or pregnant women. H.R. 3742 goes beyond the level of effort currently envisioned and needs further clarification.

Inspections. H.R. 3742 provides very broad entry and inspection authority to EPA, by consent or warrant, of places not open to the general public where the person who owns the property provides consent or where authorized by warrant. We agree with

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our colleagues at EPA that this provision needs further clarification as to its intent and scope.

CONCLUSION

We agree that the Federal laws for food safety and pesticide use need to be amended in a manner that will enhance pesticide regulation and not inhibit new scientific and technological advances. It is imperative that we proceed in a responsible manner as we work together in considering the various food safety bills pending so as not to jeopardize this Nation's agricultural industry which represents some 20 percent of our GNP. We urge the Committee in its deliberations to carefully consider any impacts of legislation affecting American agriculture and the consuming public.

Mr. Chairman, this concludes my statement. I will be glad to respond to any questions the Committee may have.



United States
Department of
Agriculture

Agricultural
Marketing
Service

P.O. Box 96456
Washington, DC
20090-6456

*This is
an important one
to read*

• February 6, 1992

INFORMATIONAL MEMORANDUM FOR SECRETARY EDWARD MADIGAN

THROUGH: Jo Ann R. Smith, Assistant Secretary
Marketing and Inspection Services

FROM: *for* Daniel D. Haley *A.D. Mancero*
Administrator

SUBJECT: Federal Pre-emption under FIFRA (H.R. 3850) -
March 4 Hearing

ISSUE:

Chairman Rose of House Agriculture's DORFA Subcommittee has scheduled a hearing March 4 on H.R. 3850 (by Congressman Hatcher/Marlenee and 54 co-sponsors), a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to make it clear that FIFRA pre-empts the regulation of pesticides by local governmental units.

DISCUSSION:

*including
NACA
→*

The Supreme Court, on June 21, 1991, in Wisconsin Public Intervenor v. Mortier, Supreme Court 89-1905, ruled that FIFRA does not pre-empt local governments from regulating the use of pesticides. This interpretation was advocated by the Environmental Protection Agency (EPA) in arguments before the Court and applauded by environmental groups. However, numerous farm, agri-business, pest control, and chemical manufacturers launched a legislative effort to reverse the Court decision and bi-partisan legislation was subsequently introduced by Congressman Hatcher/Marlenee (H.R. 3850) and 54 co-sponsors and Senators Mitchell, Pryor, Dole, Cochran, Bond, Shelby and Boren. (S. 2085). At this time, EPA has expressed serious concerns with these bills.

While the President's Food Safety Plan of 1989 dealt with the issue of Federal pre-emption under the Federal Food, Drug, and Cosmetic Act (FFDCA) as it relates to the reregistration process pursuant to the 1988 FIFRA amendments, it did not address FIFRA pre-emption since transmittal of the President's Food Safety Plan occurred prior to the Supreme Court decision. The President's Plan proposed to amend FFDCA to provide for national uniformity



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of setting chemical tolerances and pre-empted State and local laws, but allowed for waiver where special local circumstances warrant a more stringent limit.

Following are some of the arguments for and against H.R. 3850.

Pros:

(1) Local governmental units lack the technical resources and expertise to regulate pesticides with competence.

(2) Both EPA and the States can adopt local pesticide use restrictions to protect groundwater, wildlife and human health.

(3) Conflicting local ordinances could lead to regulatory chaos and prevent cost-effective pest control, limit agricultural and food marketing productivity and prevent control of disease carrying pests.

(4) Local regulation is incompatible with international negotiating efforts to establish greater harmonization of sanitary and phytosanitary standards to facilitate global commerce.

(5) Local regulation is inconsistent with Bush Administration efforts to establish national uniformity in other areas of food safety and marketing (e.g. nutrition labeling and residue tolerances).

(6) Regulation of pesticide use goes beyond the scope for which local governmental jurisdictions have been created; such control should be vested with EPA and the States.

(7) Agriculture production and economic viability could be greatly reduced by unsound regulations imposed by local governmental units, thus reducing jobs in many sectors of agriculture due to the inability to work across local jurisdictions.

Cons:

(1) EPA, in its design of national regulations, cannot be sufficiently responsive to address the myriad of local problems caused by pesticides;

(2) Federal regulations are intended as a "floor" and should not preclude States and localities from being more protective;

(3) Much concern exists that EPA and the States are not adequately protecting sensitive individuals from pesticides used for lawn, garden, and indoor care;

(4) To deprive local jurisdictions authority to control pesticide use is contradictory to other environmental law (groundwater under Safe Drinking Water Act), and infringes on States' rights in protecting health and safety of their citizens.

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SUMMARY:

Accordingly, AMS recommends the Administration support H.R. 3850. Attached for your consideration is USDA's proposed response on H.R. 3850.

Attachment

United States
Environmental Protection
Agency

Pesticides And
Toxic Substances
(H7506C)

August 1991



FOR YOUR INFORMATION

THE DELANEY PARADOX AND NEGLIGIBLE RISK

The Environmental Protection Agency (EPA) regulates pesticides under two laws, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA requires that pesticides be licensed or "registered" with EPA prior to sale and use in the United States. The FFDCA gives EPA the authority to set legally enforceable limits, or "tolerances" for pesticide residues in foods. The FFDCA specifies that a food containing a pesticide for which no tolerance has been established, or with a residue exceeding an established tolerance, is considered adulterated and subject to seizure. EPA sets tolerances for pesticide residues remaining in raw foods under section 408 of the FFDCA. Under section 409 of the FFDCA, EPA sets food additive tolerances for pesticide residues which concentrate in processed foods above raw food tolerances, or are the result of pesticide application during or after food processing.

EPA's task of regulating pesticides and their residues in foods has been complicated by the different standards in FIFRA and FFDCA, and the different standards within the FFDCA itself. In particular, section 409 of the FFDCA contains the "Delaney Clause" which, when read literally, absolutely prohibits the establishment of food additive tolerances where evidence indicates that the pesticide may cause cancer in humans or animals, no matter how small or minimal the risk. On the other hand, FIFRA requires EPA to weigh the risks and benefits of a pesticide when deciding whether to allow the continued use of that pesticide. Similarly, section 408 of the FFDCA requires EPA to consider the necessity for the production of an adequate, wholesome and economical food supply in setting tolerances. Thus, in contrast to the Delaney Clause, FIFRA and section 408 of the FFDCA require consideration of the level of risk and the benefits of pesticide use.

This inconsistency in standards has been called the "Delaney Paradox" by the National Academy of Sciences (NAS), an expert non-governmental body. In 1985, EPA commissioned the NAS to examine the scientific and regulatory implications of the varying food safety standards contained in FIFRA and the Delaney Clause of the FFDCA. One result of the inconsistency is that the same pesticide residues which may be legal on a raw food could render a processed food unacceptable under the law. Under these circumstances, for example, EPA could set a section 408 tolerance for apples for a pesticide that posed a negligible risk of cancer. But if the apples were processed into apple juice and pesticide residues became concentrated to higher levels than in the raw commodity*, then under a strict interpretation of the Delaney Clause, EPA could not set a section 409 tolerance for processed apples. As

*Various processes such as milling, drying, or juicing in some cases cause the relative amount of pesticide to increase in the processed food as compared to the raw food. For example, in drying, the ratio of the amount of pesticide to the rest of the food could increase as water is removed. Concentration of residues does not necessarily make a food unsafe for consumption because dietary exposure to a pesticide depends on the concentration of pesticide remaining on food and the quantity of food consumed.

a matter of practice, EPA would then decline to set a section 408 tolerance for the pesticide in raw apples because it would be difficult to ensure that treated apples would not be processed into apple juice. Consequently, EPA would not allow use of the pesticide on apples at all, even if EPA believed that it was as safe as other apple pesticides already on the market.

In 1987, the NAS issued its study of the Delaney Clause, and reached four principal conclusions:

1. All pesticides should be regulated on the basis of a consistent standard, so that there is no "double standard" for raw vs. processed foods or for old vs. new pesticides. The NAS found no public health reasons for treating residues on raw or processed foods differently.
2. A uniform "negligible risk" rather than a "zero risk" standard for carcinogens in food, consistently applied, would best enable EPA to improve the overall safety of the food supply, and would result in only modest reductions in the benefits of pesticide use to farmers.
3. EPA should set its regulatory priorities by focusing first on the most worrisome pesticides used on the most-consumed crops.
4. The Agency should adopt a comprehensive analytical framework for forecasting the broad-scale impact of its pesticide-specific regulatory actions on the overall safety of the food supply.

Based on these conclusions, EPA has attempted to implement a consistent negligible risk standard under each of the provisions of the laws governing pesticides. In the case of FIFRA and FFDCA section 408 which require risk/benefit balancing, EPA has treated risk in the range of 1 in 1 million (meaning that, at most, an individual would have a one in one million chance of developing cancer if exposed over a lifetime) as a reference point and required that substantial benefits be demonstrated for any risk which exceeds that level. As to the Delaney Clause, EPA has adopted an interpretation which does not prohibit the establishment of food additive regulations posing a de minimis risk (a risk so minimal that it is not worth considering). These two actions, while not completely equivalent, allow for each of the standards under the various provisions to be substantially more compatible.

EPA's interpretation of the food additive laws was challenged in a petition filed on May 25, 1989 by the State of California, the Natural Resources Defense Council (NRDC), Public Citizen, the AFL-CIO, and several individuals. The petition requested that EPA revoke 14 food additive regulations for 7 pesticides. The petitioners argued that the food additive regulations should be revoked because the pesticides to which the regulations applied were probable or possible animal carcinogens and thus the regulations violated the Delaney Clause. On February 19, 1991, EPA issued a Final Order upholding its interpretation that the law supports a de minimis exception to the Delaney Clause for pesticide uses which create at most a de minimis risk. In applying this de minimis standard, EPA declined to revoke several food additive tolerances but found that two food additive tolerances exceeded a de minimis level and would have to be revoked. The petitioners have sought review of this decision in federal court.

EPA has been working with the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) to develop legislation, as part of the President's Food Safety Plan, which would amend FIFRA and FFDCA to establish a consistent "negligible" risk standard for evaluating the safety of pesticide residues in raw and processed foods. Additional information is available from EPA on the provisions of the President's Food Safety Plan.

United States
Environmental Protection
Agency

United States
Department of
Agriculture

21T-1007
April 1991

Pesticides and Toxic Substances (H-7508W)



Minor Use and Pesticide Reregistration How Growers Can Participate

What is a Minor Use?

Minor use pesticides are those that produce relatively little revenue for their manufacturers (or "registrants"), considering the cost of maintaining these registrations. However, minor use pesticides are of major significance in agricultural production, to growers as well as consumers. Without these small-scale but vital pesticide uses, many of the fruits, vegetables and ornamentals that we enjoy in the U.S., worth billions of dollars, could not be grown successfully.

Minor use pesticide registrations include:

- * many, if not most, pesticide uses on fruit and vegetable crops;
- * uses on commercially-grown flowers, ornamentals, trees and turf grass;
- * infrequent or very limited acreage use on major crops, such as wheat, soybeans or corn, where the pest problem being treated is not widespread.

What's the Minor Use Problem?

Minor uses are not economically attractive to the pesticide industry since the amount of pesticides sold for these uses is limited and revenues are low, while the costs of obtaining and maintaining these registrations are substantial. In addition, pesticide registrants can face steep liability costs if their products do not perform as intended and high value crops are lost. Thus, there is little economic incentive for pesticide manufacturers to register new products or reregister existing

ones for minor uses, or to add minor uses to currently approved pesticide labels.

How Does Reregistration Affect the Problem?

EPA is conducting a comprehensive review of all older pesticides to be sure they meet current scientific and regulatory standards. Changes to the Federal pesticide law in 1988 set deadlines for pesticide registrants to provide updated studies on the human health and environmental effects of their products, and for EPA to review these studies and make reregistration decisions. Registrants must pay substantial fees to fund this program.

To support their pesticide products through reregistration, registrants will have to conduct studies needed to complete EPA's data requirements, and pay the required fees. Because of the costs involved, many registrants are finding that it is not economical to support some or all uses of their products. The most vulnerable uses are those that are least profitable—minor uses.

What's the Likely Outcome?

Already, the number of registered pesticide products has dropped significantly as a result of the accelerated reregistration program. About 20-25,000 out of 45,000 registered products have been cancelled, and more will follow. Many of the products cancelled so far have not been produced or sold for years, so they probably will not be missed. However, as the number of registered uses continues to

decline, it is inevitable that some important minor uses will be among those that registrants are unwilling or unable to support. Unless someone steps in to support these uses, they will be lost.

What Is Being Done About the Minor Use Problem?

EPA, USDA and the agricultural chemical companies are concerned about the minor use reregistration problem, and are taking steps to help ensure that pesticides are available as needed to control insects, plant diseases and weeds. Keeping growers informed about manufacturer's plans for reregistration is important to everyone because certain vital pesticide uses may be going off the market, and growers may not even know about this until it's too late.

To help, USDA is working closely with EPA, the National Agricultural Chemicals Association (NACA) and IR-4 (a cooperative government/industry effort), to develop an early notification network for reregistration information. Through this network, grower groups will be advised as soon as a registrant decides not to support a pesticide product or use through the reregistration process. The purpose of this service will be to inform grower groups and other interested parties of impending pesticide cancellations, giving them more time to act.

What can Growers Do?

As an agricultural producer, your awareness about the reregistration process and your readiness to act quickly and effectively may enable you to help keep needed pesticide uses on the market. If you are not already participating, the time to become involved is now.

* **Develop a needs inventory** - List your pest control needs. Consider all the alternatives--could integrated pest management or non-chemical strategies do the job? Make an inventory of the pesticide uses that are essential to you.

* **Get organized** - Get together with other growers in your area who have similar pest control needs. Join or form a grower group to share information, develop strategies, voice needs and, if necessary, act to support essential pesticide uses.

* **Get informed** - Get information about the regulatory status of pesticides that are vital to the production of your crops. Learn which are in danger of cancellation, and which of those you may be able to help support. Through your grower group, contact the appropriate pesticide registrants, your County Agent or State Cooperative Extension Service Pesticide Coordinator, your state Department of Agriculture, EPA or USDA.

* **Speak up** - If an essential pesticide use appears to be in jeopardy, speak up and let your need for that use be known. Contact the pesticide registrant through your grower group. Enlist the aid of other registrants, when appropriate.

* **Act on your own behalf** - Be prepared to jump in and help rescue a pesticide use that is vital to you and is in danger of being voluntarily cancelled! Grower groups working with pesticide registrants, under EPA's guidance, can take effective action to:

* Fund studies that must be submitted to EPA to support a pesticide product or use;

- Support the development of a petition for a crop group tolerance or regional tolerance;
- Obtain a "third party" registration.
- Pursue alternatives - Realize that sometimes it will be too late or too difficult to save a needed use. If this is the case, look for new pest control chemical and non-chemical alternatives, working closely with the Cooperative Extension Service and your State Department of Agriculture.

Pesticide reregistration is likely to mean that fewer pesticide products and uses will be available in the future, especially to meet minor use needs. Plan ahead. Be prepared to act effectively to rescue (or find good substitutes for) those pesticide "minor uses" that are essential to you.

For More Information Contact:

EPA Minor Uses - For information about EPA's pesticide minor use policies and program, please contact Hoyt Jamerson, Registration Division (H-7505C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460, telephone 703-557-2310.

EPA Reregistration - For information about minor uses and EPA's pesticide reregistration program, please contact Joanne Edwards (telephone 703-308-8046), or Kathy Davis (telephone toll free 1-800-552-8879, or 703-308-8068), Special Review and Reregistration Division (H-7508W), OPP, U.S. EPA, Washington, D.C. 20460.

USDA - For information about pesticide-related matters, please contact the Office of the Director, National Agricultural Pesticide Impact Assessment Program, U.S. Department of Agriculture, Washington, D.C. 20250, telephone 202-447-7744, or toll free 1-800-262-0216, Monday through Friday from 9:00 am - 3:00 pm EST

IR-4 Minor Use Program - For information about IR-4's pesticide minor use program, please contact the National Coordinator, Interregional Research Project No. 4, New Jersey Agricultural Experiment Station, P.O. Box 231, New Brunswick, N.J. 08903-0231, telephone 908-932-9575.

NACA - For information about the pesticide industry's Minor Use Task Force, please contact Dr. Ray S. McAllister, National Agricultural Chemicals Association, 1155 15th Street, N.W., Washington, D.C. 20005, telephone 202-296-1585.

United States
Environmental Protection
Agency

Pesticides And
Toxic Substances
(H7506C)

August 1991

EPA FOR YOUR INFORMATION

RISK/BENEFIT BALANCING UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

Pesticides are biologically active chemicals that kill or modify the behavior of problem insects, animals, microorganisms, weeds, and other pests. With pesticides, farmers can grow more and greater varieties of food more cheaply; home owners can control pests in their lawns, gardens and homes; and public health officials can control pests potentially harmful to our health. But there are disadvantages as well as benefits from using pesticides. By law, EPA must weigh the risks of pesticides to human health and the environment against their benefits with a multi-step process called risk/benefit balancing.

RISK ASSESSMENT

There are four steps in EPA's risk assessment process: hazard identification, dose/response assessment, exposure assessment, and risk characterization.

- o Hazard Identification. EPA evaluates a pesticide's inherent toxicity - i.e., the types and degrees of harmful effects a pesticide may cause. This is done principally by evaluating laboratory studies conducted on animals. For example, laboratory studies attempt to determine if a chemical is an eye irritant, causes acute poisoning, causes birth defects, or causes cancer, among other effects.
- o Dose/Response Assessment. A pesticide's potential for causing adverse health effects is identified through a battery of short-term or "acute" and long-term or "chronic" toxicity testing. In several series of tests, laboratory animals are exposed to different doses of a pesticide, and EPA scientists evaluate the tests to find the level of exposure in each of those studies that did not cause any non-cancer effect. This level is called the "No-Observed-Effect-Level," or NOEL. The most appropriate NOEL is divided by an uncertainty factor, usually 100 or more, to determine what is called the Reference Dose (RfD) (once known as the Acceptable Daily Intake, ADI). At or below this level, it is assumed that daily exposure over a lifetime will not pose significant risks to health. In addition, EPA routinely requires multi-year laboratory animal feeding studies to screen pesticides for cancer effects. The Agency uses a "negligible risk" standard to address the risk of cancer from exposure to a pesticide through the food supply. EPA defines a negligible risk to mean that the estimated cancer risk can be no greater than a risk of one in one million or less (meaning that, at most, an individual would have a one in one million chance of developing cancer if exposed over a lifetime).

- o Exposure Assessment. Once harmful health effects are identified in the laboratory tests, EPA must estimate the level, duration, frequency, and route of exposure for people. For example: Are people who regularly mix and apply pesticides exposed? Is there a chance of exposure to people through food and drinking water? Can plants and animals other than the targeted pests be harmed or killed by the pesticide?
- o Risk Characterization. Finally, the risk from exposure to pesticides is estimated by integrating the above factors. By combining estimates of likely or actual pesticide exposure with the toxicity of the pesticide, EPA can characterize the risks that it poses. This usually involves extrapolating exposure in animals to humans because little direct information about the effects on humans is available. EPA relies on animal studies, assuming that the human response is qualitatively similar to that of animals and that humans will be at least as sensitive, and frequently, more sensitive to the effects of the pesticide.

BENEFIT ASSESSMENT

EPA conducts a benefit assessment when deciding on whether to cancel a pesticide, and evaluates benefits when approving the use of a new pesticide under a conditional registration. The purpose of a benefit assessment is to determine the effectiveness and economic value of a pesticide compared to alternative chemical and nonchemical controls. A benefit assessment is specific for each registered use site (e.g., corn, soybeans, tomatoes, etc.). A benefit assessment is essentially an analysis of likely economic consequences resulting from the restriction or cancellation of a pesticide, and includes:

- o Biological Analysis. The purpose of this analysis is to identify the importance of the pesticide in controlling the intended pest. As part of this process, EPA collects information on the nature and extent of the pest problem, the effectiveness of the pesticide and other chemical and non-chemical controls, and the biological impacts of controlling the pest. For agricultural pesticides, the analysis would compare the effects on crop yield or quality for the pesticide and its alternatives; the information is used to determine the pesticide's value in the production of the crop.
- o Economic Analysis. An economic analysis translates the biological impact of yield loss, reduced crop quality, and alternative pest control methods into economic terms. EPA evaluates the economic impacts that are expected to occur for all of the affected sectors of the economy. For agricultural pesticides, economic effects include the costs and ability of farmers to produce the crops and, where appropriate, the subsequent costs to consumers who purchase those foods. In addition, secondary effects such as local employment are evaluated when appropriate. A low cost pesticide that produced substantial benefits to farmers, resulted in lower food costs to consumers, and had few alternatives, would be rated as having high benefits. On the other hand, if there were several alternatives to a pesticide that were comparably priced and equally effective, the pesticide would have relatively low benefits.

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FOR YOUR INFORMATION

Pesticide Tolerances

As part of its program to regulate the use of pesticides, EPA is responsible for setting "tolerances," which are the maximum amount of pesticides that may remain in or on food and animal feed. Tolerances are set at levels that ensure that the public (including infants and children) is protected from unreasonable health risks posed by eating foods that have been treated with pesticides in accordance with label directions.

To set tolerances that are protective of human health, EPA needs information about the anticipated amount of pesticide residues found on food, the toxic effects of these residues, and estimates of the types and amounts of foods that make up our diet. A tolerance petitioner (generally a pesticide manufacturer) begins the tolerance-setting process by proposing a tolerance level, which is based on field trials reflecting the maximum residue that may occur as a result of the proposed use of the pesticide. The petitioner also must provide food residue and toxicity studies to show that the proposed tolerance would not pose an unreasonable health risk.

Studies of Pesticide Residues in Foods

EPA requires petitioners to submit several types of information to estimate the amount and type of pesticide residues that may remain in food products. One requirement is for product chemistry data, which is information about the content of pesticide products, including the concentration of the ingredients and any impurities. EPA also requires information about how plants and animals metabolize (break down) pesticides to which they are exposed, and whether residues of the metabolized pesticides are detectable in food or feed. Any products of pesticide metabolism, or "metabolites," that may be significantly toxic are considered along with the pesticide itself in setting tolerances.

Field experiments are required for pesticides and their metabolites for each crop or crop group for which a tolerance is requested, including each type of raw food derived from the crop. In these studies, the pesticide is applied to crops in a manner similar to that described by the use directions that eventually will appear on the pesticide label if the tolerance petition is approved. Finally, pesticide manufacturers must provide information on residues found in many processed foods (such as raisins), and in animal products if animals are exposed to pesticides directly or through their feed.

Toxicology Studies

A pesticide's potential for causing adverse health effects — such as cancer, birth defects and other reproductive disorders, and adverse effects on the nervous system or other organs — is identified through a battery of toxicity tests. Tests are conducted for both short-term or "acute" toxicity and long-term or "chronic" toxicity. In several series of tests, laboratory animals are exposed to different doses of

a pesticide, and EPA scientists evaluate the tests to find the highest level of exposure that did not cause any effect. This level is called the "No Observed Effect Level," or NOEL. When evaluating pesticides for potential effects other than cancer, the Agency divides that level by an uncertainty factor, usually 100 or more, to determine what is called the Reference Dose (RfD). (This 100-fold factor compensates for the fact that humans could be more sensitive than the animals used in laboratory tests.) At or below the RfD, it is assumed that daily exposure over a lifetime will not pose significant risks to health. In addition, EPA routinely requires multi-year laboratory animal feeding studies to screen pesticides for cancer effects.

Food Consumption Estimates

The next step in the process is to estimate the amount of the pesticide to which the public may be exposed through the food supply. EPA uses the Dietary Risk Evaluation System (DRES) to estimate the amount of the pesticide in the daily diet, which is based upon a national food consumption survey conducted by the U.S. Dept. of Agriculture. The USDA survey provides information about the diets of the overall U.S. population and a number of subgroups, including several different ethnic groups, regional populations, and age groups, such as infants and children.

Tolerance Decisions

Finally, for non-cancer risks EPA compares the estimated amount of pesticide in the daily diet to the Reference Dose. If the DRES analysis indicates that the dose consumed in the diet by the general public or key subgroups exceeds the Reference Dose, then generally EPA will not approve the tolerance. Similarly, for potential carcinogens, EPA ordinarily will not approve the tolerance if the dietary analysis indicates that exposure will cause more than a negligible risk of cancer (i.e., the theoretical risk is more than about one in one million).

EPA believes that the tolerance process is protective of human health because it is based on extensive animal tests and on a combination of conservative assumptions and risk assessment practices. Tolerances are set at the lowest level necessary to accommodate the maximum application rate and frequency being approved for the pesticide use, even if higher levels would be safe for human consumption.

Enforcing Tolerances

Tolerances are enforced by the Food and Drug Administration (FDA), the U.S. Dept. of Agriculture (USDA), and state enforcement agencies. Inspectors commonly sample food and feed products before they enter the channels of trade so that any violations may be traced to their sources. Tolerances established by EPA apply equally to domestically grown and to imported food. Imported foods may be denied entry into the U.S. if they are found to contain pesticide residue levels that exceed the established U.S. tolerances, or for which there are no U.S. tolerances.

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Pesticide Reregistration

The Environmental Protection Agency (EPA) is required by law to reregister existing pesticides that originally were registered years ago when the standards for government approval were less stringent than they are today. This comprehensive reevaluation of pesticide safety is critical to protecting human health and the environment and maintaining public confidence in our food supply. In 1988, Congress amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to strengthen and accelerate EPA's reregistration program. This fact sheet provides an overview of the nine-year reregistration scheme mandated by "FIFRA '88," which applies to each registered product containing any active ingredient registered before November 1, 1984.

Lists of Pesticides to be Reregistered

In 1988, approximately 600 groups of related pesticide active ingredients, or "cases," — representing 1,150 active ingredients in 45,000 formulated products — required reevaluation. Following FIFRA '88 requirements, EPA divided these 600 cases into four lists: Lists A, B, C, and D.

o List A. List A consists of the 194 chemical cases (350 individual active ingredients) for which EPA had issued Registration Standards prior to the effective date of FIFRA '88. The Registration Standards program, begun in 1980, was a systematic process for reevaluating existing pesticides. Each Registration Standard summarized available information for a given pesticide case, and identified the conditions that registrants had to meet before EPA would reregister it, such as submitting additional data. In 1988, the 194 Standards issued accounted for about 85 percent of the total volume of conventional pesticides used in the U.S.

o Lists B, C, and D. The remaining pesticides were divided into three lists based upon their potential for exposure and other factors, with List B being of highest concern and D of least. Some of the classification criteria included potential for residues of concern in food or drinking water; significance of outstanding data requirements; potential for worker exposure; Special Review or restricted use status; and unintended adverse effects to animals and plants.

The Reregistration Process

FIFRA '88 established mandatory reregistration timeframes and duties. The law requires EPA to complete its reregistration review over approximately a 9-year period. The five phases of the reregistration process are described below. Because EPA already had performed substantial review of the List A chemicals under the Registration Standards program, in essence List A chemicals move directly to Phase 5. Products of registrants who fail to comply with the requirements of any of the phases are subject to cancellation or administrative suspension action.

o Phase 1: Listing of Active Ingredients

FIFRA '88 required EPA to publish lists A, B, C, and D within 10 months. As required, EPA also asked registrants of these pesticides whether they intended to seek reregistration.

o **Phase 2: Declaration of Intent and Identification of Studies**

Phase 2 required registrants to notify EPA whether or not they intended to reregister their products; to identify and commit to providing necessary new studies; and to pay the first installment of the reregistration fee. During this phase, EPA issued guidance to registrants for preparing their Phase 2 and Phase 3 responses. Phase 2 activities were completed during 1990.

o **Phase 3: Summarization of Studies**

During Phase 3, following EPA guidance, registrants were required to submit summaries and reformatted acceptable studies, "flag" studies indicating adverse effects, re-commit to satisfying all applicable data requirements, and pay the final installment of the reregistration fee. Phase 3 ended in October 1990.

o **Phase 4: EPA Review and Data Call-In's**

In Phase 4, EPA must review all Phase 2 and 3 submissions and require registrants to meet any unfulfilled data requirements within four years. Phase 4 ends in July 1992.

o **Phase 5: Reregistration Decisions**

In this phase, EPA reviews all the studies that have been submitted for a chemical case, and decides whether or not to reregister products containing the active ingredients in that case. A pesticide will be considered eligible for reregistration if its data base is substantially complete, and if it does not cause unreasonable adverse effects to people or the environment when it is used according to product label directions and restrictions.

Status of Reregistration

The overall trend for all four lists is a substantial reduction in the number of pesticides being supported for reregistration by pesticide companies. The number of chemical "cases" being considered for reregistration declined from about 600 in 1988 to about 400 in early 1991. Pesticide product registrations declined from about 43,000 to 20-25,000. Registrants are not supporting for reregistration about half of the original List B, C, and D active ingredients.

EPA generally views this decline in pesticide product registrations as a positive result. In many instances, the pesticides that dropped out had not been produced or marketed for many years. However, the decline in pesticide registrations also could have a negative impact on pesticide users who depend on so-called "minor uses," specialty pesticide uses with limited market potential. EPA is participating in joint government, industry, and user efforts to help preserve needed minor uses.

EPA issued the first six Reregistration Eligibility Documents (REDs) by early 1991, and expects to issue many more during the next few years. REDs announce that products containing the active ingredient are eligible for reregistration; products will be reregistered once product-specific data and labeling are submitted to and accepted by the Agency. Even after a pesticide is reregistered, however, EPA will continue to reassess it based on new information that becomes available. Reregistration is but one major milestone in a continuing review process.

In conclusion, as a result of FIFRA '88, EPA has greatly accelerated the pesticide reregistration process. A new and more efficient infrastructure has been developed, and EPA is moving ahead briskly with the reregistration effort. The wave of reregistration decisions will rise steadily during the 1990's, until the task set forth by Congress and the American public is completed.

Testimony of Jay J. Vroom, President,
National Agricultural Chemicals Association
before the
Senate Agriculture, Nutrition and Forestry Committee

September 20, 1991

Senator Leahy, members of the committee, thank you for the opportunity to make three important points for the record today.

1. The National Agricultural Chemicals Association strongly supports a ban on the export of agricultural chemicals that have been removed from use by the U.S. Environmental Protection Agency for reasons of human health and safety.
2. Every agricultural chemical made in the United States undergoes thorough safety, health and environmental testing before it is exported for use abroad.
3. To ensure that imported food is as safe as is humanly possible, we need increased monitoring and testing by the U.S. Food and Drug Administration, the country's chief guardian of our imported and domestic food supplies.

The American public needs to understand that agriculture, which includes the manufacture of pesticides, is a worldwide industry. As only one segment of this global activity, American agrichemical makers alone cannot guarantee the total safety of all the foods produced in other countries and brought into the U.S.

This is simply not feasible.

What is feasible, as well as appropriate, is to expect us to do everything we can to assure the safety of our products... in the lab, the factory and the field. Our primary concern is safety.

Each agricultural chemical undergoes nearly 120 separate safety tests before it is ready to be considered for registration by the EPA.

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On average, only 1 in every 20,000 active ingredients makes it to this stage. And it takes from five to seven years and \$40 million to do so. For the committee's further information, I am attaching a detailed summary of the American agricultural chemicals industry.

Like you, Mr. Chairman, we are concerned about reports of pesticides used improperly abroad, and about public apprehension over pesticide residues on imported food. We have consistently supported tough measures to improve the capability of foreign governments to regulate pesticides responsibly. Effective regulation in every nation where pesticides are sold and used is the surest way to protect the world environment and human health everywhere.

I have with me a sampling of books, training tapes, multi-lingual safety manuals, brochures and pamphlets that reflect my industry's commitment to product safety and stewardship. These materials are produced by my own association, by the international industry federation (GIFAP) and by individual member companies specifically to educate farmers and workers in the safe handling and use of our products.

We augment these informational materials with safety and training programs in many countries. We know that the food we eat and the fiber we wear is made safer through this kind of responsible stewardship.

However, more needs to be done. We would like to continue to work with this committee to improve the safety of our imported food. That is why we support a proposal that would prohibit export

of products canceled for human health reasons by the U.S. government. This is responsible public policy.

With reference to your bill, S. 898 addresses two major objectives which we support: First, protecting the health of farmers and consumers in those countries to which we export pesticides; and, second, ensuring that imported food meets U.S. standards of safety and that U.S. farmers are able to compete with others on a level playing field. We believe that these objectives can be achieved without corresponding injury to U.S. agricultural trade.

Turning to U.S. exports of pesticides, I would like to state the following facts.

The U.S. accounts for about \$7.75 billion of the \$21 billion total world sales. Throughout the developed world -- Europe, Japan, Australia, Canada and elsewhere -- there are large manufacturing and exporting interests involving a wide range of pesticides.

Moreover, many newly industrialized and even developing countries have sophisticated chemical manufacturing capabilities. Taiwan, Korea, Brazil, Mexico and India, for example, produce and export substantial quantities of pesticides. It should be noted here that many of the pesticides of most concern to this committee are made in these countries.

For example, India makes DDT and BHC (benzenehexachloride). Brazil and the People's Republic of China produce BHC, while Korea manufactures Captafol and EPN. No controls on U.S. exports will

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change or regulate this trade. Indeed, the handicapping of responsible U.S. companies is likely to encourage countries like this to expand their export trade. Not only would such less-desirable compounds be encouraged by artificially limiting U.S. exports, but the presence in those markets where American commitment to stewardship keeps a sharp focus on education and training also would be lost.

When it comes to banned pesticides, we know of no member of NACA that exports such products from the U.S. Aggressive foreign production and trade in pesticides highlights the need for international cooperation. We recommend that Congress support the international activities of EPA, and those of such United Nations' organizations as FAO, WHO and UNEP, by supplying pesticide trade information and notification.

Next, it is worth noting that S. 898 does not clearly distinguish between banned and severely restricted pesticides -- the products which may entail significant problems -- from pesticides which are merely not registered in the U.S.

American companies should not have to spend millions of dollars to secure domestic registrations for products used on crops not found in the U.S. There is no reason for such treatment as long as these products are registered in countries where they are used.

For example, if a company has a product to control brown rice hoppers in Japan, and has secured Japanese registration, should

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that company be penalized for not registering the product in the U.S., where brown rice hoppers are not a problem?

Another common example of U.S. export of unregistered products involves products with pending U.S. registrations that have already been registered in foreign countries. England, France and Germany often issue registrations well before the U.S. EPA does. Naturally, our manufacturers wish to begin marketing and selling them as soon as possible. Should they be made to wait? Are exports of U.S.-unregistered products to these countries really cause for concern?

Although not perfect, current U.S. law works. Pesticides must be registered to be sold here. Some are not registered in the U.S. for good reason: they are meant for pests and crops not common to the U.S. Also, most U.S.-made products are registered in and/or exported to countries with regulatory standards and enforcement resources comparable to our own; the lack of a U.S. registration does not indicate the product is untested or unregulated.

Mr. Chairman, through its proposed maze of restrictions, paperwork and delays, S. 898 would be likely to drive most agricultural chemical research overseas. This would raise the cost of remaining U.S. research and production. American farmers would pay the price, as we all know, from an increasing dependence on foreign sources for crop protection innovations.

If production were to shift abroad, American farmers' reliance on imported pesticides, which has risen from 5 percent to 15 percent over the last 16 years, would likely become greater. Since

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average farm prices of imported pesticides are more than 40 percent higher than U.S.-made products, farm production costs would rise, finally being reflected in the nation's supermarkets.

A pesticide export ban would have a severe impact on the American agricultural chemical industry, threatening practically one-third of our American pesticide producers' export business, or an estimated \$750 million in annual sales volume. According to a study we commissioned last year on this issue, pesticide prices would have to increase an average 12.5 percent, to recoup the potential losses. Farmers' costs of production would rise across-the-board for corn, soybeans, rice and cotton.

Our research-based, high-technology industry, which is right now the envy of the world, would ultimately be dislocated, left to be eclipsed by the Europeans, Japanese and others.

While no doubt well-meaning, unilateral U.S. requirements for blanket registration of exports, bureaucratic mechanisms for foreign government consent on imports, and failure to recognize the validity of foreign registrations are condescending, at best.

Penalizing countries for not adopting U.S. laws and practices could result in reciprocal trade barriers. To discriminate against countries because of different scientific and regulatory judgments from ours, insults our friendly trading partners and leads to further restrictions in international trade.

The American farmer deserves a level playing field to compete with his counterparts across the world, but crippling U.S. pesticide exports will not help U.S. farmers. Foreign agricultural

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competitors who choose to use pesticides not registered in the U.S. will still be able to get them from foreign sources. U.S. agriculture's best protection against unfair competition from imported food lies in an effective residue monitoring program of food imports.

FDA must have the level of personnel, skills and modern equipment necessary to continue to assure that all food sold and consumed here meets U.S. standards.

We fully support existing U.S. efforts to provide meaningful information to other countries about significant U.S. regulatory actions, especially those focused on cancellation, suspension, new registrations and tolerances, and denials for health and environmental reasons. However, we should recognize pragmatic limits on the reach of U.S. law to impose comparable limitations on pesticide use in other countries. Other countries are equally justified and able to make their own judgments on the risks and benefits of pesticides and how those judgments are communicated.

The agricultural chemicals industry is one of the most regulated industries in America and we are keenly aware our business depends on our safety record. My industry does care about keeping people, and food, safe.

To ensure ever-safer supplies of imported food, America's agricultural chemical makers stand ready to offer their latest scientific and technological expertise to bolster the FDA's food monitoring technologies. NACA member companies endorse a policy of providing FDA with the analytical methods capable of detecting

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pesticides, for which there is no established U.S. tolerance, on food which residues could theoretically occur as well as a list of countries where the pesticide is registered and the crops for which it is approved for use on. This is where our science, working with government, can yield a harvest of trust with the American people.

Attachment to the Testimony of Jay J. Vroom, President
National Agricultural Chemicals Association
September 20, 1991

Profile: U.S. Agricultural Chemicals Industry

The Industry -- The United States is the major producer, user and exporter of crop protection chemicals, known generically as "pesticides." Included in this category are four major groups: herbicides, insecticides, fungicides, and rodenticide.

The National Agricultural Chemicals Association (NACA) represents the manufacturers, formulators and distributors of the vast majority of crop protection chemicals developed, registered, sold and used in the United States for agricultural purposes.

As part of the global agricultural industry, American pesticide producers serve world markets, supplying farmers with crop protection products designed for specific regions, climatic conditions, and unique crops, insect pests, weeds and diseases.

The crop protection chemicals used by American farmers are often not available to foreign producers, and vice versa. Hence, the agricultural "playing field" tends to level out, with no one group gaining undue market advantage.

U.S. Agricultural Chemicals Industry

	Domestic	Export	Total
Sales	\$ 4.45 bill.	\$ 1.95 bill.	\$ 6.40 bill.
Pounds A.I.*	700 mill.	400 mill.	1.10 bill.
Employees	23,000	10,400 est.	23,000
Plants	88	37	88

Source: NACA 1990 Exports Survey

U.S. Exports -- The American agricultural chemicals industry exports pesticides to most countries in the world. Despite being exported, many pesticides await approval by the U.S. Environmental Protection Agency for use on specific crops in the United States. All have been approved for use by the governments of the importing countries, based on extensive human safety and environmental test data.

Generally there are four reasons why some American-made chemicals are exclusively regulated abroad and exported:

1. The chemical has been designed for conditions and crops not found in the U.S.
2. Similar or duplicate products are already serving the U.S. agricultural market.
3. The products currently may be under EPA review for approval for specific U.S. crops, conditions, pests and diseases.
4. Adequate demand and sales potential exists only in foreign countries.

Whatever the reason, American-made agricultural chemicals must be registered in the country of use. They have to withstand all appropriate health and environmental scrutiny prior to approval for use on specific crops.

Whether in the U.S. or a foreign country, the process in moving from pesticide discovery and research through to final approval, manufacture, marketing, sales and distribution takes approximately seven years to complete, at an average investment of some \$40 million.

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Government Approval of Pesticides -- In reply to a congressional inquiry, the U.S. EPA noted on April 12, 1991:

"With few exceptions, the requirements for registrations [of agricultural pesticides] in other OECD countries appear very similar to U.S. requirements... these countries require pre-market approval for pesticides, granted after review of test data to determine quality, safety and efficacy... Requirements for toxicity testing appear nearly uniform across OECD nations...

"In addition, requirements for residue detection methods, product chemistry data, crop-specific residue studies, and most wildlife toxicity data are quite similar in all OECD countries."

Imported Food: Ensuring Safety -- Under the Federal Food, Drug and Cosmetic Act, the U.S. Food and Drug Administration is charged with protecting the foods (both domestic and imported) that Americans consume.

At America's border points -- including airports, ports and terminals, and points of entry with Canada and Mexico -- food imports are subject to random, rigorous spot checking.

By law imported foods must meet the same standards as those for domestically produced foods, including analysis for some 270 different pesticides.

In its most recent report, "Residues in Foods" (October, 1990), the FDA reported that imported foods were even more closely monitored than domestic foods, by a margin of 58 percent to 42 percent. Less than 1 percent of food imports are found by the FDA to be in violation of pesticide regulation.

Pesticides in the Developing Countries -- American agricultural chemical makers work hard to see that their products are used safely in other countries, especially those of the so-

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called "Third World." Afflicted by limited technical resources, inadequate infrastructures and rapidly growing populations, the demands placed on Third World agriculture are staggering.

Acutely aware of the need for more and better product stewardship to guard the safety of farmers, the environment and food supplies, the National Agricultural Chemicals Association, the international pesticide manufacturers association (GIFAP) and individual American companies invest heavily in informational and training materials to educate Third World pesticide users.

Prohibiting the export of needed U.S.-made crop protection chemicals (though not approved for U.S. use by the EPA), would encourage Third World nations to broaden pesticide production on their own, to the detriment of product stewardship, and farmer and food safety.

Partial List of U.S. Banned Chemicals Produced Abroad

Chemical	Country
BHC	People's Republic of China
Captafol	India
Cyhexatin	India, Israel, Korea, Taiwan
DDT	Italy, Korea
Dinoseb	India, People's Republic of China
EPN	Germany
Mirex	Korea, Japan
TOK (nitophen)	Brazil
	People's Republic of China
	Taiwan

Source: NACA Producer Survey

Impact of Potential Exports Ban -- Since last year, when the initiative to prohibit export of U.S.-made crop chemicals not approved by the U.S. EPA began, pesticide discovery research by

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American-based companies has declined. Research and development expenditures in the U.S. on existing products either has remained stable or increased only slightly.

Clearly, decisions affecting the basic make-up and future health of the American agricultural chemicals industry are being held in abeyance. There is even indication that planned multi-million dollar U.S. plant expansions have been delayed or canceled.

WRITTEN STATEMENT OF
JAY J. VROOM, PRESIDENT
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
BEFORE THE
COMMITTEE ON LABOR AND HUMAN RESOURCES
OF THE
UNITED STATES SENATE

JULY 10, 1991

Mr. Chairman and members of the Committee, on behalf of NACA and its member companies, I am pleased to have this opportunity to comment on S. 1074, the "Safety of Pesticides in Food Act of 1991."

It is obvious that the authors of S. 1074 have expended a great deal of effort in responding to shortcomings, both real and imagined, with the current system of regulating the permissible level of pesticide residues in America's food supply. NACA's members are this nation's leading manufacturers of crop protection chemicals. We too eat the food grown with the help of our products, and we share your concern about the safety of our food.

However, S. 1074 goes far beyond what is needed. Indeed, it is difficult to suggest amendments that would fix this bill. Accordingly, NACA must oppose S. 1074. Instead, NACA proposes that we start over with a new bill which addresses attainable goals, which is based on sound science and utilizes realistic risk assumptions, and which is sensitive to both agriculture and the broader public policy issues involved.

Many of the provisions in S. 1074 which NACA believes cannot be fixed have already been identified as unacceptable by a wide cross-section of the public, including

farmers, commodity groups, food processors and distributors, and scientists from both the public and private sectors. The flaws in S. 1074 include:

- o the confusing, rigid and extreme assumptions used in calculating risk assessment;
- o the bill's failure to consider the benefits from the use of pesticides (which will have a devastating effect on agriculture);
- o the misguided attempt to regulate all inert ingredients, metabolites and degradation products;
- o deadlines which are not achievable; and
- o the many damaging inconsistencies between S. 1074 and current law and practice.

There are other flaws which you and your subcommittee no doubt will hear a great deal more about during and after these hearings. However, do not misinterpret NACA's objections to S. 1074. We believe that the continued safety of America's food supply is of vital importance, and we are prepared to work with Congress to develop and implement fair, appropriate and effective legislation. We simply do not believe that S. 1074 is a rational or appropriate means to continue to assure a safe food supply. In that regard, we shall now discuss in detail the shortcomings of the proposed legislation.

THE NEGLIGIBLE RISK STANDARD

S. 1074 would replace existing FFDCA standards for tolerance-setting with a new "negligible risk" standard applicable to both raw and processed food. Currently, FFDCA Section 408 (raw commodities) encompasses a risk-benefit analysis (by requiring consideration of "the necessity for the production of an adequate, wholesome and economical food supply), for setting pesticide residues at a level "necessary to protect the public health." Under Section 409, the Delaney Clause bars carcinogenic pesticide residues which concentrate in processed foods. The effect of these two provisions has

been discussed, and appropriately criticized, in the National Academy of Sciences' (NAS) report, Regulating Pesticides in Foods: The Delaney Paradox. That report concluded that the strict requirements of the Delaney Clause actually interfere with measures to reduce cancer risks, and block safer product introduction. The report recommended that the Delaney Clause be replaced with a "de minimis" or "negligible risk" standard.

EPA currently sets tolerance levels under Section 409 by using a "de minimis" standard. That standard is described in detail in EPA's October 19, 1988 policy, issued in response to the 1987 NAS recommendations, and in their Final Order of February 15, 1991, issued in response to a petition to revoke certain tolerances. EPA's use of that standard results in a workable and logical interpretation of the Delaney Clause, and NACA supports that approach. While S. 1074 purports to use a "negligible risk standard," the bill prescribes methods of calculation which would make "negligible risk" essentially a "zero risk" standard. Therefore, rather than leaving room for discretion to define risk as truly negligible, the bill cleverly defines negligible risk with a no risk standard. This is a distortion of the concept of "negligible risk."

S. 1074 defines a risk as negligible if "exposure to a residue is reasonably certain to cause no harm to human health." In addition, the bill mandates that risk from exposure to residues from non-threshold pesticides is negligible only if the lifetime risk were 1-in-one million, with a special standard of 1-in-one million divided by 70 for any single year of exposure during the first five years of life of an exposed person. Neither the NAS nor any of the parties involved in this regulatory process endorses the concept of a fixed numerical value being stipulated in a statute. In testimony before the House Agriculture Subcommittee in 1988, the Executive Director of the NAS Board on Agriculture testified, in part, that:

The NAS committee discussed at virtually every meeting whether to recommend a quantitative benchmark for negligible risk as part of its definition of this important concept. The committee was both sensitive and

well aware of valid arguments both for and against specifying a quantitative benchmark in the definition of negligible risk. In the end, the committee was persuaded that quantitative risk estimates of oncogenic risks were too fragile and changeable to either assert that risks below a certain level are truly "negligible", or that risks above the "negligible" level indeed pose a significant risk of cancer in man. Such judgments, in the committee's view, can only be made on a case-by-case basis following a thorough review of the complete toxicological database available on a particular chemical.

The reluctance to fix a numerical value for negligible risk is prudent and understandable. Knowledge is rapidly advancing in the science bearing on risk assessment, and society needs the flexibility to modify its perception as conditions change, and as views of acceptable risk and the ways to measure it change.

For threshold pesticides, negligible risk is determined using a "no observable effect level" ("NOEL"). The NOEL is the level of exposure at which reliable experimental data, derived from actual exposure to pesticides, show no adverse effects in experimental animals. While a safety factor of tenfold has been recognized among scientific experts as adequate for establishing a safe level of human exposure to cholinesterase pesticides, S. 1074 instead prescribes a 1/100th NOEL (i.e. the NOEL divided by 100) for all risks. A 1/100th NOEL has justification because it provides an extra measure of prudence. For that reason, NACA continues to support the use of 1/100th NOEL for arriving at an Acceptable Daily Intake (ADI). However, when taken in conjunction with the conservative risk assessment model requirements elsewhere in the bill, this level is unreasonably high.

S. 1074 further calls for the use of "conservative" risk assessment models in determining negligible risk, even though such conservative mathematical risk assessment models are not necessarily the most accurate. In making the negligible risk determination, EPA would also be required to take into account the special sensitivities of individuals. No national legislative scheme can be effective if it attempts to set standard for the entire population based on the exceptional needs of a few. This provision alone would bury S. 1074 of its own weight.

The bill does not stop there. It also requires a separate negligible risk calculation for seven specific age groups of infants and children. This provision is premature because the NAS report on pesticides in the diets of infants and children has not yet been released. It would be highly inappropriate at this time to mandate by legislation such specific calculations just months before the results of this important study are made known.

That is not to say that the diets of our children are not currently being considered in the regulatory process. EPA currently accounts for the needs of these groups in setting tolerances. When reviewing petitions to establish a tolerance, EPA considers the special consumption patterns of various age groups. S. 1074, however, has aimed this provision well beyond the necessary mark. Carving such a detailed data requirement scheme in stone only a few months in advance of the very study which will verify the need for such regulation is not legislatively responsible. NACA continues to support the protection of identifiable groups with quantifiable exposure differences. However, we support such legislation only after release and review of the NAS report. In the meantime, this bill's proposed use of conservative assessment models, in conjunction with the truly low definition of negligible risk, offers protection enough to any conceivable population group.

ELIMINATION OF "BENEFITS" FROM CONSIDERATION

EPA is currently required to consider both the risks and benefits of pesticide use in registering pesticides under FIFRA. Benefits of a pesticide may also be considered in granting raw commodity and processed food tolerances under FFDCA. Only the Delaney Clause implicitly prohibits consideration of pesticide benefits for carcinogens. S. 1074, however, eliminates all consideration of benefits in setting tolerances in all foods. Rather than resolving the inconsistency between the two statutes prompted by the Delaney Clause, the Act actually exacerbates that inconsistency. Under S. 1074, a pesticide could receive a FIFRA registration because the benefits of its use are such that they outweigh

a known risk. Yet that same pesticide may fail to receive a tolerance because the risk exceeds the (now zero-level) negligible risk standard, and because the benefits are not considered. The incongruous result is that a pesticide could lawfully be sold and applied under FIFRA, but the treated produce or crop would be illegal under FFDCA. By eliminating all consideration of benefits under FFDCA, S. 1074 has merely substituted one paradox for another.

But S. 1074 has an even more basic failing. Consideration of pesticide benefits, along with their risks, is good public policy and an appropriate consideration for making regulatory decisions on pesticides. In the context of FFDCA, decisions on permissible pesticide residues are directly related to the ability of agriculture to provide inexpensive and quality food, and to the ability of others to provide clean and healthy eating, working and living conditions. However, in no case should a benefits analysis allow an otherwise dangerous product to reach, or stay on, the market. The key is balance and informed, rational decision making, concepts which this bill's silence on the benefits issue will frustrate.

The benefits from use of pesticides in assuring a safe, wholesome and abundant food supply are important, relevant factors for consideration. They include:

- o Pesticides provide America's farmers with a strategic resource in the battle to control pests that would otherwise cause widespread and significant damage to almost all crops grown in the U.S. They allow for selective control of harmful insects, nematodes, weeds, rodents and plant pathogens. In the pest management context, insecticides are the only practical control measure for insect pest populations approaching or at infestation levels that will cause major crop damage or health risks. They have rapid curative action, offer a wide variety of uses and methods of application, are low in cost, and are associated with substantial labor savings to growers.
- o Pesticides lead to increased availability, lower prices, and improved quality of commodities, especially fruits and vegetables. At a time when malnutrition and hunger are no longer solely remote problems

of the third world, this benefit is of increasing importance. The availability of a wide variety of food all year is an invaluable benefit to the public.

Yet even these facts do not tell the real benefits from use of pesticides. Protection from the devastation of entire local and regional crop loss is available from judicious use of crop protection chemicals. In many areas and on many crops, pesticides are the only means to control pests whose presence would otherwise prohibit production of certain crops. Without these tools to protect crops, many individual farms may fail. For example, most fruits and vegetables simply cannot be produced in most parts of the eastern and southeastern United States without insecticides and fungicides. This fact was even acknowledged by the NAS Alternative Agriculture study, and by an eminent organic farmer (Ward Sinclair), who stated that he can't produce organic potatoes on his farm in Pennsylvania because he can't control the Colorado Potato Beetle without insecticides.

In current practice, EPA, correctly, does not place primary importance on benefits analysis. According to the March 7, 1991 GAO report on EPA's use of the benefits assessment, the agency "bases initial tolerance and registration decisions primarily on perceived risks to health and on environmental considerations...the principal role of benefit analysis is to inform EPA decision makers during special review ... about the extent of the benefits associated with a specific pesticide's use." However, by eliminating these important considerations, the agency will be required to make tolerance and registration decisions in a vacuum.

EXPOSURE ASSUMPTIONS

EPA is free under current law to employ any reasonable and scientifically defensible exposure data in making pesticide tolerance decisions. Although EPA often employs conservative exposure assumptions, it is free to, and has used, actual residue data for exposure calculations where reliable and accurate information is available. S. 1074 would virtually prohibit use of such data.

The risk posed by a substance depends both on its affect and exposure to it. In essence, no exposure means no risk. S. 1074 not only assumes that there is always exposure to a pesticide -- a bold and inaccurate assumption -- but also assumes the most extreme case. In calculating exposure to a pesticide, S. 1074 requires EPA to make the following assumptions and considerations:

- o The residue occurs in 100% of commodities for which treatment is legal,
- o All crops have the maximum permitted residue,
- o The residue is consumed for a lifetime,
- o All other dietary exposures, including drinking water, are included,
- o Consumption by seven different groups of infants and children, and
- o Consumption by individuals and groups with special food consumption patterns.

Even for those with little knowledge of pesticide risks, these assumptions are clearly preposterous. No national crop ever tested, much less all authorized crops, has ever contained the maximum permitted residue. Further, no pesticide has been used for 70 years. As newer, safer and more effective products are introduced, older products are removed and replaced. Yet, S. 1074 requires EPA to establish tolerances based on these rigid and extreme assumptions and considerations. By making these assumptions and considerations mandatory, rather than merely permissible, EPA is required to ignore reality.

To blunt criticism of its outrageous and unreasonable exposure calculations, S. 1074 contains a narrow exception to permit use of actual exposure data. Under the bill, EPA would be allowed to calculate dietary exposure on the basis of the percentage of the commodity actually treated only where it had reliable, statistically significant data on the percentage of food containing residues, and could show (1) that such percent is not likely to increase significantly in the subsequent five years, (2) that "the national distribution of

such percent of such food...does not vary significantly from the distribution of the total amount of that food," and (3) that the aggregate risk from all pesticide residue on the food are negligible. This exception calls for data that does not exist — making it the "no-exception, exception." Given the wide disparity of pests, pesticide usage, and marketing of agricultural commodities, it would seem that few foods with residues are distributed evenly throughout the nation. Showing that the percent treated would not increase in the next 5 years is an impossible prediction. These requirements would establish a virtually insurmountable evidentiary barrier.

INERT INGREDIENT TOLERANCE REQUIREMENTS

In practice, most inert ingredients are currently subject to tolerance exemptions, although EPA is reviewing inert ingredients which pose a toxicological concern and using data call-in procedures to determine conditions of safe use. By amending the definition of a pesticide chemical to include active and inert ingredients, S. 1074 will now require manufacturers to seek and obtain a tolerance or exemption for each inert ingredient. This is required, notwithstanding the fact that many of these products are currently either "generally recognized as safe," ("GRAS"), or have been granted exemptions. Nevertheless, under this bill EPA will be forced to review hundreds of inert ingredients, and possibly thousands of toxicity studies, when it could and should be focusing its attention on new pesticide chemicals, re-registration, new active ingredients, or those with the most toxic inert ingredients.

To complicate matters, EPA would be required to review all existing tolerances and exemptions, including inerts, within one year. And because the inerts would have to meet the negligible risk standard, new tolerances and/or exemptions would have to be established for virtually all inert ingredients. NACA believes that risks associated with inert ingredients need to be monitored. However, the scheme proposed by this bill would merely create chaos. The reevaluation of all inerts, without regard to how much could be present or as to toxicity, simply does not make sense.

PRACTICAL METHODS OF ANALYSIS

NACA strongly supports the proposition that FDA should have the necessary analytical tools to be able to quickly and accurately enforce the FFDCA. Currently, a tolerance will not be granted unless the petitioner submits a proposed method for analysis, and EPA has approved that method. This bill, however, insists that manufacturers develop only one type of analytical method. S. 1074 requires a "practical method of analysis," which is later defined as a "multi-residue" method that can be performed on a routine basis as part of surveillance and compliance sampling. What the drafters apparently have failed to grasp is that some molecules and products are unique, and either do not lend themselves to such methods, or cannot be detected by such methods. In its zeal to consolidate residue monitoring, S. 1074 will instead hamstring FDA. Rather than simply mandate one type of test, NACA supports residue monitoring requirements where the agency would get the most - In terms of accuracy and quantity - for its money.

The only exception is that EPA would be authorized to permit a non-practical method of analysis only if a practical method was not available. This determination would have to be reevaluated every two years. This too, is a very limited exception. Multi-residue methods, when available and practical to use, can represent savings of time and effort in residue monitoring. However, this inflexible requirement will actually result in more expensive, less accurate and less efficient monitoring, because not all residues monitored in a multi-residue test are present in each food or crop tested. In such a case, the multi-residue method would be wasteful. EPA must be given the discretion to work with the petitioner to develop tests deemed appropriate by the Agency. Consultation with FDA would be only as needed.

S. 1074 simply misses the point on routine residue monitoring. In reality, not all pesticide chemical residues need to be routinely monitored. Even setting aside the administrative burden this bill would place on FDA, usage patterns of pesticides do not

require multi-residue methods. It would be pointless to routinely monitor for substances where there is no reasonable expectation for residues and a tolerance is set at the sensitivity of the analytical method.

PHASED RISK REDUCTION

Currently, there is no statutory requirement under FFDCA that EPA review existing tolerances. However, under FIFRA, EPA is involved in a massive reevaluation of all registrations. That process includes a review of tolerances for food use pesticides.

Nevertheless, with the objective of expediting review of all existing tolerances to bring them in line with the new "negligible risk" standard, S. 1074 requires EPA to reevaluate existing data regarding the safety of each and every tolerance and exemption. Within one year, EPA must determine whether existing data is sufficient to make that determination. If EPA can't determine that the pesticide is "safe," its tolerance will be revoked. If EPA determines that it needs more data, it can then demand new safety studies. Under this scenario, EPA must have completed its review of all such tolerances within seven years.

These proposed requirements are intended to be separate and distinct from the FIFRA re-registration process. Assuming that this redundant review is even necessary (which NACA does not believe), absolutely no attempt has been made to coordinate the two processes. NACA can see no reason to establish separate reevaluation requirements for pesticide tolerances and registrations. In fact, FIFRA re-registration contemplates review of each pesticide's tolerance. We believe that S. 1074 would interfere with FIFRA's re-registration, which is already behind schedule and overburdened by inadequate staff and insufficient funds. EPA has already testified in other hearings that they believe the deadlines established in FIFRA '88 cannot be met. Because this additional burden on EPA will only serve to exacerbate those problems, NACA opposes this provision in its entirety.

DATA CALL-IN

In view of the many complexities and potential for statutory conflicts that it introduces, it is a mystery why S. 1074 grants EPA data call-in authority under FFDCA. This is especially true since EPA already has broad existing authority to require the same data under FIFRA.

Scattered throughout the bill, but particularly in Section 408(c), as amended, the bill gives EPA sweeping power to require new health and safety data in support of both new and existing tolerances and exemptions. Similar to FIFRA, there are few limits on the type and quantity of testing requirements. Unlike FIFRA, however, any failure to submit the data on time (except for "extraordinary circumstances"), will result in automatic revocation of the tolerance or exemption. This penalty seems unreasonably harsh, and is unrelated to the severity of the omission.

Also, unlike FIFRA, a hearing on the merits of the data call-in and deadlines would be available only after the tolerance or exemption is revoked. Since the cost of data development and potential for legitimate controversy are so great, S. 1074 goes far beyond what is needed, or indeed, reasonable, in granting EPA both the authority to require data, and the procedural hammer to argue the equity and lawfulness of its demand after-the-fact.

DATA CONFIDENTIALITY

S. 1074 utterly fails to protect confidential information from public disclosure, both before and after EPA acts on a tolerance or exemption. While purportedly providing "limited public access," even a cursory reading of the "Disclosure" paragraph reveals that the confidentiality provisions are more accurately described as "limited confidential treatment."

Currently, FFDCA prohibits public disclosure of data supporting tolerances until after the agency has taken final action on a petition. This is for good reason. Manufacturers spend millions of dollars developing products, conducting in-house safety tests, and conducting EPA required safety and efficacy testing. Until this data becomes a product and receives a patent, or until the manufacturer becomes entitled to data compensation under FIFRA, this information is arguably the most sensitive information maintained by the manufacturer.

In practice, data supporting both tolerance and registration petitions are submitted under FIFRA. FIFRA limits public disclosure, at any time, of certain confidential business information, bars disclosure of registration data to competitors, and provides for use exclusivity and gives compensation for certain data. Current practice adequately protects the manufacturer, and provides EPA with all of the information it needs to conduct its review of the product.

S. 1074 renders current protection under FIFRA meaningless, and would make it impossible for manufacturers to keep confidential trade secrets and business information out of the public domain. Under this exception-riddled provision, data submitted in support of a petition would be entitled to confidential treatment for only 45 days — until the Administrator publishes the initial Notice that a petition to establish a tolerance has been filed. Thereafter, the Administrator is required to publish a summary of the safety data submitted in support of the petition. In addition, under Section 408(g), the Administrator shall provide ... "public access to health and safety data that are submitted or cited in support of such petition." Of course, anyone requesting that data must attest that they are not a competitor. However, it does not take much foresight to envision the following scenario. A person wishes to contest the data supporting a petition, and he files a lawsuit seeking to enjoin issuance of a regulation establishing a tolerance. In the process, the information in the petition becomes public. And while the person seeking access to the data prior to EPA action must state that he will not "intentionally or recklessly" violate that subsection, there is no protection should that person ever

negligently disclose confidential information. Therefore, the affirmation is meaningless; this type of protection is no protection.

Furthermore, data in support of a petition may be released before agency action on the petition to "either House of Congress or any committee or subcommittee thereof to the extent of matter within the jurisdiction of the committee or subcommittee." Mr. Chairman, we can imagine absolutely no justification for this intrusion into the exclusive decision making domain of an agency prior to agency action. Indeed, this provision does not even limit the information to members of the committee or subcommittee. Presumably, staff members, who are not bound by the confidentiality provisions of proposed Section 408(g)2, would also have access to this information. This provision is understandably unacceptable.

On a more pragmatic level, disclosure of such data (whether before or after final agency action on the petition), undercuts both the data compensation and confidentiality provisions of FIFRA. Millions of dollars in research and development depend on the protection provided under FIFRA. Without the guarantee of exclusive use, companies would not risk the costs associated with the development of any new product. The effect on safer pesticides, minor use, and eventually all products, would be devastating.

PROCEDURES FOR ESTABLISHING OR MODIFYING A TOLERANCE

The proposed requirements of S. 1074 for establishing a tolerance are unworkable. FFDCA tolerance-setting will now be subject to the imprecision, delay and frustration known as "notice and comment rulemaking." Such rulemaking typically suffers from lack of agency accountability, indifferent rulemaking records, and arbitrary results. Taken in combination with (1) provisions for public access to supporting data, (2) elimination of the input of the NAS scientific advisory committee, and (3) the rights of persons with no direct interest to submit comments and participate in the proceeding, the proposed procedure will quickly cause the administrative wheels to grind to a halt. Even those petitions which

would be entitled to priority under the bill are given no procedural advantage. Presumably, the drafters were aware of the certain delays, as they have given the agency fully three times as long to make its decision establishing a tolerance. Manufacturers have invested heavily in research and development for new products. To subject them to such long delays gives them no incentive to bring new products to market. Understandably, these provisions are also unacceptable.

The provisions of S. 1074 for revocation/modification of a tolerance suffer the same procedural flaws. Additional problems involve the right of any citizen to petition to have a tolerance revoked, revocation for failure to pay maintenance fees, and the revocation of existing residue tolerances without adequate opportunity to defend their safety.

JUDICIAL REVIEW

S. 1074 contains major deficiencies in its judicial review provisions. Making objections and requesting a hearing would not be required as a prerequisite to obtaining judicial review of action on a petition. In fact, a person whose petition was denied would not even be entitled to file objections or obtain an evidentiary hearing before the denial becomes final. Additionally, the right to obtain judicial review is substantially enlarged by allowing any person who may be adversely effected to seek judicial review. This, in conjunction with new provisions-providing attorney and expert witness fees (which may be substantial in such technical cases) will no doubt encourage frivolous, time consuming and expensive litigation.

However, the most unusual provision regarding judicial review is the inexplicable shift of the initial burden of proof, typically on the petitioner, to the agency. This "guilty until proven innocent" approach is fraught with several practical, and potentially legal, pitfalls. For example, the agency may well find itself so inundated with challenges from disinterested third parties that it will be unable to carry out its administrative functions in a timely manner. Placing the initial burden of proof to justify its action only encourages

litigation. A petitioner is able to rely on a largely undeveloped administrative record, because there is no provision for an evidentiary hearing prior to appeal. In addition, the person who originally sought the petition is held captive to a cumbersome judicial process, and products which may have been a tremendous benefit to production agriculture will be lost. At the very least, the cost of litigation for the agency in terms of time, money and energy will be substantial.

It is difficult to see why the issuance, amendment or revocation of tolerances should be judicially challengeable only after both formal and informal rulemaking, while petition denials could be the subject to direct judicial review, without opportunity to develop or supplement the administrative record, or without consideration of the views of other interested persons under either formal or informal rulemaking.

PIPELINE PROVISION

It is true that FFDCA currently does not contain an express pipeline provision allowing treated crops to "move through the system" if a tolerance is modified or revoked. However, any potential problem in this area is solved by current EPA and FDA authority to delay action, or to utilize "action levels" to trigger discretionary enforcement action. Under S. 1074, however, EPA allows a revoked tolerance to remain in effect for raw agricultural commodities and processed foods which, on the date of publication of the regulation, contain pesticide residues in compliance with the original tolerance. This provision does nothing to protect the majority of existing legally treated food – including growing but unharvested crops. In addition, it is not clear whether the exemption would extend to processed food that is made after the date of the regulation from raw agricultural commodities which contained legal residues prior to the date of the regulation.

This provision is wholly inadequate to protect this country's farmers who legally apply products registered with EPA. On an even more basic level, the bill fails to coordinate with similar pipeline provisions of FIFRA. FIFRA authorizes EPA, upon

cancellation of a product, and within EPA discretion, to allow pesticides to be used until supplies are exhausted, on the assumption that limited use over the country is environmentally preferable to concentration of the product in stopping its use, and ordering its disposal. S. 1074 counteracts this sound environmental policy by effectively prohibiting use of all unapplied pesticides in storage and inventory.

USER FEES

Current FFDCA provisions require those seeking to establish or lower a tolerance to pay a fee, typically ranging from \$10,000 to modify an existing tolerance, to \$50,000 to establish a new tolerance. S. 1074 will not only continue to assess these same fees, but also authorizes (1) payment of an annual maintenance fee, and (2) payment of a fee sufficient to cover the costs associated with reevaluation of all existing tolerances. This amounts to two new fees. If history is any indication, S. 1074 may well be the death knell for minor use products.

As a result of the additional fees levied on manufacturers through the FIFRA '88 re-registration process, hundreds of product registrations have been and will continue to be dropped because the manufacturers are unable to afford to keep them. Included in the lost registrations will be safer pesticides and minor use products. At best, the additional fees required here will increase the cost of the product to the manufacturer, who will be forced to pass the increase on to the producer, who will pass them on to the consumer. Higher food prices may not sound an alarm for the well-healed who regulate and advocate. However, for the vast majority of Americans, higher food prices are not a realistic option when the result is food no safer than it was before. Of course, the other possibility is to lose more minor use products.

CONCLUSION

Again, Mr. Chairman, I wish to thank you and the members of this Committee for the opportunity to present these remarks on S. 1074.



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National Agricultural Chemicals Association Fact Sheet

- o The National Agricultural Chemicals Association is the not-for-profit trade organization of U.S. manufacturers, formulators and distributors of agricultural crop protection and pest control products.
- o NACA member companies produce, sell and distribute virtually all of the herbicides, fungicides, insecticides, miticides and rodenticides registered for use in the United States.
- o Safety is the number one concern of the agricultural chemicals industry.
- o Today every new pesticide on the market undergoes approximately eight years of testing at an average cost of some \$40 million before becoming registered for use.
- o Only one out of approximately 25,000 pesticide active ingredients discovered actually becomes registered by the U.S. Environmental Protection Agency, which monitors 120 different tests on health, safety and environmental protection.
- o With the aid of the agricultural chemicals industry, and government and university scientists, farmers are reducing their use of pesticides each year through the introduction of Integrated Pest Management (IPM) techniques.
- o The agricultural chemicals industry supports the Alliance for a Clean Rural Environment (ACRE), a non-profit, non-political organization which produces and distributes information on a variety of topics that farmers and other agricultural chemicals users can follow to protect their water resources, both surface and ground water.



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Statement of
Jay J. Vroom, President,
National Agricultural Chemicals Association
on
"Circle of Poison Prevention Act"

Senator Leahy's erroneously dubbed "Circle of Poison Prevention Act" will not improve the safety of America's imported food supply. Banning the export of unregistered U.S. pesticides does not stop foreign farmers from using the same pesticides produced in and purchased from other countries.

The best way to ensure the safety of America's domestic and imported food supply is through international harmonization of pesticide regulation, as has been proposed by the Food Agriculture Organization (FAO) of the United Nations, increased monitoring and testing by U.S. FDA of our imported food, and promoting safe, proper application of products according to their label and authorized uses.

Senator Leahy's proposed legislation puts American farmers, workers and agrichemical manufacturers behind the technological 8-ball for the following reasons:

- Because many of the targeted pesticides are used for crops not grown here in the U.S. (e.g., coffee, bananas), U.S. farmers are not put at a competitive disadvantage. In fact, pesticide exports help hold down domestic prices paid by U.S. farmers;

According to an industry-commissioned study, if exports of U.S. pesticides are curtailed, most manufacturers will have little or no option but to raise domestic prices of agricultural chemicals an average of 12.5%.

- Prohibiting the export of unregistered products immediately impacts 79 products, which account for up to 9,000 U.S. jobs.
- U.S. agrichemical manufacturers could lose as much as \$750 million -- one-third -- of their annual export sales. In addition, more than 90% of the research and development activities directed at new product research could be impacted adversely.

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