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SPECIAL

9/5/96

LEGISLATIVE REFERRAL MEMORANDUM

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TO: Legislative Liaison Officer - See Distribution below:

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(for) Assistant Director for Legislative Reference

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SUBJECT: Environmental Protection Agency Qs and As RE: S1166, Food Quality
Protection Act of 1995

DEADLINE: 10:00 AM Tuesday, September 10, 1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before
advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go"
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(from 6/12/96 Senate By Otter
Leahy)

DRAFT 9/4/96

EPA'S ANSWERS TO SENATE QUESTIONS ON PESTICIDE SAFETY

Question 1 (Senator Leahy) - Dr. Goldman, if fees to fund safety reviews are not extended and increased next year, will the safety studies on the remaining pesticide products be halted? What are the health and safety implications of stopping the studies?

Studies previously requested by EPA to support pesticides in the reregistration process are being conducted by industry and will continue even without an extension of funding. The major impact of failing to extend fee authority would be delays in the review of submitted studies, and in discovering data gaps and requesting additional studies where needed. An absence of fees would result in major personnel upheavals and adversely affect the skill mix EPA currently employs to conduct reregistration. In addition, EPA's ability to manage risks would be adversely affected and completion of reregistration would be significantly delayed. These factors would contribute to an erosion of public confidence in the food supply and disrupt the advancements the Agency has made in this program and the risk reduction that has resulted.

Question 2 (Senator Leahy) - Dr. Goldman, can you do more to protect children if your budget is cut back any further?

The U.S. food supply remains among the safest in the world but even under the current budget conditions we have had to make very tough choices and have not been able to do all we had planned in carrying out the recommendations of the 1993 National Academy of Sciences Report "Pesticides in the Diets of Infants and Children". Further reductions would jeopardize current efforts and would certainly inhibit our ability to do more to assure that children are fully protected.

Question 3 (Senator Leahy) - Dr. Goldman, would you please explain how the proposed benefit based exemptions compare to your current authority. As a follow up, do you think it is appropriate to require consideration of benefits when setting a health standard?

The proposed benefit exemptions in S. 1166, as introduced, differ from current law in a number of ways. The benefits considerations are much broader than current law. EPA would be required to consider both direct and indirect benefits, which are not clearly defined. The current language in S. 1166, as introduced, does not limit the amount of dietary risk that would be acceptable and would allow use of greater than negligible risk pesticides indefinitely. S. 1166, as introduced, allows benefits to the environment to be weighed against consumer's health risks; this would seem to allow problem pesticides to stay on the market if it could theoretically be replaced by an even riskier product,

R. Colorado

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even if neither the current product or its potential replacement provided any benefits to society. Finally, S. 1166, as introduced, would expand the requirement to consider the "availability of an adequate, wholesome, and economical food supply" by requiring EPA to also consider regional effects.

If benefits are to be considered when setting a health standard, they should be benefits that accrue to the party who is at risk. Only health benefits which directly counteract health risks should be appropriate for consideration.

Question 4 (Senator Leahy) - Dr. Goldman and Mr. Elworth will you tell us please what has been accomplished as a result of the effort to develop pest control systems to replace pesticides which will be removed from the market because of health and environmental concerns?

EPA has experienced great success in its Pesticide Environmental Stewardship Program, which takes advantage of voluntary public/private partnerships to reduce both the use of pesticides and the risks associated with pesticide use. The Agency has streamlined ways to register biological pest control products, registering 20 new biological pesticides in FY 1995. In addition, a recent EPA/USDA Memorandum of Understanding (discussed below) holds great promise.

Also, based on these results, what are the prospects for successfully mobilizing research to find alternatives when prudence dictates that use of a particular pesticide be stopped.

In August 1994, USDA and EPA signed a Memorandum of Understanding designed to foster cooperative efforts to develop alternatives to pesticides likely to be canceled or suspended. This effort will be particularly important for minor crop producers. Research is currently underway in 26 different states on more than 20 crops. This program, which receives public and private funding and relies on input from producers and the farming community, holds great promise. Emphasis will be placed on identifying at risk chemicals and expediting research and approval of alternatives, preferably nonchemical. To insure progress and accountability, non-governmental interest groups will have an opportunity to evaluate the program's performance as part of annual reports.

Question 1 (Senator Cochran) - Last year Mississippi cotton producers experienced a devastating pest outbreak which resulted in tremendous financial losses (tobacco budworm). Fortunately, EPA provided a Section 18 (Emergency temporary registration) for a product called "Pirate", which helped alleviate some of the crop losses.

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It is my understanding that over the last several months, EPA and industry have been discussing an expedited registration fee program which could substantially reduce the time it takes to register a compound. In the EPA's opinion, would the expedited registration fee program currently being discussed help products like "Pirate" get registered quicker?

The system would hold benefits for all pesticide registration applications. The additional fees will allow EPA to introduce process improvements and reduce study backlogs, resulting in more timely completion of reviews.

Question 2 (Senator Cochran) - It is also my understanding that industry would help pay for a substantial portion of the expedited registration fee program. What assurances can you provide to industry that funds received by the Agency will only be used for the registration program?

The primary assurance would be the target and maximum decision times imposed for each type of registration action covered by the program. If these times are not met, provisions requiring a refund of paid fees would apply. In addition, registration fees would be earmarked for registration activities and the program will be subject to independent audits.

Question 3 (Senator Cochran) - Last year the EPA instituted a new Section 18 (process) to speed approvals in cases of emergency. How is this new process working?

Due to the government shutdowns late last year and early this year, EPA has not been able to make all the improvements in the Section 18 program that we had hoped for. We have, however, begun the process by beginning some activities designed to improve the efficiency of the Section 18 process. For instance, we have decentralized the authority to grant repeat exemption requests. In addition, we have placed a great deal of emphasis on improving our communications with states and assisting them in working with each other to submit joint requests, which will improve processing times. The Agency will be meeting with interested parties to discuss further refinements this fall and hopes to fully implement the revised system next year.

Question 4 (Senator Cochran) - Dr. Goldman, in your testimony you supported a "health-based" standard. By this do you mean to say, "risk-only" standard as opposed to a "risk-benefit" standard? Is the Administration at least supportive of the concept of a "risk-benefit" standard?

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Any consideration of benefits should be limited to those benefits which accrue to the person facing the risk. Language in S. 1166, as introduced, would broaden benefits consideration and allow pesticides posing greater than negligible risks to remain in use for an indefinite period. The Administration supports a strong health-based standard that would only allow for a phase out of pesticides that do not meet that standard.

Question 5 (Senator Cochran) - Do you consider the current system for setting pesticide tolerances "health-based" or not?

While health considerations are certainly a very strong component of current law, the current system is not entirely "health based" as it does allow consideration of non-health benefits.

Question 6 (Senator Cochran) - Dr. Goldman, do you believe that the use of pesticides to grow food benefits society?

There is no doubt that pesticides, when used properly, can benefit food production. It is equally certain, however, that new methods can be utilized which will reduce pesticide use or employ less toxic pesticides. These methods will maintain or improve the benefits provided by pesticide use while reducing the risks associated with that use.

Question 7 (Senator Cochran) - Dr. Goldman, you have been critical of the consideration of benefits in S. 1166. Do you also oppose provisions in current law which require you to give "appropriate consideration" to the "necessity for the production of an adequate, wholesome, and economical food supply"?

Giving "appropriate" consideration to an adequate, wholesome, and economical food supply is not problematic as long as it is not the primary factor and does not override consideration of risk. Of more concern is the current language in S. 1166 which would add, among other things, consideration of regional effects to the definition.

Question 8 (Senator Cochran) - S. 1166 advocates federal agencies to coordinate the development and implementation of procedures to ensure that pesticide tolerances adequately safeguard the health of infants and children based on the NAS study. Therefore, how does S. 1166 put this sub-population at risk?

S. 1166 does not pose additional risk for this subpopulation but neither does it improve upon current law. (Further explanation is given in the following answer).

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Question 9 (Senator Cochran) - Dr. Goldman, current law does not have specific provisions relating to infants and children. And yet, under current law the EPA has developed a system to evaluate dietary exposures to subpopulation, including infants and children. In fact, there is not a single recommendation of the NRC report on Infants and Children that you could not implement under current law. Why then are you waiting for Congress to pass a law to implement the recommendations of the National Research Council?

This Administration has not waited and has, in fact, been very active in implementing the NRC recommendations. To insure future regulatory consistency in this area, however, requires explicit mandates. Mandatory requirements for EPA actions to implement the key NAS recommendations are needed. Specifically, EPA should be required to issue an explicit finding that pesticide tolerances are safe for infants and children, consider all sources of exposure to a pesticide when issuing tolerances, and obtain and use more information on children's diets and exposure to pesticides when setting tolerance levels.

Question 10 (Senator Cochran) - The EPA's decision in 1988 to apply a negligible risk concept to Delaney Clause was an attempt by the Agency to conform with the 1987 recommendations from the National Research Council in the report, "Regulating Pesticides in Food: The Delaney Paradox", meant to reduce risks to the public, isn't that correct?

[Answer to be submitted under separate cover].

Question 11 (Senator Cochran) - There have been so many accusations that our food supply is less than safe. Do you believe that any use of a pesticide on food is safe?

The U.S. food supply is the safest in the world. We can, however, further improve it and we certainly should avoid any weakening of the current level of safety. Pesticide use, when properly regulated, is an important component of food production in the U.S. There is, however, an opportunity to replace some pesticide use with non-chemical methods and, as past history has shown, there is also an opportunity to develop less toxic and more efficient pesticides.

Question 12 (Senator Cochran) - There have been many requests by the Administration to ensure that tolerances are health-based. Under current law, aren't tolerances already health-based?

See answer to Senator Cochran's fifth question.

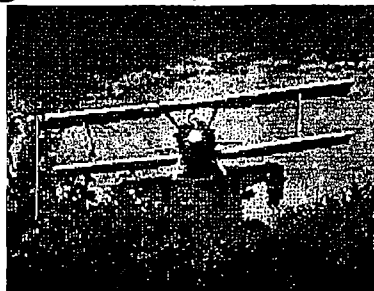
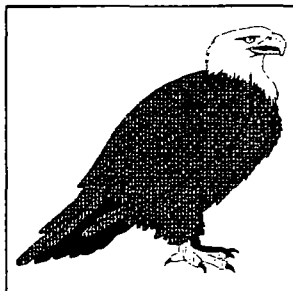
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Question 1 (Senator McConnell) - Can't EPA currently consider special risks to infants and children from pesticide residues? Why is additional authority needed?

EPA can, and does, consider special risks to infants and children. To insure future regulatory consistency in this area, however, requires explicit mandates. Mandatory requirements for EPA actions to implement the key NAS recommendations are needed. Specifically, EPA should be required to issue an explicit finding that pesticide tolerances are safe for infants and children, consider all sources of exposure to a pesticide when issuing tolerances, and obtain and use more information on children's diets and exposure to pesticides when setting tolerance levels.

Lack of resources has hindered efforts to collect new and better data on the consumption patterns of this subpopulation. To provide adequate assurance of protection for infants and children, funding should also be provided for efforts to collect data on age-related differences between children and adults and to establish a National Pesticide Residue Data Base, as recommended by the NAS report.

OFFICE OF PESTICIDE PROGRAMS
Policy and Special Projects Staff (7501C)
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TO:

ELIZABETH DRYE

COMMENTS:

Elizabeth
Jim Cudala had us prepare these 2 documents for you: 1) 3 pages TAKING POINTS on 1621 and 2) 5 pages on O+A's for Major points of 1627.

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H.R. 1627 - Food Quality Protection Act of 1996 Draft Talking Points

- > H.R. 1627 is the long awaited result of a bipartisan effort to develop comprehensive food safety legislation.
- > The Clinton Administration has long supported the effort to strengthen food safety laws and welcomes the improvements in current law that would result from the bill's enactment.
- > Among other things, H.R. 1627 would:

Health Based Safety Standard

- > Correct longstanding problems posed by multiple standards for pesticide residues by establishing a single, health-based standard for both raw and processed foods.
- > Create new standard ^{of} which would require food to be "safe", defined as a reasonable certainty of no harm to exposed individuals.

Protection of Infants and Children

- > Strengthen EPA's protection of infants and children by enhancing our ability to implement key recommendations of the National Academy of Sciences report "Pesticides in the Diets of Infants and Children", including,
 - o requiring an explicit determination that tolerances are safe for children,
 - o adding an additional "safety factor" of up to ten-fold to account for uncertainty in children's exposure data,
 - o mandating consideration of the special sensitivities of children.

Limitation on Benefits Consideration

- > Place specific limits on the consideration of benefits (economic ^{benefits}) during tolerance setting;
 - o Benefits would only apply to non-threshold (cancer) effects.
 - o No benefits considerations would be allowed when setting tolerances for pesticides with reproductive or other non-cancer effects.

- o There would be limits set for maximum allowable risk for any one year and for maximum allowable lifetime risk.
- o No benefits could be used to override the health based standard for children.

Consumer Right to Know

- > Require the distribution of brochures to provide consumers with greater information on pesticide use and discuss the health effects of pesticides, how to avoid risks associated with pesticide use, and listing foods which may have higher pesticide residues due to consideration of benefits in tolerance setting.

Endocrine Disruptors

- > Recognize the need to evaluate the potential effects of endocrine disruptors during the tolerance setting process.

Minor Uses

- > Encourage "minor use" registrations through extensions for exclusive use of data and the submission of some residue data, waiving of some data requirements, and requiring EPA to expedite review of "minor use" applications.
- > Establish a minor use program within EPA to foster coordination on minor uses between government agencies, and initiate a program within USDA to provide grants for research on minor use pesticides.

Reregistration Fees

- > Authorize continued collection of fees necessary to complete the re-evaluation of older pesticides, begun in 1988.

State Regulatory Authority

- > Recognize a state's right to require warnings or labeling of food that has been treated with pesticides, such as California's Proposition 65.
- > Prohibit states from setting tolerance levels that differ from the national level unless they first petition EPA.

Other Notable Provisions

Tolerances for Section 18s - EPA is required to establish time limited tolerances when a Section 18 Emergency Exemption is granted for food use chemicals.

Codex Standard - EPA is required to mention the existence of a Codex standard if it proposes to establish a level different than the Codex level. The Agency must also explain why it set a level that differs from Codex.

Monitoring and Civil Penalties - The bill would authorize more funding for FDA monitoring and would increase civil penalties for violations of FFDCA.

SOME CRITICAL QUESTIONS AND ANSWERS FOR H.R. 1627

Major Issue: How does H.R. 1627 resolve the Delaney Paradox?

Current Practices: If a pesticide or residue causes cancer in man or laboratory animals and is detectable in a processed ready to eat food at a level greater than the tolerance for the raw agricultural commodity, the Delaney Clause that is currently in effect prohibits the setting of a tolerance.

What H.R. 1627 Does: H.R. 1627 preserves a distinction between raw agricultural commodities and processed foods. However, it solves the Delaney Paradox by allowing EPA to set a single tolerance (408) for the processed food as long as the pesticide or degradate in or on the processed food is either removed or less than the tolerance on the raw agricultural commodity.

Implications: This legislation removes pesticides from 409 (processed food) tolerances and regulates them with a single 408 (raw agricultural commodity) tolerance. It allows the establishment of tolerances for carcinogenic residues in processed foods as long as EPA determines that the level is "safe". Safe is defined in H.R. 1627 as "reasonable certainty of no harm". As this legislation solves the Delaney issue, we will be able to devote the resources being used for Delaney actions to assess and act on higher risk pesticide situations.

Major Issue: How does H.R. 1627 assess and act on specific risks to children?

Current Practices: EPA is already addressing some of the high priority areas and risks to non-nursing infants and children identified in the National Academy of Sciences "Kids" Report.

What H.R. 1627 Does: H.R. 1627 expands the areas of accountability for EPA in addressing NAS' recommendations and will require the Agency to address more elements and implement more recommendations of the report. It will require special provisions in risk analysis and assessment and additional safety factors to address risk to non-nursing infants and children.

Implications: EPA agrees that "Children are not just little adults." and there is a critical need to specifically and rapidly address the risks from pesticide exposure to this subpopulation. We strongly support the addition of these explicit requirements.

Major Issue: What is the Regulatory Standard for tolerance setting?

Current Practices: EPA currently uses a negligible risk standard. Because of the Delaney Paradox, this standard is unclear and is interpreted as "zero-risk" by some and "acceptable risk" by others for cancer causing pesticides and residues, leading to lawsuits and large resource expenditures.

What H.R. 1627 Does: H.R. 1627 requires that the standard be "safe". "Safe" is then specifically defined in the statute as "reasonable certainty of no harm" for aggregate exposure using anticipated dietary residues and all other reliable exposure information.

Implications: This will allow the resolution of the Delaney Paradox by effectively removing cancer causing pesticides from regulation as 409 (processed food) tolerances which sometimes results in conflicting standards, and regulating them under a single 408 standard of reasonable certainty of no harm.

Major Issue: What role do Benefits have under H.R. 1627?

Current Practices: Current law states that tolerances be set recognizing "the necessity of an adequate, wholesome and economical food supply." In practice, EPA has stated that benefits considerations have never been used to allow an unsafe pesticide in food.

What H.R. 1627 Does: H.R. 1627 allows certain tolerances to be "eligible" if their loss would represent "a significant disruption" of the food supply or prevent and even greater health risk to the consumer.

Implications: This provision narrows the range of possible applications of benefits and places limits on the maximum level of risk that these provisions could outweigh.

Major Issue: What does H.R. 1627 require about Endocrine Disruptors (Estrogenic Substances)?

Current Practices: EPA does not currently ask specifically for testing for endocrine disruption. However, there are some longer term tests that we receive that may be used as indicators of possible disruption to the endocrine system. Additionally, under FIFRA Section 3(c)(2)(b), EPA has the authority to require specific tests if deemed necessary to protect human health and the environment.

What H.R. 1627 Does: H.R. 1627 expands EPA's authority to require specific tests and information on estrogenic effects for all pesticide chemical residues. It also requires that EPA develop a screening program for identifying endocrine disruptors within 2 years, and to obtain public comment and implement such a program within 3 years after enactment of the bill.

Implications: EPA will have 2 Years to develop a screening program and 3 years (total) to implement such a program. Little is known about mechanisms of endocrine disruption and possible synergistic effects of different chemicals in causing such effects. It is presumed that developing this screening program and analyzing the data will greatly increase our knowledge in this area.

Major Issue: Under H.R. 1627, what Factors will EPA use in the tolerance setting process?

Current Practices: EPA already uses many of the factors stated in the legislation to identify and address risk in the tolerance setting process.

What H.R. 1627 Does: H.R. 1627 requires that EPA shall consider the following factors in tolerance setting:

- valid scientific data

- toxic effects
- human risk
- dietary consumption and subpopulation groups
- cumulative effects
- aggregate exposures (including subpopulations)
- variability of subgroups
- endocrine effects
- appropriate safety factors

Implications: Most likely, additional information and scientific data on cumulative and aggregate effects, as well as information of subgroups and subpopulations will have to be requested and factored into the risk assessments. This may entail modification of our pesticide data requirements in 40 CFR Part 158.

Major Issue: What is the "Consumer Right to Know" provision?

Current Practices: This is a new provision. EPA currently has no practices in this area for pesticides.

What H.R. 1627 Does: H.R. 1627 would require EPA to publish and distribute yearly to "...large retail grocers..." in a "...format understandable to a lay person..." the following information:

- discussion of risks and benefits of pesticide residues in or on food purchased
- list of "eligible pesticides" that may present a lifetime risk greater than that allowed under normal tolerance setting
- recommendations for reducing dietary exposure to pesticide residues, including a list of foods that may be substituted for ones having eligible pesticides in or on them

Implications: EPA will have to coordinate with USDA and HHS in order to accomplish the third requirement. It would be a new part to our mission. The requirement in terms of resources to annually publish and distribute such a document is unclear, but will supplement EPA's other efforts to expand "Right to Know."

Major Issue: Does H.R. 1627 extend Reregistration Fees under FIFRA?

Current Practices: EPA has authority to collect fees to implement the reregistration program (evaluating and managing the risk of older, registered pesticides) until September 30, 1997. At that time, the authority will expire unless this legislation is enacted. Without the additional resources supplied by these fees, reregistration would not be completed until approximately 2006.

What H.R. 1627 Does: H.R. 1627 extends the fee collection authority for EPA from FY-1998 until September 30, 2001. It provides for the collection of \$14 million/year to support reregistration and expedited processing, with an additional \$2 million/year to be collected in 1998, 1999 and 2000. It also requires EPA to undergo a yearly IG audit of the program, not to exceed \$100,000. The purpose is to ensure attainment of performance measures and goals, and to review indirect and direct costs, allocations and expedited processing.

Implications: When the current funds expire, EPA will have only completed approximately one-half of the reregistration program. The Agency will not yet have evaluated a number of high risk pesticides, including a number of substances that are used on foods most often eaten by non-nursing infants and children. The extension of fees will help EPA to more quickly review these older pesticides.

Major Issue: Does H.R. 1627 require a review of all Tolerances?

Current Practices: EPA reassesses tolerances as the chemicals pass through the reregistration process. Pesticides approved since 1985 are not subject to EPA's reregistration requirements.

What H.R. 1627 Does: H.R. 1627 will require a new review of all tolerances in place on the date of enactment on the following schedule:

- 33% within 3 years
- 66% within 6 years
- 100% within 10 years

The priority for this review will be given to those that pose the greatest risk to public health.

Implications: EPA currently has not determined the costs for this activity. The magnitude of this task is considerable, but it should be noted that a number of tolerances have already been recently reassessed in the reregistration process. As written, H. R. 1627 might require EPA to reassess some of those tolerances sometime over the next ten years.

Major Issue: What does H.R. 1627 do about Antimicrobial pesticides?

Current Practices: Antimicrobial pesticides are treated equally with other classes of pesticides with respect to review, scheduling and regulatory decision-making.

What H.R. 1627 Does: H.R. 1627 will amend the definition of antimicrobials under FIFRA to exclude liquid chemical sterilants (they would be covered under FFDCA). Additionally, it would reform the antimicrobial registration process to result in significantly reduced review periods with the goal of reducing the review period for each action:

- 540 days for a new active ingredient
- 270 days for a new use of an existing pesticide
- 120 days for any other action
- 90 days for a substantially similar use (a.k.a. "me-too")
- 90 days for a label amendment not requiring scientific review

Implications: These goals may be difficult to meet in some instances but EPA feels that they are attainable and will strive to meet them and be held accountable for meeting them.

Major Issue: Does H.R. 1627 help to foster the development of minor use pesticides?

Current Practices: Minor Uses in EPA are dealt with in the IR-4 Program, which is administered in conjunction with USDA. Under IR-4, recognition is given to specific problems encountered with minor use pesticides and the reluctance of registrants direct resources to support them with data. The program assists grower groups and registrants in developing methods and data to help circumvent and address these problems.

What H.R. 1627 Does: H.R. 1627 will require EPA to establish a specific program to coordinate minor use activities within the Agency. For new chemicals being registered, it extends the period for the exclusive use of data that supports minor uses by one year for each three minor uses supported. For existing chemicals, it affords ten years of data protection for addition of a new minor use. This will create a large economic incentive for major pesticide companies to develop and use innovative strategies to bring minor use pesticides to market.

Implications: This process directly addresses the problems in support of minor use pesticides by offering significant incentives to registrants to support minor uses for registrations. It will work in concert with the existing IR-4 Programs in place.

Major Issue: How does H.R. 1627 improve the Suspension and Cancellation process?

Current Practices: When EPA suspends a pesticide, the Agency must concurrently issue a Notice of Intent to Cancel (NOIC) the registration.

What H.R. 1627 Does: H.R. 1627 Allows the Agency to suspend a pesticide registration in an emergency situation without the NOIC. However, the NOIC would still need to be issued within 90 days of the emergency order suspending the pesticide, or the order would be automatically revoked.

Implications: This change to current law will allow EPA more flexibility in situations that warrant immediate and decisive action in areas that present serious risks to human health and the environment, while preserving the legal rights of registrants afforded in the cancellation process.

THE WHITE HOUSE
WASHINGTON

Office of Legislative Affairs
House Liaison
Fax Cover Sheet

Date 7/22/96
To: E. DATE

Fax number: 67028

From: TATE at (202) 456-6620

Comments: _____

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Number of pages including cover: 5

DRAFT -- NOT FOR RELEASE

July 22, 1996
(House)

H.R. 1627 - Food Quality Protection Act of 1996
(Bliley (R) VA and 241 cosponsors)

The Administration strongly supports the enactment of H.R. 1627 as reported. This bipartisan bill meets the Administration's goals of a strengthened health-based food safety standard; enhanced protection for infants and children; and common-sense reform of regulatory requirements.

* * * * *

(Do Not Distribute Outside the Executive Office of the President)

This draft position was developed by LR (Fitter) in consultation with NRD (Tuccillo/Rowley/Fairweather/Cogswell), OIRA (Fitzpatrick), BASD (Kolalan), BRCD (Dendurent), OVP (Simon), CEQ (Campbell), DPC (Drye), USDA (Elsworth), EPA (Coronado), HHS (Wallace), Commerce (Brown), Interior (Markell), and USTR (Haverkamp).

Justice (Smith for Schiffer) nonconcurs on the SAP. Justice believes that H.R. 1627 would not provide sufficient enforcement authority under FIFRA and fails to rectify deficiencies in the current judicial review provisions. Justice will be conferring with CEO about the best strategy for addressing these concerns.

H.R. 1627 was reported by the House Agriculture Committee on July 11, 1996, by a voice vote and was ordered reported by the House Commerce Committee on July 17, 1996, by a vote of 45-0.

Administration Position to Date

On July 17, 1996, the Vice President and the EPA Administrator released statements urging enactment of H.R. 1627 as ordered reported by the House Commerce Committee.

SENT BY: Xerox Telecopier 7020 ; 7-22-96 ; 3:58PM ;

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Major Provisions of H.R. 1627

H.R. 1627 would amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA) as described below.

FIFRA Amendments

-- Background

FIFRA requires EPA to regulate the distribution and use of pesticides used in the United States and to evaluate their risks to human health and the environment. Pesticides must be registered for use by EPA before they can be marketed, and pesticides registered prior to 1984 must be reregistered based on current safety standards.

-- Registration and Reregistration

H.R. 1627 would establish a goal for EPA to review each pesticide registration every 15 years to ensure the pesticide meets current health and safety standards. It would also expedite registration of reduced risk pesticides. EPA would be authorized to collect up to \$14 million annually for pesticide reregistration maintenance fees during 1998-2001 and to collect an additional \$2 million annually in fees during 1998-2000. EPA's authority to collect pesticide reregistration fees would otherwise expire at the end of 1997.

*Total = 76 million
fees - review - latest
science*

-- Minor Use Pesticides

EPA and USDA would be directed to establish programs to facilitate the registration of minor use pesticides. Minor use pesticides are defined as pesticides used for crops grown on less than 300,000 acres nationwide. Appropriations of \$10 million would be authorized annually to USDA for grants to develop data to support minor use pesticide registration. Appropriations of \$12 million would be authorized for the Department of Health and Human Services (HHS) in 1997 for grants to develop data to register pesticides used predominantly in public health programs.

*new
pest
7/2/96*

-- Data Collection

The Secretary of Agriculture would be required to develop and implement procedures to improve data collection on food consumption patterns of infants and children. The Secretary is to undertake this activity in consultation with the EPA Administrator and the Secretary of HHS.

-- Preemption of Local Governments and Indian Tribes

Local governments would be preempted from imposing or continuing enforcement of local pesticide regulations unless State laws affirmatively grant local governments such authority. Similarly, Indian tribes would be preempted from regulating the sale or use of federally registered

pesticides within reservation boundaries unless 50 percent or more of the reservation land is owned by tribal members.

FFDCA Amendments

-- Background

FFDCA requires the establishment of food safety standards (a.k.a. tolerances) for chemical residues in all foods. FFDCA's section 409 includes the "Delaney Clause", which establishes a zero tolerance for cancer risks attributable to chemical residues in processed food. Section 408 of FFDCA, however, allows carcinogenic chemicals to be used on raw foods when the risk to the public is negligible. The Delaney Clause has forced EPA to cancel food safety standard tolerances that pose only negligible risks. This has occurred because scientists can now detect chemical residues in smaller concentrations (parts per trillion) than was possible when the Delaney Clause was enacted in 1958.

-- Delaney Clause

H.R. 1627 would replace the Delaney Clause with a single health-based safety standard that would require EPA to determine that there is "a reasonable certainty of no harm" from exposure to the chemical residues in either processed or raw foods. The bill includes requirements to ensure that infants and children are protected.

-- HHS Activities

Appropriations of \$12 million would be authorized for the Secretary of HHS for increased monitoring of pesticide residues in imported and domestic food. The Secretary would also be authorized to impose civil penalties for introducing adulterated food into interstate commerce.

-- Miscellaneous Provisions

The EPA Administrator would be required to:

- ✓ -- conduct a safety review of all existing tolerances and exemptions from tolerances within 10 years of enactment of this Act to ensure they meet the updated safety standards;
- ✓ -- develop and implement a program to screen pesticides for estrogenic effects; and
- distribute a brochure at food stores on the health effect of pesticides, how to avoid risks, and which foods may contain higher pesticide residues.

Pay-As-You-Go

RTK
Peet

4

NR (Tuccillo) and BASD (Kolaian) advise the H.R. 1627 would affect direct spending and therefore would be subject to the pay-as-you-go requirements of the Omnibus Budget Reconciliation Act of 1990. This Office estimates that the reauthorization of pesticide reregistration fees would result in new offsetting receipts of \$16 million in 1998 and new direct spending of the same amount resulting in a net effect of zero. The increased civil penalties could also increase receipts by a negligible amount. CBO concurs (Final).

Legislative Reference Division
7/22/96 -- 3:30 p.m.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 22, 1996
(House)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 1627 - Food Quality Protection Act of 1996
(Bliley (R) VA and 241 cosponsors)

The Administration strongly supports the enactment of H.R. 1627 as reported. This bipartisan bill meets the Administration's goals of a strengthened health-based food safety standard; enhanced protection for infants and children; and common-sense reform of regulatory requirements.

* * * * *

To: E. Dye

From: Hutter

Per your request

Draft #2

DRAFT 7-26-96

STATEMENT BY THE PRESIDENT

Today I am pleased to sign into law H.R. 1627, the "Food Quality Protection Act," which brings much needed, comprehensive reform of the food safety laws of the United States

pesticide and
Americans have every right to expect that the world's most bountiful food supply will also be the world's safest. Meeting goals I set early in my Administration to strengthen our pesticide laws, this Act is a major step forward. The Act greatly strengthens current law by providing a single, protective, comprehensive health-based standard for pesticide residues in all foods, thereby increasing the American public's protection from pesticide exposure in food. All pesticide residue levels will be required to meet the new standard, and safe pesticide substitutes will be approved more quickly so they can reach the market sooner.

The Act also contains special new provisions to protect the health of America's infants and children from pesticide health risks. These provisions will implement the key recommendations set forth in the National Academy of Sciences' 1993 report, Pesticides in the Diets of Infants and Children.

This Act also protects our Nation's health and safety by allowing the use of the best science available when making decisions regarding pesticides found in the American food supply.

This Act demonstrates how Congress and the Administration can work together to help farmers and consumers, and I am pleased to sign it into law.

WILLIAM J. CLINTON

THE WHITE HOUSE

August , 1996

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

July 24, 1996

Statement by the President

I am pleased that the Senate tonight passed the Food Quality Protection Act.

Americans have every right to expect the world's most bountiful food supply will also be the world's safest. Earlier this month, I announced tough new measures to improve meat and poultry safety. Meeting goals I set early in my Administration to strengthen our pesticide laws, this legislation is another major step forward. It puts in place a strong health-based standard, provides special safeguards for children, and protects our health and safety using the best science available. This bill demonstrates how Congress and the Administration can work together to help farmers and consumers, and I look forward to signing it.

###

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

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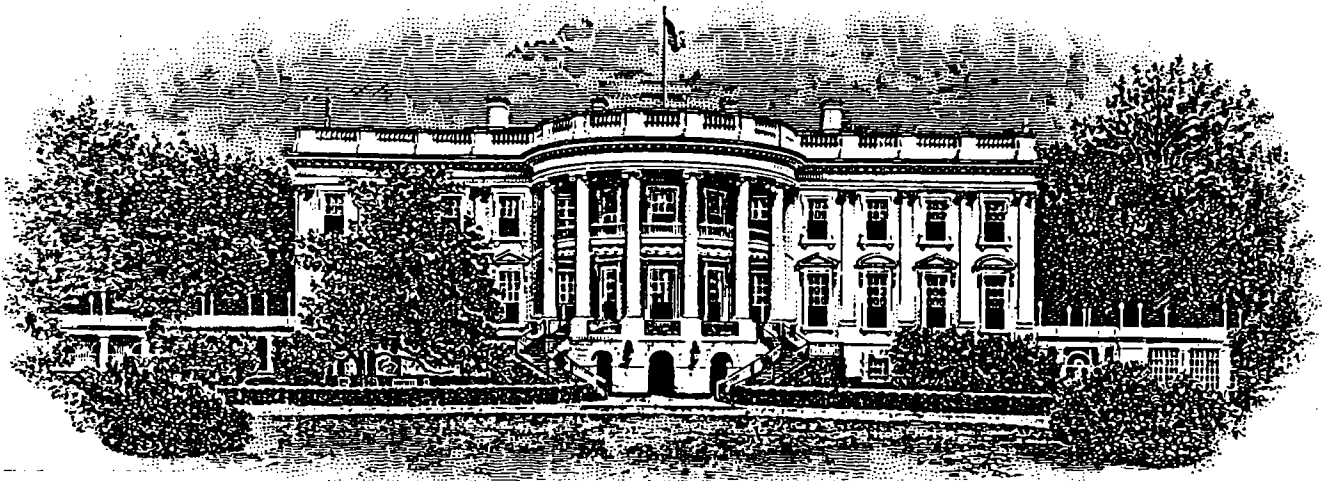
1 among infants and children. In the case of
2 threshold effects, for purposes of clause (ii)(I)
3 an additional tenfold margin of safety for the
4 pesticide chemical residue and other sources of
5 exposure shall be applied for infants and chil-
6 dren to take into account potential pre- and
7 post-natal toxicity and completeness of the data
8 with respect to exposure and toxicity to infants
9 and children. Notwithstanding such require-
10 ment for an additional margin of safety, the
11 Administrator may use a different margin of
12 safety for the pesticide chemical residue only if,
13 on the basis of reliable data, such margin will
14 fully protect infants and children.

15 "(D) FACTORS.--In establishing, modifying,
16 ing, leaving in effect, or revoking a tolerance or
17 exemption for a pesticide chemical residue, the
18 Administrator shall consider, among other rel-
19 evant factors--

20 "(i) the validity, completeness, and re-
21 liability of the available data from studies
22 of the pesticide chemical and pesticide
23 chemical residue;

24 "(ii) the nature of any toxic effect
25 shown to be caused by the pesticide chemi-

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Greg Dodson

FAX NUMBER: 225-4099

TELEPHONE NUMBER: _____

FROM: Elizabeth Dye

TELEPHONE NUMBER: 456-5573

PAGES (INCLUDING COVER): 2

COMMENTS: _____



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 22, 1996
(House)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 1627 - Food Quality Protection Act of 1996
(Bliley (R) VA and 241 cosponsors)

The Administration strongly supports the enactment of H.R. 1627 as reported. This bipartisan bill meets the Administration's goals of a strengthened health-based food safety standard; enhanced protection for infants and children; and common-sense reform of regulatory requirements.

* * * * *

202-~~667~~-1336

Schiffman

← this evening -

- Lois Schiffman -

FFDCA - C

FFDRA - Enforcement provisions in the bill

she'll be in the office -

Lois Schiffman

- enforcement provisions in FFDRA are unworkable too -

- 574-2701 -

CEO - needs to call her -

Catie McIntyre -
- Substantive -

202-667-1336

FDA

301-827-3370

- process concern - for being cut out -

- pushed hard for strong enforcement provisions in all our env. bills

- make ~~environmental~~ bill

- Katie Mill

Polly Milios
Bob Hudse

574-2586

362-8570

- Louise Milkman -

- Leg Affairs -

574-2848

- Bill Schultz -

Jim Ardala - call

THE WHITE HOUSE
WASHINGTON

July 23, 1996

MEMORANDUM FOR MIKE MCCURRY

FROM: Elizabeth Drye, ^{ES}DPC

SUBJECT: House passage of H.R. 1627 -- the Food Quality
Protection Act of 1996

The House today passed unanimously the Food Quality Protection Act of 1996 -- a bipartisan bill that will improve food safety by strengthening our pesticide laws. We support the bill -- it is similar to legislation the President proposed during the 103rd Congress.

The bill repeals the Delaney clause for pesticides -- a potential point of controversy -- and replaces it with a stonger, more comprehensive health-based standard. You may be asked why we're letting cancer-causing pesticides into foods. A Q&A is attached.

The Vice President has called for the Congress to "respect the delicate balance of this bipartisan bill so that the President can sign legislation this year to improve food safety for all Americans." His statement, the SAP, and two recent favorable editorials are attached.

cc: John Angell

A28

THE NEW YORK TIMES OP-ED FRIDAY, JULY 26, 1996

In America

BOB HERBERT



Finance The Meat Bill

Three weeks ago President Clinton announced that the Department of Agriculture was adopting a set of new regulations designed to improve the nation's meat inspection system.

The idea was to move inspectors away from the ancient and often unreliable "sniff and poke" method of testing carcasses for contamination. Inspectors, newly trained, would be eased into the scientific era. Among other things, microbial testing would be used to detect the presence of potentially deadly contaminants like salmonella and *E. coli* bacteria.

Mr. Clinton said, "These new meat and poultry contamination safeguards will be the strongest ever."

The disastrous outbreak of food poisoning in Japan is dramatic evidence of the importance of such safeguards. A deadly strain of *E. coli*, known as O157:H7, has sickened 8,000 people in Japan and killed at least 7. Public health officials believe food poisoning caused by *E. coli* is increasing around the world. Several cases have occurred in the United States in the past few months.

So there would seem to be no reason to object to the Clinton Administration's initiative on meat safety, which has been widely praised, and which won't even be fully instituted for three years or more. Nevertheless, the President's good intentions are in danger of being derailed by the Senate.

The House of Representatives has approved the necessary appropriations for the new inspection system. But the Senate has eliminated funding for the training and upgrading of inspectors, for a computerized data and field communication system designed especially for the new program, and for a new prevention effort designed to reduce the level of contamination in live animals.

If these cuts are not restored, the new inspection program will be crippled.

"You can't do a 21st-century program with 19th-century tools," said Carol Tucker Foreman, a former Assistant Secretary of Agriculture who has lobbied for improvements in the inspection process.

Citing the importance of the prevention program, she said: "You have to be able to address the food safety issues that start on the farm. If the animal arrives at the slaughterhouse covered with fecal matter, it's a lot harder to keep it out of the food supply. If it arrives just lousy with salmonella germs, it's a lot harder to keep it out of the finished product."

The amounts of money involved are not great. The prevention program is budgeted at just \$2.8 million. Senator Bob Kerrey, a Nebraska Democrat who has been trying to get funding restored, said yesterday that an additional \$16 million or \$17 million is all that would be necessary to finance the Food Safety and Inspection Service (the agency that carries out the inspections) at the level the Administration has requested. The Senate has been unwilling to provide that money.

Mr. Kerrey's immediate efforts

Senate cuts would cripple inspection reform.

are focused on the restoration of \$8.5 million for the computer system, and he said, "We may still get that done in the conference committee."

But the essential question, he said, is whether the inspection service is sufficiently funded "to carry out two inspection systems simultaneously, because we have to keep the old one in place until the new one is ready."

The answer to that, he said, "is no."

"I think we can do it so that this year consumers will still be safe," Senator Kerrey said. But in the long run, "You are really risking a great deal when you underfund an agency like this."

Any attempt to thwart improvements in the nation's outmoded meat inspection system is unconscionable. The system has not been overhauled since 1907 and Mr. Clinton's planned improvements are modest, especially when you consider the threat to human health. Food poisoning traced to salmonella and other pathogens in meat and poultry products kills more than 4,000 Americans each year and sickens about five million. Public health officials estimate that *E. coli* O157:H7 kills a few hundred Americans a year and sickens some 20,000.

At some point enough Americans will die of food poisoning to get the Senate to act. Unfortunately, we don't know yet how many fatalities will prove sufficient. □

U.S. Department of Agriculture
Office of the Under Secretary
Natural Resources and Environment
(202) 720-7173 - Phone
(202) 720-4732 - Fax

DATE: 7/70/96

TO: Elizabeth Dye

PHONE NUMBER: _____

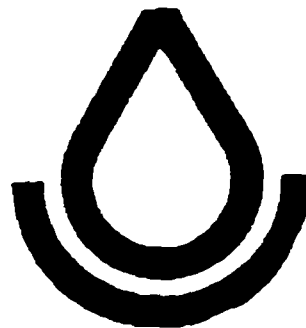
FAX NUMBER: 456-7431

TOTAL PAGES: _____

FROM: Larry

REMARKS: _____

** IF YOU DID NOT RECEIVE THE TOTAL AMOUNT OF PAGES, PLEASE CALL (202) 720-7173 AND SOMEONE WILL ASSIST YOU **



July 26, 1996

FEDCA PROVISIONS

Strengthens Current Law with a Health-based Safety Standard: The bill establishes a strong, health-based safety standard for pesticide residues on all foods. It uses "reasonable certainty of no harm" as the general safety standard, the same approach used in the Administration's 1994 bill.

- ◆ A single, health-based standard eliminates longstanding problems posed by multiple standards for pesticides in raw and processed foods.
- ◆ Requires EPA to consider all non-occupational sources of exposure, including drinking water, and exposure to other pesticides with a common mechanism of toxicity when setting tolerances.
- ◆ The bill also distinguishes between pesticides with 'threshold' and 'non-threshold' effects, an important distinction to strengthen health-based risk determinations.

Special Provisions for Infants and Children: The bill incorporates language virtually identical to the Administration's 1994 bill to implement key recommendations of the National Academy of Sciences report "Pesticides in the Diets of infants and Children."

- ◆ Requires an explicit determination that tolerances are safe for children.
- ◆ Includes an additional safety factor of up to ten-fold, if necessary, to account for uncertainty in data relative to children.
- ◆ Requires consideration of children's special sensitivity and exposure to pesticide chemicals.

Limitations on "Benefits" Considerations: Unlike current law, which contains an open-ended provision for the consideration of a pesticides "benefits" when setting tolerances, the bill would place specific limits on benefits considerations.

- ◆ Benefits considerations would apply only to non-threshold effect pesticides (e.g., carcinogens), so that no benefits considerations would be allowed when setting tolerances for all other pesticides that may have reproductive or other effects.
- ◆ Further limited by three "backstops" on the level of risk that could be offset by benefits considerations. The first is a limit on the acceptable risk in any one year -- this limitation greatly reduces the risks. The second limitation is on the lifetime risk, which would allow EPA to remove risky tolerances after specific phase-out periods. The third limitation is that benefits could not be used to override the health-based standard for children.

Tolerance Reevaluation: Requires that all existing tolerances be reviewed within 10 years to make sure they meet the requirements of the new health-based safety standard.

Endocrine Disruptors: The bill incorporates the Safe Drinking Water provisions for endocrine testing, and also provides new authority under FFDCA to require that chemical manufacturers provide data on their products, including data on potential endocrine effects.

Enforcement: Includes enhanced enforcement of pesticide residue standards by allowing FDA to impose civil penalties for tolerance violations.

Right to Know: Requires distribution of a brochure in food stores on the health effects of pesticides, on how to avoid risks, and on which foods may contain higher pesticide residues because of benefits considerations. The bill also specifically recognizes a state's right to require warnings or labeling of food that has been treated with pesticides, such as California's Proposition 65 requirements.

Uniformity of Tolerances: States will be unable to set tolerance levels that differ from national levels unless the state petitions EPA to set a tolerance based on state-specific situations. National uniformity, however, would not apply to tolerances that included benefits considerations.

FIFRA PROVISIONS

Minor Use Pesticides:

- ◆Encourages "minor use" registrations through extensions for submitting pesticide residue data, extensions for exclusive use of data, flexibility to waive certain data requirements, and requiring EPA to expedite review of minor use applications.

- ◆Establishes minor use programs within EPA and USDA to foster coordination on minor use regulations and policy, and provides for a revolving grant fund to support development of data necessary to register minor use pesticides.

Pesticide Reregistration Program: Reauthorizes and increases (from \$14M to \$16M per year) user fees necessary to continue the review of older pesticides to ensure they meet current health and safety standards.

Registration of Safer Pesticides: Expedites review of safer pesticides to help them reach the market sooner to replace older and potentially more risky chemicals.

Anti-microbial Pesticides: Establishes a new requirement to expedite the review and registration of anti-microbial pesticides.

Pesticide Registration Renewal: Requires EPA to periodically review pesticide registrations, with a goal of reviewing a pesticide's registration every 15 years, to ensure that all pesticides meet updated safety standards.

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US POST 7/28/96

Finishing the Job on Meat

IS THE COUNTRY getting a new meat safety inspection program or isn't it? You'd be hard put to figure it out from the contradictory accusations and characterizations that have marked the appropriations argument in the Senate in the weeks since the president announced the reforms on July 6. The House and Senate both allocated money for implementing the new, scientifically based method for meat inspection. The question raised by groups such as the Safe Food Coalition and STOP (Safe Tables Our Priority) is whether the Senate's budgeting leaves out key elements necessary for the plan to be put into effect.

That some new money will go immediately to the program, called Hazard Analysis and Critical Control Points Analysis, is clear. The House has voted the full amount requested and the Senate some. The need for the change is beyond question. The intent is to replace the turn-of-the-century method of testing meat cleanliness, known as "poke and sniff," with a scientific analysis of the points in the often messy meat slaughtering, cleaning and packing process where bacteria might be likely to enter and contaminate the product—mainly through the presence of feces, which contain *E. coli*. This is enough of a shift from previous methods that it requires not just obvious forms of spending, such as retraining for

inspectors, but also money for computerization and materials and to cover the brief period of time when both systems are operating together.

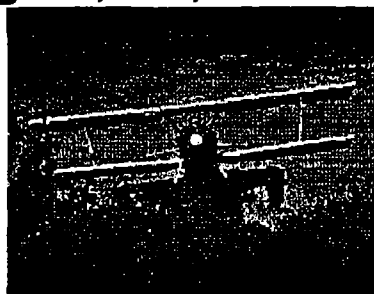
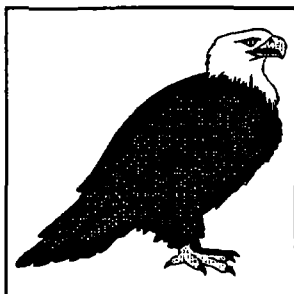
The advocacy groups insist that there is a danger, perhaps a disabling danger, in skipping the few categories that do not receive funding in the Senate version of the program. Senators of both parties on the committee respond that the danger is not immediate, though more funding down the road would be better. Since the Food Safety Inspection Service, charged with implementing the new programs in the field and training the new inspectors, is undergoing what it describes as a reorganization and is streamlining operations and cutting funds in some areas for other reasons, it's impossible to state categorically that the transition to the new programs will or won't be possible at the budget levels described.

What is clear is that these regulations, floated and mooted and tatted around repeatedly since they were first recommended in 1987, have been undercut many times at the appropriations step of the process by legislators who declared they were in favor of these regulations but declined to vote for the money to make them possible. That shouldn't happen again. If we've come this far on making meat safer, it's about time we finished the job.

Bill Clinton

↓ always
pesticide
boxes

OFFICE OF PESTICIDE PROGRAMS
Policy and Special Projects Staff (7501C)
US Environmental Protection Agency
Facsimile Cover Sheet
401 M St., SW, Washington, DC, 20460



TO: *ELIZABETH DRYE*

COMMENTS: *Elybeth*
Jim Cudala had in prepare these 2 documents for you: 1) 3 pages TAKING POINTS on 1627 and 2) 5 pages on O+A's for Major points of 1627.

FAX NO: *202-456-~~7058~~ 7431*

OFFICE: *White House*

DATE: *7/19/96*

NUMBER OF PAGES:

(Includes Cover Sheet)

9

FROM: *Dr. Paul F. Schuda*

Deputy Director, Policy and Special Projects Staff

OFFICE: *Office of Pesticide Programs*

PHONE: 703-305-7102 FAX: 703-305-6244

MAIL CODE: H7501C

H.R. 1627 - Food Quality Protection Act of 1996 Draft Talking Points

- > H.R. 1627 is the long awaited result of a bipartisan effort to develop comprehensive food safety legislation.
- > The Clinton Administration has long supported the effort to strengthen food safety laws and welcomes the improvements in current law that would result from the bill's enactment.
- > Among other things, H.R. 1627 would:

Health Based Safety Standard

- > Correct longstanding problems posed by multiple standards for pesticide residues by establishing a single, health-based standard for both raw and processed foods.
- > Create new standard which would require food to be "safe", defined as a "reasonable certainty of no harm" to exposed individuals.

Protection of Infants and Children

- > Strengthen EPA's protection of infants and children by enhancing our ability to implement key recommendations of the National Academy of Sciences report "Pesticides in the Diets of Infants and Children", including,
 - o requiring an explicit determination that tolerances are safe for children,
 - o adding an additional "safety factor" of up to ten-fold to account for uncertainty in children's exposure data,
 - o mandating consideration of the special sensitivities of children.

Limitation on Benefits Consideration

- > Place specific limits on the consideration of benefits during tolerance setting;
 - o Benefits would only apply to non-threshold (cancer) effects.
 - o No benefits considerations would be allowed when setting tolerances for pesticides with reproductive or other non-cancer effects.

- o There would be limits set for maximum allowable risk for any one year and for maximum allowable lifetime risk.
- o No benefits could be used to override the health based standard for children.

Consumer Right to Know

- > Require the distribution of brochures to provide consumers with greater information on pesticide use and discuss the health effects of pesticides, how to avoid risks associated with pesticide use, and listing foods which may have higher pesticide residues due to consideration of benefits in tolerance setting.

Endocrine Disruptors

- > Recognize the need to evaluate the potential effects of endocrine disruptors during the tolerance setting process.

Minor Uses

- > Encourage "minor use" registrations through extensions for exclusive use of data and the submission of some residue data, waiving of some data requirements, and requiring EPA to expedite review of "minor use" applications.
- > Establish a minor use program within EPA to foster coordination on minor uses between government agencies, and initiate a program within USDA to provide grants for research on minor use pesticides.

Reregistration Fees

- > Authorize continued collection of fees necessary to complete the re-evaluation of older pesticides, begun in 1988.

State Regulatory Authority

- > Recognize a state's right to require warnings or labeling of food that has been treated with pesticides, such as California's Proposition 65.
- > Prohibit states from setting tolerance levels that differ from the national level unless they first petition EPA.

Other Notable Provisions

Tolerances for Section 18s - EPA is required to establish time limited tolerances when a Section 18 Emergency Exemption is granted for food use chemicals.

Codex Standard - EPA is required to mention the existence of a Codex standard if it proposes to establish a level different than the Codex level. The Agency must also explain why it set a level that differs from Codex.

Monitoring and Civil Penalties - The bill would authorize more funding for FDA monitoring and would increase civil penalties for violations of FFDCA.

SOME CRITICAL QUESTIONS AND ANSWERS FOR H.R. 1627

Major Issue: How does H.R. 1627 resolve the Delaney Paradox?

Current Practices: If a pesticide or residue causes cancer in man or laboratory animals and is detectable in a processed ready to eat food at a level greater than the tolerance for the raw agricultural commodity, the Delaney Clause that is currently in effect prohibits the setting of a tolerance.

What H.R. 1627 Does: H.R. 1627 preserves a distinction between raw agricultural commodities and processed foods. However, it solves the Delaney Paradox by allowing EPA to set a single tolerance (408) for the processed food as long as the pesticide or degradate in or on the processed food is either removed or less than the tolerance on the raw agricultural commodity.

Implications: This legislation removes pesticides from 409 (processed food) tolerances and regulates them with a single 408 (raw agricultural commodity) tolerance. It allows the establishment of tolerances for carcinogenic residues in processed foods as long as EPA determines that the level is "safe". Safe is defined in H.R. 1627 as "reasonable certainty of no harm". As this legislation solves the Delaney issue, we will be able to devote the resources being used for Delaney actions to assess and act on higher risk pesticide situations.

Major Issue: How does H.R. 1627 assess and act on specific risks to children?

Current Practices: EPA is already addressing some of the high priority areas and risks to non-nursing infants and children identified in the National Academy of Sciences "Kids" Report.

What H.R. 1627 Does: H.R. 1627 expands the areas of accountability for EPA in addressing NAS' recommendations and will require the Agency to address more elements and implement more recommendations of the report. It will require special provisions in risk analysis and assessment and additional safety factors to address risk to non-nursing infants and children.

Implications: EPA agrees that "Children are not just little adults." and there is a critical need to specifically and rapidly address the risks from pesticide exposure to this subpopulation. We strongly support the addition of these explicit requirements.

Major Issue: What is the Regulatory Standard for tolerance setting?

Current Practices: EPA currently uses a negligible risk standard. Because of the Delaney Paradox, this standard is unclear and is interpreted as "zero-risk" by some and "acceptable risk" by others for cancer causing pesticides and residues, leading to lawsuits and large resource expenditures.

What H.R. 1627 Does: H.R. 1627 requires that the standard be "safe". "Safe" is then specifically defined in the statute as "reasonable certainty of no harm" for aggregate exposure using anticipated dietary residues and all other reliable exposure information.

Implications: This will allow the resolution of the Delaney Paradox by effectively removing cancer causing pesticides from regulation as 409 (processed food) tolerances which sometimes results in conflicting standards, and regulating them under a single 408 standard of reasonable certainty of no harm.

Major Issue: What role do Benefits have under H.R. 1627?

Current Practices: Current law states that tolerances be set recognizing "the necessity of an adequate, wholesome and economical food supply." In practice, EPA has stated that benefits considerations have never been used to allow an unsafe pesticide in food.

What H.R. 1627 Does: H.R. 1627 allows certain tolerances to be "eligible" if their loss would represent "a significant disruption" of the food supply or prevent and even greater health risk to the consumer.

Implications: This provision narrows the range of possible applications of benefits and places limits on the maximum level of risk that these provisions could outweigh.

Major Issue: What does H.R. 1627 require about Endocrine Disruptors (Estrogenic Substances)?

Current Practices: EPA does not currently ask specifically for testing for endocrine disruption. However, there are some longer term tests that we receive that may be used as indicators of possible disruption to the endocrine system. Additionally, under FIFRA Section 3(c)(2)(b), EPA has the authority to require specific tests if deemed necessary to protect human health and the environment.

What H.R. 1627 Does: H.R. 1627 expands EPA's authority to require specific tests and information on estrogenic effects for all pesticide chemical residues. It also requires that EPA develop a screening program for identifying endocrine disruptors within 2 years, and to obtain public comment and implement such a program within 3 years after enactment of the bill.

Implications: EPA will have 2 Years to develop a screening program and 3 years (total) to implement such a program. Little is known about mechanisms of endocrine disruption and possible synergistic effects of different chemicals in causing such effects. It is presumed that developing this screening program and analyzing the data will greatly increase our knowledge in this area.

Major Issue: Under H.R. 1627, what Factors will EPA use in the tolerance setting process?

Current Practices: EPA already uses many of the factors stated in the legislation to identify and address risk in the tolerance setting process.

What H.R. 1627 Does: H.R. 1627 requires that EPA shall consider the following factors in tolerance setting:

- valid scientific data

- toxic effects
- human risk
- dietary consumption and subpopulation groups
- cumulative effects
- aggregate exposures (including subpopulations)
- variability of subgroups
- endocrine effects
- appropriate safety factors

Implications: Most likely, additional information and scientific data on cumulative and aggregate effects, as well as information of subgroups and subpopulations will have to be requested and factored into the risk assessments. This may entail modification of our pesticide data requirements in 40 CFR Part 158.

Major Issue: What is the "Consumer Right to Know" provision?

Current Practices: This is a new provision. EPA currently has no practices in this area for pesticides.

What H.R. 1627 Does: H.R. 1627 would require EPA to publish and distribute yearly to "...large retail grocers..." in a "...format understandable to a lay person..." the following information:

- discussion of risks and benefits of pesticide residues in or on food purchased
- list of "eligible pesticides" that may present a lifetime risk greater than that allowed under normal tolerance setting
- recommendations for reducing dietary exposure to pesticide residues, including a list of foods that may be substituted for ones having eligible pesticides in or on them

Implications: EPA will have to coordinate with USDA and HHS in order to accomplish the third requirement. It would be a new part to our mission. The requirement in terms of resources to annually publish and distribute such a document is unclear, but will supplement EPA's other efforts to expand "Right to Know."

Major Issue: Does H.R. 1627 extend Reregistration Fees under FIFRA?

Current Practices: EPA has authority to collect fees to implement the reregistration program (evaluating and managing the risk of older, registered pesticides) until September 30, 1997. At that time, the authority will expire unless this legislation is enacted. Without the additional resources supplied by these fees, reregistration would not be completed until approximately 2006.

What H.R. 1627 Does: H.R. 1627 extends the fee collection authority for EPA from FY-1998 until September 30, 2001. It provides for the collection of \$14 million/year to support reregistration and expedited processing, with an additional \$2 million/year to be collected in 1998, 1999 and 2000. It also requires EPA to undergo a yearly IG audit of the program, not to exceed \$100,000. The purpose is to ensure attainment of performance measures and goals, and to review indirect and direct costs, allocations and expedited processing.

Implications: When the current funds expire, EPA will have only completed approximately one-half of the reregistration program. The Agency will not yet have evaluated a number of high risk pesticides, including a number of substances that are used on foods most often eaten by non-nursing infants and children. The extension of fees will help EPA to more quickly review these older pesticides.

Major Issue: Does H.R. 1627 require a review of all Tolerances?

Current Practices: EPA reassesses tolerances as the chemicals pass through the reregistration process. Pesticides approved since 1985 are not subject to EPA's reregistration requirements.

What H.R. 1627 Does: H.R. 1627 will require a new review of all tolerances in place on the date of enactment on the following schedule:

- 33% within 3 years
- 66% within 6 years
- 100% within 10 years

The priority for this review will be given to those that pose the greatest risk to public health.

Implications: EPA currently has not determined the costs for this activity. The magnitude of this task is considerable, but it should be noted that a number of tolerances have already been recently reassessed in the reregistration process. As written, H. R. 1627 might require EPA to reassess some of those tolerances sometime over the next ten years.

Major Issue: What does H.R. 1627 do about Antimicrobial pesticides?

Current Practices: Antimicrobial pesticides are treated equally with other classes of pesticides with respect to review, scheduling and regulatory decision-making.

What H.R. 1627 Does: H.R. 1627 will amend the definition of antimicrobials under FIFRA to exclude liquid chemical sterilants (they would be covered under FFDCA). Additionally, it would reform the antimicrobial registration process to result in significantly reduced review periods with the goal of reducing the review period for each action:

- 540 days for a new active ingredient
- 270 days for a new use of an existing pesticide
- 120 days for any other action
- 90 days for a substantially similar use (a.k.a. "me-too")
- 90 days for a label amendment not requiring scientific review

Implications: These goals may be difficult to meet in some instances but EPA feels that they are attainable and will strive to meet them and be held accountable for meeting them.

Major Issue: Does H.R. 1627 help to foster the development of minor use pesticides?

Current Practices: Minor Uses in EPA are dealt with in the IR-4 Program, which is administered in conjunction with USDA. Under IR-4, recognition is given to specific problems encountered with minor use pesticides and the reluctance of registrants direct resources to support them with data. The program assists grower groups and registrants in developing methods and data to help circumvent and address these problems.

What H.R. 1627 Does: H.R. 1627 will require EPA to establish a specific program to coordinate minor use activities within the Agency. For new chemicals being registered, it extends the period for the exclusive use of data that supports minor uses by one year for each three minor uses supported. For existing chemicals, it affords ten years of data protection for addition of a new minor use. This will create a large economic incentive for major pesticide companies to develop and use innovative strategies to bring minor use pesticides to market.

Implications: This process directly addresses the problems in support of minor use pesticides by offering significant incentives to registrants to support minor uses for registrations. It will work in concert with the existing IR-4 Programs in place.

Major Issue: How does H.R. 1627 improve the Suspension and Cancellation process?

Current Practices: When EPA suspends a pesticide, the Agency must concurrently issue a Notice of Intent to Cancel (NOIC) the registration.

What H.R. 1627 Does: H.R. 1627 Allows the Agency to suspend a pesticide registration in an emergency situation without the NOIC. However, the NOIC would still need to be issued within 90 days of the emergency order suspending the pesticide, or the order would be automatically revoked.

Implications: This change to current law will allow EPA more flexibility in situations that warrant immediate and decisive action in areas that present serious risks to human health and the environment, while preserving the legal rights of registrants afforded in the cancellation process.

Don Desbie

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 4329

FILE NO: 851

SPECIAL

5/6/96

LEGISLATIVE REFERRAL MEMORANDUM

Total Page(s): _____

TO: Legislative Liaison Officer - See Distribution below:

FROM: Ron PETERSON *RFP* (for) Assistant Director for Legislative Reference

OMB CONTACT: Holly FITTER 395-3233 Legislative Assistant's Line: 395-6194
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fitter_e@a1.eop.gov
Beverly BOYD 395-3445

SUBJECT: Environmental Protection Agency Proposed Report RE: HR1627, Pesticide Food
Safety Act of 1995

DEADLINE: 10:00 AM Thursday, May 09, 1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before
advising on its relationship to the program of the President.

**Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go"
provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

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If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.

If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

- (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: Holly FITTER 395-3233
Office of Management and Budget
Fax Number: 395-5691
Branch-Wide Line (to reach legislative assistant): 395-6194

FROM: _____ (Date)
 _____ (Name)
 _____ (Agency)
 _____ (Telephone)

SUBJECT: Environmental Protection Agency Proposed Report RE: HR1627, Pesticide Food Safety Act of 1995

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

5-6-96

Honorable Henry Waxman
House of Representatives
Washington, DC 20515

Dear Representative Waxman:

Thank you for your letter of March 5, 1996. I understand that action on H.R. 1627, legislation to amend the nation's food safety and pesticide laws, may take place in the near future. In anticipation of that action, I wish to reiterate our serious concerns about the legislation as currently drafted.

In testimony presented before the Health and Environment Subcommittee of the Committee on Commerce, representatives from the Environmental Protection Agency, the Food and Drug Administration and the Department of Agriculture indicated that we cannot support H.R. 1627 without significant changes. The testimony outlined a number of our concerns with the FFDCA portion of the legislation, including inadequate protection for infants and children, the expanded benefits considerations, the presumption accorded to Codex standards, and federal preemption of state and local standards. I have enclosed a copy of that testimony and a summary of our concerns. I would like to focus on one of the most important of those concerns here.

More specifically, the standards established in H.R. 1627 will not adequately protect the health of infants and children. While the legislation does include references to children's diets, it does not require a specific finding that pesticide residue levels are safe for infants and children nor does it expressly mandate Agency decisions to incorporate the key recommendations of the National Academy of Sciences study on Pesticides in the Diets of Infants and Children. Any legislation that intends to ensure safe food for all Americans must include strong provisions to protect children, our most vulnerable population. H.R. 1627 does not meet that test.

H.R. 1627 does not currently contain the provisions necessary to strengthen the nation's pesticide and food safety laws. In fact, key provisions of the legislation would weaken both FIFRA and FFDCA and jeopardize our ability to protect the public health. Although the Commerce Committee has jurisdiction over the FFDCA and not FIFRA, EPA believes that H.R. 1627 must be assessed as a whole. Even if our concerns about the FFDCA provisions are addressed we will continue to oppose H.R. 1627 if it does not strengthen current laws. Only through genuine efforts to preserve and strengthen our food safety laws will we be able to resolve longstanding problems and enhance public confidence in the safety of our food supply.

Sincerely,

DRAFT

Lynn R. Goldman, M.D.
Assistant Administrator

Need clearance paragraph

R. Conrad

<Date>

**Summary of Administration Concerns
H.R. 1627 - THE FOOD QUALITY PROTECTION ACT OF 1995**

On June 7, 1995, representatives of the Environmental Protection Agency, the Department of Agriculture, and the Food and Drug Administration testified before the House Committee on Commerce regarding H.R. 1627, the Food Quality Protection Act of 1995. In that testimony, the Administration indicated that it could not support H.R. 1627. This legislation does not adequately protect children, it greatly expands consideration of economic benefits when setting health standards for pesticide residues in food, and it does not provide fees to complete reregistration. While the Administration supports comprehensive legislative reforms to improve food safety and ensure that consumers are provided a safe, abundant and affordable food supply, we believe H.R. 1627 could actually hinder our efforts to protect public health. The following is a summary of our major concerns with H.R. 1627, as mentioned in testimony. The prepared testimony is also available for a more complete analysis of H.R. 1627.

KEY ADMINISTRATION CONCERNS

Federal Food, Drug and Cosmetic Act (FFDCA):

H.R. 1627 will not adequately protect the health of infants and children. The National Academy of Sciences 1993 report, Pesticides in the Diets of Infants and Children, concluded that current pesticide regulatory practices do not fully protect infants and children. While H.R. 1627 contains some brief language on this issue, it will not ensure that the recommendations of the NAS will be implemented.

H.R. 1627 weakens current law by expanding the kinds of economic benefits that can be considered when setting standards for pesticide residues in food, and by allowing these economic benefits to override risks to consumers and the environment. Pesticides that do not meet the bill's negligible risk standard could still remain on the market indefinitely if the risks are outweighed by the benefits considerations.

H.R. 1627 retains cumbersome, time-consuming hearing processes and establishes internally inconsistent procedures for actions on pesticide levels in foods.

H.R. 1627 contains very broad pre-emption language that would override state and local laws, including consumer right-to-know laws concerning the presence of pesticide residues in food, such as California's Proposition 65.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA):

H.R. 1627 replaces the existing procedures for removing risky chemicals from the market, which can already take years, with an untested and even more burdensome process. These changes attempt to shift the "burden of proof" for demonstrating a pesticide's safety from the pesticide producer to EPA, which would dramatically weaken current law.

H.R. 1627 does not extend authority to collect industry fees necessary to complete the legislatively mandated health and safety review of older pesticides - a major tool in managing the risks of pesticide use.

ADDITIONAL COMMENTS FROM ADMINISTRATION TESTIMONY ON H.R. 1627:

- Require specific Agency actions to incorporate key recommendations of the NAS report, Pesticides in the Diets of Infants and Children, when setting food safety standards. Requirements should include issuing a specific finding that legal limits on pesticide residues in food are safe for infants and children, considering all sources of exposures to a pesticide and its related compounds, and using more information on children's diets and exposures to pesticide residues.
- Clearly delimit the kind of benefits that can be considered when setting legal limits on pesticide residues in food, and set a limit on the maximum amount of risk that could be balanced against benefits.
- Set a time limit on any benefits considerations so that over time there is a transition to a purely health-based food safety standard.
- Streamline cancellation proceedings to allow for quicker resolution of pesticide risk concerns, and maintain the "burden of proof" in cancellation proceedings on the pesticide manufacturer.
- Extend EPA's authority to collect industry fees so that the review of older chemicals can be completed in a timely manner.
- Update penalties for violations under FIFRA and FFDCA so that they are better related to the severity of the offense and commensurate with other environmental laws, and strengthen EPA and FDA's ability to enforce food safety laws.

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PHILIP M. GONZALEZ
ADMINISTRATIVE ASSISTANT

Congress of the United States

House of Representatives

Washington, DC 20515-0529

HENRY A. WAXMAN
29TH DISTRICT, CALIFORNIA

March 5, 1995

The Honorable Carol M. Browner
Administrator, Environmental Protection Agency
401 M Street, S.W.
Mail Code 1101
Washington, D.C. 20460

Dear Administrator Browner:

In the near future, H.R. 1627, "The Food Quality Protection Act of 1995," will likely be considered in the House Commerce Committee. This bill would amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

I am very concerned about the consequences H.R. 1627 could have on the presence of pesticides in the food supply. I am requesting that you share your views on this legislation with me, and would appreciate a response at your earliest convenience.

With every good wish, I am

sincerely,


Henry A. Waxman
Member of Congress

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

To	Henry A. Waxman	From	Robert L. GONZALEZ
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Congress of the United States
House of Representatives

Washington, DC 20515-0529

HENRY A. WAXMAN

29TH DISTRICT, CALIFORNIA

TELEFAX COVER SHEET

TO: Elizabeth Drye

FROM: Greg Dotson

Number of pages including cover sheet: 2

If you have any problems reading this material, please call
(202) 225-3976.

New Section 408(b)(2)(A)-*Determination of Safety* defines "safe" as a determination that there is a reasonable certainty that no harm will result from aggregate exposure to the residue, including all dietary exposures and all other exposures for which there is reliable information.

In Section 408(b)(2)(A)(iii) there is a rule of construction that clarifies that if a determination is made under 408(b)(2)(A) the provisions of section of 408(b)(2)(B) do not apply.

Subsection (b)(2)(A) establishes the standard of "safe" for tolerances for pesticide chemical residues in or on food. For the purposes of this section, "safe" means there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. The Committee understands "aggregate exposure" to the pesticide chemical residue to include dietary exposures under all tolerances for the pesticide chemical residue, and exposure from non-occupational sources as well.

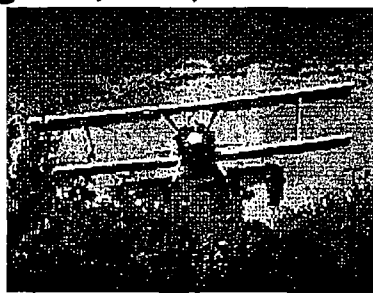
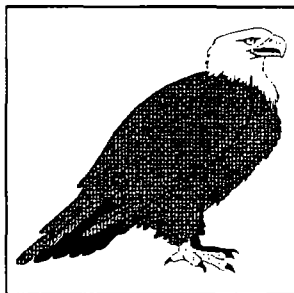
The Committee has adopted the standard of "reasonable certainty of no harm" based on the Environmental Protection Agency's current application of the standard. The Committee understands that the Administrator currently applies this standard differently to threshold and nonthreshold effects. A threshold effect is an effect for which the Administrator is able to identify a level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. A nonthreshold effect is an effect for which the Administrator is not able to identify such a level.

In the case of a threshold effect for a pesticide chemical residue, the Committee expects that a tolerance will provide a "reasonable certainty of no harm" if the Administrator determines that the aggregate exposure to the pesticide chemical residue will be lower by an ample margin of safety than the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. The Committee further expects, based on discussions with the Environmental Protection Agency, that the Administrator will interpret an ample margin of safety to be a 100-fold safety factor applied to the scientifically determined "no observable effect" level when data is extrapolated from animal studies.

In the case of a nonthreshold effect which can be assessed through quantitative risk assessment, such as a cancer effect, the Committee expects, based on its understanding of current EPA practice that a tolerance will be considered to provide a "reasonable certainty of no harm" if any increase in lifetime risk, based on quantitative risk assessment using conservative assumptions, will be no greater than "negligible." It is the Committee's understanding that under current EPA practice utilizing quantitative risk assessment to calculate Potency Factors called "Q star," ~~the EPA~~ ~~currently~~ interprets a negligible risk to be a one-in-a-million lifetime risk. The Committee expects the Administrator to follow this interpretation.

The statutory language does not preclude EPA from changing its risk assessment methodology as the science of risk assessment evolves. If the Administrator in the future chooses to adopt a different interpretation of "reasonable certainty of no harm," however, the new interpretation should be adopted by regulation and should be at least equally protective of public health. Any new interpretation must be scientifically based and the Administrator should bear the burden to demonstrate that the revised interpretation is equally protective of the public.

OFFICE OF PESTICIDE PROGRAMS
Policy and Special Projects Staff (7501C)
US Environmental Protection Agency
Facsimile Cover Sheet
401 M St., SW, Washington, DC, 20460



TO:

ELIZABETH DRYE

COMMENTS:

*Delaney ?!**Jim Adala has sent approval*

FAX NO:

202-456-7028

OFFICE:

White House

DATE:

7/17/96

NUMBER OF PAGES:

(Includes Cover Sheet)*2*

FROM: Dr. Paul F. Schuda

Deputy Director, Policy and Special Projects Staff

OFFICE: Office of Pesticide Programs

PHONE: 703-305-7102 FAX: 703-305-6244

MAIL CODE: H7501C

1.) What does the Delaney clause do?

the use of pesticides that cause cancer
 The Delaney clause prohibits setting tolerances (~~maximum residues levels~~) for carcinogens in ~~processed food~~. The Delaney clause applies to any substances that may be present in processed food, including pesticides that carry over from raw foods, ~~or are applied directly to processed food~~, non-pesticide chemicals added during processing, ~~or directly to processed food~~, and color additives in processed food. *to food including certain color additives foods*

The Delaney clause also applies to other

2.) Who does it protect and what does it protect them from?

It protects the American public, including infants and children, from cancer-causing substances in processed foods.

Equally important are the limitations of the Delaney clause, what it does NOT protect against.

It does not protect against harmful effects other than cancer, such as reproductive or neurological effects.

It does not protect against pesticide residues in raw food, such as fresh fruits and vegetables, meat, milk or eggs. These foods may contain residues, even of carcinogens, that have been determined to be safe.

It does not protect against pesticide residues, even carcinogens, at levels below raw food levels.

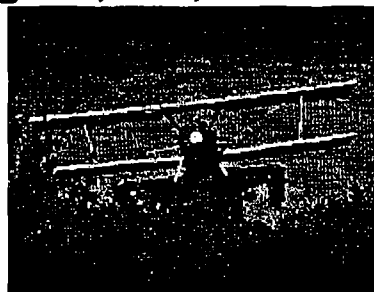
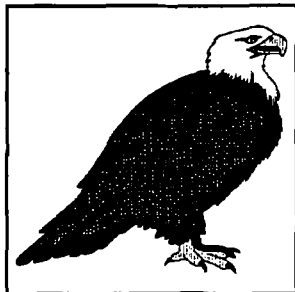
Thus it protects against only one harmful effect, and then only some pesticide residues in some foods.

3.) What is the Administration and Congress doing to address the concerns handled by the Delaney Clause if H.R. 1627 eliminates this provision?

HR 1627 will not weaken the limited protections offered by the Delaney clause, but will extend and enhance protections against harmful pesticide residues because it will encompass all harmful effects (not just cancer) in all foods (not just processed foods) by employing a single, health-based standard for tolerance setting.

It is also important to note that HR 1627 affects only pesticide residues—it does not remove the Delaney clause for other food additives or color additives in processed foods.

OFFICE OF PESTICIDE PROGRAMS
Policy and Special Projects Staff (7501C)
US Environmental Protection Agency
Facsimile Cover Sheet
401 M St., SW, Washington, DC, 20460



TO:

ELIZABETH DRYE

COMMENTS:

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FAX NO:

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OFFICE:

White House

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7/19/96

NUMBER OF PAGES:

(Includes Cover Sheet)*2*FROM: *Dr. Paul F. Schuda**Deputy Director, Policy and Special Projects Staff*OFFICE: *Office of Pesticide Programs*PHONE: *703-305-7102* FAX: *703-305-6244*MAIL CODE: *H7501C*

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THE NEW YORK TIMES,

MONDAY, JULY 22, 1996

Progress on Pesticides

In a remarkable bipartisan effort, and after more than a decade of trying, House Democrats and Republicans have reached agreement on regulating pesticides in food. This is a welcome and indeed surprising achievement given the House's 18-month effort to roll back important environmental protections.

The compromise negotiated in recent days gives something to the food industry and something to environmental and consumer groups. It would do away with the 38-year-old Delaney clause, the law that prohibits adding cancer-causing substances to processed foods but does not apply to fresh foods, which are allowed to contain cancer-causing residues.

Under the agreement, Delaney would be replaced by a broader but still tough standard for all pesticides regulated by the Environmental Protection Agency. The new standard would allow pesticide residues in processed and raw foods as long as there was a "reasonable certainty of no harm" to consumers. Reasonable certainty is generally defined as a one-in-a-million chance of causing cancer.

As a practical matter, that is actually more stringent than what is sometimes allowed today. The fact that Delaney does not apply to fresh foods has led to bizarre circumstances in which a new, safer pesticide on raw tomatoes, for example, might be rejected because it formed a carcinogenic residue when processed as tomato paste or tomato soup, while an older pesticide, apt to cause more cancer deaths, was retained. With technology that can measure even the most minuscule risk of

cancer posed by food substances, the food industry, supported by a decade-old report from the National Academy of Sciences, has long argued that Delaney's absolutist approach is outmoded.

The agreement favors national uniformity for pesticide-residue tolerances, which was sought by the food industry, although a state can still put warning labels on products that might pose a particular risk to its population. For consumers, the agreement calls for the E.P.A. to make more information about pesticides available through supermarket booklets. In addition, the agreement specifically takes into account the different effects that pesticides have on infants and children and offers them special protection.

Apart from its details, the agreement is most remarkable for how quickly it came together. Updating the Delaney clause has been a subject of Congressional debate since about 1980. A 1993 Clinton Administration proposal, offered in response to a Federal appeals court decision that would have required the E.P.A. to stringently enforce Delaney in pesticides, went nowhere.

But with the court ruling still driving E.P.A. pesticide policy and an election campaign around the corner, longtime House members and frequent adversaries — Thomas Bliley, a Virginia Republican, and Henry Waxman of California and John Dingell of Michigan, both Democrats — sat down and in just about a week reached agreement.

After an expected favorable vote by the full House this week, the hard work of three determined Congressmen deserves approval by the Senate and the Administration.

The Washington Post
7/22/96

Sound Compromise on Pesticides

A CONGRESS that was supposed to be incapable of compromise on environmental issues appears to be on the verge of a compromise that has eluded legislators for years. A unanimous House Commerce Committee has reported out a bill, supported by both the food and chemical industries and environmental groups, that would rationalize the regulation of pesticides.

It is the second such major bill the panel has produced without dissent in a month. Safe drinking water legislation was sent to the floor and thence to conference with the Senate in June. The drinking water bill still has some obstacles to overcome. But some congressional aides and lobbyists think that the pesticide trade-offs so long in the offing could actually be on the president's desk by the end of the month—and he is prepared to approve them.

The great dispute with regard to pesticides has always been what should be the standard of safety. The law is uneven. For residues on certain processed foods, it sets a standard—the so-called Delaney clause—widely regarded as too strict, while in other cases critics say it has been too lax. The committee bill would repeal Delaney, thereby pleasing the grocery manufacturers, but in its place impose the single strong standard, “reasonable certainty of no harm,” on all foods, raw as well as

processed, thereby satisfying most advocates of careful regulation as well.

Special consideration would have to be given to the particular susceptibilities of infants and children. And while the Environmental Protection Agency could take into account the cost of regulations to growers of particular products—another concession to industry—it could only do so in fairly narrow circumstances. The bill would also preserve, while limiting, the right of states to issue stronger regulations than the feds. It gives EPA, which has often lagged in the past, 10 years to put the new standards into effect.

The industry and environmental groups alike had resisted such trade-offs in the past. Industry was driven to the table this time by a court decision that for the first time requires strict enforcement of the Delaney clause; it had to deal lest it get hurt. Likewise, the House Republicans, who suffered in opinion polls last year for taking too harsh a stance on environmental issues, badly wanted an environmental achievement to take to the voters this fall. Here's a case where the public knew better than the ideologues, the hard-edged positions of a year ago gave way to common sense and the public interest has been well served. Everyone wins if this one passes.

House Increases Funding to Curb Illegal Aliens

By DAVID ROGERS

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — The House approved big election-year increases in spending to curb the flow of illegal immigrants into vote-rich border states like Texas and California.

Funding for the Immigration and Naturalization Service would jump more than 21% in the fiscal year beginning Oct. 1. In a time of relative austerity, the \$542.7 million increase reflects the politics surrounding immigration issues, and the two major parties are already airing warring television advertisements on the subject.

Yesterday, Republicans strained to outbid President Clinton by adding \$30 million to his request for the immigration service. Together with spending approved earlier this year, Congress is on track to increase the agency's budget more than 50% — or more than \$1 billion over a two-year period.

Final passage came on a 246-179 vote approving funding for the Justice, State and Commerce departments. Total funding for the Justice Department would grow 11%, but funding for the two other departments would be frozen or cut from current levels.

In a vote that matched the American Medical Association against the biotechnology lobby, lawmakers voted 295-128 to bar the government's patent office from issuing patents for medical procedures.

Rep. Greg Ganske (R., Iowa), who practiced plastic surgery before coming to Congress last year, said the provision would apply only to medical patents and makes important exceptions so as not to interfere with gene-therapy patents or patents for the new use of old drugs, such as the use of AZT in the treatment of AIDS. Medical professionals, who have been critical of the increased use of patents on medical procedures, supported the prohibition. But opposition from the biotechnology industry could lead to a fight in the Senate.

Going into last night, the House took up a separate \$19.4 billion energy and water bill — the last of the 13 annual spending measures to move through the chamber. While making progress on spending bills, the GOP leadership is increasingly concerned about the pace of the rest of its agenda before the August recess.

The Senate, however, remains a major obstacle. Majority Leader Trent Lott (R., Miss.) is anxious to break the deadlock that has so far prevented final action on long-promised health-insurance reforms and an increase in the federal minimum wage.

As part of the health-insurance bill, negotiators are near agreement on the outlines of a four-year trial of a Republican

Disparities in Welfare Bills May Be Settled Next Week

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON — A final welfare bill meshing the recently passed House and Senate versions is expected to pass Congress and be sent to the president by the end of next week, Republican leaders said.

The two welfare bills, both of which stress work and curtail future benefits, differ in a handful of areas, but Republicans said they were confident disparities would be resolved by early next week. That would allow for a final vote before Congress's scheduled monthlong August recess.

President Clinton remained silent on whether he will sign the measure and appears prepared to wait until differences between the bills are resolved. But Senate Democratic Leader Tom Daschle of South Dakota sounded a pessimistic note yesterday, saying, "It's going to have to be improved for the president to sign it."

Senate Majority Leader Trent Lott (R., Miss.) said only minor modifications would be made before a final vote.

plan to extend tax preferences to individual medical savings accounts. But before closing this deal, Democrats want a chance to review agreements reached separately by GOP leaders on other aspects of the bill to ensure that workers will be allowed to carry health coverage from one job to the next regardless of pre-existing health conditions.

Both sides say they are committed to the common goal, but the distrust is so great that they could lose the chance for agreement. And the very presence of Sen. Edward Kennedy, the old liberal lion, seems to set the GOP on edge.

Conservatives have sought to single out Mr. Kennedy, the ranking Democrat on the Senate Labor Committee, as the major impediment to progress on the health bill. Unabashed, the Massachusetts senator seems to relish the fight, and by design or chance, he has engaged the GOP on several fronts at once.

The latest encounter was on a \$54.3 billion bill funding the Agriculture Department and the Food and Drug Administration. The measure cleared the Senate last night by a lopsided 97-1 margin but not before Sen. Kennedy forced concessions from the GOP in its effort to restrict the FDA's role in crafting so-called Med-guide rules to encourage drug companies and pharmacists to provide more information to consumers buying prescription drugs.

The industry is seeking a 120-day window to show what it can come up with voluntarily. The bill would preserve that opening by blocking implementation of a draft FDA rule. But an amendment by Sen. Kennedy would tighten the standards to be met in terms of content and speed of implementation, while also preserving a role by the FDA in any government review.

Congress Eases Rules for Pesticides In Processed Foods

By TIMOTHY NOAH

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — Ending two decades of fighting between consumer groups and the food industry, Congress voted to eliminate the Delaney Clause, a 1958 law that prohibits even minute traces of carcinogens in processed foods.

The bill, which President Clinton last night said he looks forward to signing, would apply tighter restrictions for pesticides used on raw fruits and vegetables while easing those on processed foods. The measure, which cleared the Senate last night, will be the first major environmental measure to become law in two years. It is identical to a measure that cleared the House July 17, with the support of the Clinton administration.

As recently as two weeks ago, the pesticide bill was given little chance of passing. But last week Reps. Tom Bliley (R., Va.) and Henry Waxman (D., Calif.), who previously had been bitterly opposed on how to overhaul pesticide regulation, struck a compromise that was embraced by key lobby groups for industry and the environmental community. The measure was adopted unanimously by the Senate Agriculture Committee yesterday morning, then passed the full Senate by unanimous consent shortly before adjournment last night.

One key area of compromise involved the extent to which the federal government may prevent states from imposing more restrictive pesticide regulations than those imposed by the federal government. In the final version, states are permitted to impose strict pesticide labeling requirements, and may ban a pesticide approved by the federal Environmental Protection Agency. But the states may impose other kinds of restrictions only with the EPA's approval.

John Cady, president of the National Food Processors Association, said in a written statement, "This is an historic event for U.S. food safety regulation." Caroline Smith DeWaal, director of the Center for Science in the Public Interest, an environmental group, said the bill "will result in safer pesticides, safer foods, and better consumer information about the hazards of pesticides."

The last time a major environmental measure became law was in 1994, when President Clinton signed a bill creating new federal parkland in the California desert. That measure was the only significant environmental bill to become law during the first two years of President Clinton's term.

Perhaps not coincidentally, this pesticide bill is also a matter of intense interest in California, a crucial state for the 1996 election.

Steve, Elizabeth
Lyn, Diana, Jennifer
Jeremy

House eases rule on additives

Delaney Clause too restrictive

By Brian Blomquist
THE WASHINGTON TIMES

Congress is on the verge of changing a 38-year-old food-processing rule that has grown obsolete with advances in technology.

Known as the Delaney Clause, the rule was adopted in 1958 when public fears about the causes of cancer were high but information was scant. It prohibits those in the food business from adding anything that poses even the most remote risk of causing cancer.

New technology, however, can detect the tiniest bits of residue, one part per billion, an amount so small that scientists don't consider it a health risk. Yet the detection of such residue might cause the government to prohibit more than 80 pesticides.

On Tuesday, the House voted 417-0 to replace the Delaney Clause with a new rule, and the Senate Agriculture Committee voted 18-0 for the same bill yesterday. The Senate could pass the bill this week, and White House officials say President Clinton will sign the bill into law.

The bill would create a single standard for raw and processed foods, permitting pesticides that pose less than a one-in-a-million lifetime risk of cancer. The bill also builds in a safety factor for health risks other than cancer.

Exemptions from the standards to ensure a stable food supply would be strictly limited, and the measure requires that the public be informed when crop emergen-

Conservatives have tried for years to repeal the Delaney Clause as an example of government overregulation.

cies dictate relaxation of the cancer standard.

The key provision of the bill is the elimination of the Delaney Clause.

"Delaney absolutely was so inflexible that it was harmful to both the producers of food and the consumer," said Sen. John W. Warner, Virginia Republican and a member of the Senate Agriculture Committee.

Elizabeth

Conservatives have been trying to repeal the Delaney Clause for years, often pointing to it as a typical example of harmful government overregulation.

Rep. Thomas J. Bliley Jr., Virginia Republican and chairman of the House Commerce Committee, negotiated the repeal of the Delaney Clause with Reps. John D. Dingell, Michigan Democrat and Mr. Bliley's predecessor as chairman, and Henry A. Waxman, California Democrat.

The impetus to move the bill quickly was a recent federal court decision that ordered the government to strictly enforce the Delaney Clause in areas where it hadn't. To satisfy the court, the Environmental Protection Agency was prepared to ban more than 80 pesticides by the end of the year.

EPA Administrator Carole M. Browner called the bill "a major step forward in ensuring a safe, healthy life for American families."

Mr. Bliley called it "a landmark bipartisan agreement that will bring federal regulation of food producers into the 21st century."

Under current law, fresh foods are subject to a different standard than processed foods.

Because of the separate standard for processed foods, such as ketchup, Mr. Bliley said, "a new safer pesticide often couldn't be used on raw tomatoes, simply because it formed a carcinogenic residue when processed as tomato paste — while an older pesticide, posing potentially greater risks, would be retained."

Mrs. Browner said the bill includes three major items requested by the administration: standards to limit health risks, new protections for children and expansion of the consumer's right to know about pesticide risks.

A 1993 report by the National Academy of Sciences identified infants and children as especially vulnerable to the risks.

The bill would require the EPA to screen for substances known as endocrine disruptors that could raise the risk of breast cancer or reproductive illnesses.

• This article is based in part on wire service reports.

Doctors deny health value of late abortions

By Julia Duin
THE WASHINGTON TIMES

President Clinton is preaching medical nonsense by claiming that a form of late-term abortion protects a mother's health or fertility, three physicians said yesterday.

"So many physicians like myself watch in disbelief as false medical facts about partial-birth abortions get circulated in the public square," Dr. Nancy Romer, a Dayton, Ohio, obstetrician, said at a briefing to announce the founding of the Physicians Ad-hoc Coalition for Truth (Phact).

"In fact," she said, "there's a lot of evidence they may do harm to women."

Phact, to be based in Alexandria, aims to counteract pro-choice claims about partial-birth abortion, in which a doctor delivers an unborn child feet first up to its neck, punctures the skull and sucks out the brain.

She and two Michigan doctors said they were most incensed by the president's claim that such abortions are medically necessary for mothers of deformed children.

Mr. Clinton made this argument in his April 10 veto statement on the Partial Birth Abortion Ban Act. The ceremony featured five women who said they underwent such abortions for health reasons.

"These were honest women who were sadly misinformed," said Dr. Joseph DeCook, a Grand Rapids, Mich., obstetrician. "There is no literature that testifies to the safety of partial-birth abortion. It's a maverick procedure devised by maverick doctors who wish to deliver a dead fetus."

Instead of protecting a woman's fertility, such abortions endanger it by using methods that could lead to an infection, causing sterility, Dr. DeCook said.

He also said that drawing out the child in a breech position "is a very dangerous procedure, and you could tear the uterus." He said a ruptured uterus could cause the mother to bleed to death in 10 minutes.

The puncturing of the child's skull also produces bone shards that could puncture the uterus.

"It sounds like science fiction," Dr. DeCook said. "It's not taught in any residency program in the country."

Joining the doctors were five women who said they elected not to abort when they discovered they were carrying deformed children.

Among them was Whitney Goin, who was with her husband, Bruce. The Orlando, Fla., couple arrived holding their 10-month-old son, Andrew, whom doctors offered to abort when they learned he would be born with several vital organs outside his body.

The child, who cooed and gurgled while Mrs. Goin spoke, has undergone many painful surgeries and eight blood transfusions, she said, as the organs, one by one, have been inserted into his body.

"The worst-case scenarios that were painted by the doctors did not come to fruition, and we are thankful that our son was allowed the opportunity to fight," she said. "My ability to have more children was not affected at all."

The other four women, who have requested a meeting with the president, displayed photos of children who died.

Several said their conditions were similar to those of the women with whom Mr. Clinton spoke.

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BACKGROUND ON ENFORCEMENT ISSUE

Currently, FIFRA does not contain the full array of enforcement tools that exist in the major environmental statutes and have resulted in effective enforcement of those statutes. Therefore, its enforcement scheme needs to be revised. A rational enforcement scheme should have three separate prongs: 1) administrative orders and penalties for the least serious violations, where the penalty sought is low and any corrective action necessary to address the violation can be accomplished quickly, and expeditious hearing procedures are therefore appropriate; 2) civil injunctive relief and penalty authority for the more serious violations, where a court's authority should be called upon to oversee the defendant's actions and/or where administrative action has not been sufficient to deter the violator; and 3) criminal penalties for instances where knowing misconduct or serious harm should bring the full weight of society's censure on the violator. The following provisions should be added to FIFRA to give the government the flexibility necessary to ensure fair and effective enforcement.

-- Administrative Compliance Orders: the Administrator or her designee should be authorized to issue administrative compliance orders for the full breadth of violations of FIFRA that may occur. Currently, FIFRA does not authorize EPA to issue administrative orders to compel compliance with the requirements of FIFRA. When EPA wishes to obtain compliance, it may now issue a Stop Sale, Use or Removal Order. However, that tool does not provide an administrative remedy for all violations of the Act. It only precludes the sale, use or distribution of a pesticide in violation of FIFRA. The other mechanism available to EPA -- seeking civil injunctive relief -- can be cumbersome and time-consuming and requires, sometimes unnecessarily, the resources of the Department of Justice.

In addition, the Administrator should be able to recover penalties for failure to comply with an Administrative Compliance Order.

-- Enhanced Administrative Penalties: administrative penalties should be increased to the greater of \$25,000 per day of violation or the economic benefit of noncompliance. This is comparable to other environmental statutes and provides a more meaningful disincentive to violate the FIFRA regulations than the current maximum penalties of \$1000/\$5000.

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-- Civil Judicial Penalties: civil judicial penalties should also be available with a maximum penalty that is the greater of \$25,000 per day of violation or the economic benefit of noncompliance. As the enforcement provisions of FIFRA are now structured, a violator may not have to pay a civil penalty until after the completion of both an administrative penalty proceeding and a subsequent civil action to collect the penalty. That process can result in an untenable delay from the time of the violation to the time of judgment. Adding civil judicial penalties as an enforcement tool will enable the United States to take immediate forceful action against a violator, strengthening the deterrent effect of the penalties. It will also reduce the use of governmental resources, eliminating the need for two adversary proceedings before a penalty is collected.

-- Civil Injunctive Relief: FIFRA section 16(c) currently provides for broad injunctive relief to remedy violations of FIFRA. This authority should remain as it is an important part of the comprehensive civil enforcement regime. It should, however, be moved into the section of Act that details the other available enforcement mechanisms.

-- Criminal Penalties: The criminal sanctions available under Section 14(b) of the Act should be somewhat expanded and the structure of the maximum penalties to be imposed should be based on culpability. Activities prohibited by Section 12 of the Act could be punished as serious felony level offenses with terms of imprisonment of up to 5 years and fines of up to \$50,000 per day.

A knowing endangerment provision (modeled after those found in RCRA, the Clean Water Act and the Clean Air Act) should also be added to the Act. Where a person commits any of the criminal violations set forth immediately above and in the course of or in connection with committing such violation knew at the time that he placed another person in imminent danger of death or serious bodily injury, that person would be subject to enhanced felony level criminal penalties with terms of imprisonment of up to 15 years and fines of up to \$250,000 in the case of an individual and up to \$1,000,000 in the case of an organization.

For convictions after a first conviction under each of these criminal provisions, the maximum punishment should be doubled.

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TALKING POINTS RE: ENFORCEMENT ISSUES IN FIFRA

- Improperly used pesticides pose a threat to health and safety, and to the environment. Congress enacted FIFRA which has provided protection against such improper use. In FIFRA Congress directs EPA to promulgate regulations that protect against these threats but the Act does not make violations of these regulations unlawful. Thus the regulations carry less weight as pesticides producers, distributors and applicators have little incentive to comply with them.
- In addition, made certain activities, including the violation of some EPA regulations, unlawful. However, absent a meaningful enforcement scheme, making these activities unlawful is not of great consequence.
- There are two reasons why the current mechanisms for enforcing FIFRA are inadequate.
 - For many violations the available penalties are either too weak or too harsh: those charged with enforcement of the Act are therefore required to choose between penalties which give the regulated community little incentive to comply, and penalties that would be unusually harsh given the nature of the violation.

Example - A private applicator illegally disposes of empty pesticide containers into a ravine. Pesticide residues in the containers leach into the ground and pollute the groundwater. Under the current version of FIFRA the private applicator could face either, in the case of a first time violation, a written warning or a criminal conviction with the possibility of jail time.
 - For the most egregious violations, however, the existing penalties are not strong enough. The maximum penalty for a knowing violation of a provision of the Act is \$50,000 and one year in jail. In light of the potential for loss of human life or severe and long-lasting damage to the environment, these penalties are inadequate.

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Example - In West Virginia the chemical chlordane was misapplied in the home of a couple. The chlordane was used to coat silverware when the applicator was dusting for roaches in the couple's kitchen. Both husband and wife sustained physical injury including neurological damage and memory loss. The chlorodane was applied on two separate days (two separate counts). Under the current version of FIFRA not more than a \$5,000 can be assessed per offense.

- The enforcement provisions contained in FIFRA and other environmental laws not only serve to protect human beings and the environment from hazardous or improperly applied pesticides, they also protect those who abide by the provisions of the laws from being economically disadvantaged by those who choose not to. A well constructed enforcement scheme does not permit the wrongdoer to retain the economic benefits of her noncompliance with the law. The current level of the administrative fines contained in FIFRA, however, do not offer this protection to those who abide by the law.

Example - If one company spends two million dollars to properly train its employees in the proper handling, use and storage of a pesticide, and to provide its employees with the appropriate respirators, it is at an economic disadvantage compared to a second company that decides to ignore its obligations under FIFRA. One of the objectives of any enforcement action against the company that isn't complying with FIFRA should be to make sure that it is not able to retain the economic benefit that it has unlawfully obtained. Under the current statute, the second company would probably be able to retain most of its illgotten wealth.

- FIFRA's enforcement provisions should be commensurate with the seriousness of the potential harm to public health and the environment posed by violations of the Act, and should be comparable to the enforcement provisions of the other environmental statutes.
- In order to ensure that regulation is fair, Government needs the full array of enforcement tools, including comprehensive administrative, civil judicial, and criminal relief.

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- Administrative orders and penalties are optimal where any action necessary to address the violation can be accomplished quickly, and expeditious hearing procedures are appropriate.
- Civil injunctive relief and penalty authority are optimal (1) to address important or precedential legal issues; (2) in cases where a court's authority is needed to oversee the defendant's actions; (3) where administrative actions have not been sufficient to deter the violator; or (4) where the added deterrent of a judicial decision is desired.
- Criminal penalties are optimal for instances where acts of knowing misconduct or acts that result in serious harm should bring the full weight of society's censure to bear on the violator. Criminal enforcement provides the strongest possible deterrent.

PROPOSED LEGISLATION:**SEC. XX. INSPECTION AUTHORITY.**

Section 9(a) (7 U.S.C. 136g(a)) is amended to read as follows:

"(a) **AUTHORITY TO ENTER, INSPECT, COPY, AND OBTAIN SAMPLES.**-An officer or employee of the United States or of any State, duly designated by the Administrator, is authorized at reasonable times as provided by this section-

"(1) to enter and inspect-

"(A) any place where any pesticide, active ingredient, or device is produced, sold, distributed, stored, packaged, used, or found;

"(B) any place where any records required under this Act are kept;

"(C) any pesticide testing facility;

"(D) any place where such officer or employee has reason to believe that this Act has been or is being violated; or

"(E) any place when the Administrator or States seek information as part of an inquiry into specific environmental or health problems.

"(2) to obtain-

"(A) samples of any pesticide (or any ingredient, metabolite, or degradation product thereof) or device, or any container or packaging of any pesticide or device;

"(B) copies of any records required under this Act or of any labels or labeling of a pesticide, active ingredient, or device;

"(C) copies of documents related to compliance with the provisions of this Act;

"(D) copies of any data or samples of any specimens involved in the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof) or device; or

"(E) samples of any places where pesticide residues may be found, including without limitation, agricultural commodities, animals, pests, soil, or water:

*Provided, *That, nothing in this Act shall be construed as authorizing officers or employees of the United States or of any State to enter and inspect private residences or land, property, and appurtenances used in agricultural production unless there is a suspected violation of this Act or the Administrator or any

State is seeking information as part of an inquiry into specific environmental or health problems.

SEC. XX. UNLAWFUL ACTS.

Section 12 (a)(2)(O) (7 U.S.C. 136j (a)(2)(O)) is amended to read as follows:

"(O) to violate any regulation issued pursuant to this Act."

SEC. XX. ENFORCEMENT.

ENFORCEMENT AUTHORITY.-Section 14 (7 U.S.C. 136l) is amended to read as follows:

"(a) REQUIREMENTS FOR ADMINISTRATIVE ORDERS.-

"(1) IN GENERAL.-Any person who has violated, or is in violation of, any provision of this Act or a regulation promulgated thereunder, may be ordered by the Administrator to cease their violative activities or to comply with applicable requirements of this Act or regulations issued under this Act.

"(2) VIOLATION OF ORDER.-If a violator fails to take corrective action within the time specified in the order, the Administrator may assess a civil penalty of not more than \$25,000 for each day of continued noncompliance with the order.

"(3) CONSULTATION WITH ADMINISTRATOR.-The recipient of an order issued under this section (other than an administrative penalty order as described in subsection (c)), shall have an opportunity, within 10 days of the order's issuance, to consult with the Administrator or any duly designated representative concerning the alleged violation.

"(b) ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES.-

"(1) IN GENERAL.-Any person who has violated, or is in violation of, any provision of this Act or regulation promulgated thereunder shall be liable to the United States for a civil penalty in an amount not to exceed \$25,000 or the economic benefit of noncompliance, whichever is higher, for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of the Act. The Administrator's authority under this paragraph shall be limited to matters where the total penalty sought does not exceed \$400,000, except where the Administrator and the Attorney General jointly determine that a matter or matters involving a larger penalty amount are appropriate for administrative penalty action. Any such determination by the Administrator and the Attorney General shall not be subject to judicial review.

"(2) HEARING.-A civil penalty for a violation of this Act shall be assessed by the Administrator by an order made on the record after an opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of Title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order by the Administrator, and shall provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

"(3) DETERMINATION OF PENALTY.-In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations (including whether the violation was a first-time violation), the degree of culpability, the economic benefit of noncompliance, and such other matters as justice may require.

"(4) The minimum penalty the Administrator must assess under this subsection upon a determination of liability is the amount of the economic benefit resulting from the violation, where such economic benefit, if any, is calculable, provided that nothing in this subsection shall limit the Administrator's discretion to issue warning notices pursuant to section 14(b)(3) of the Act. The Administrator may issue a warning notice for a first-time violation of the Act by a private applicator, unless the violation is a knowing violation.

"(5) JUDICIAL REVIEW.-Any person who requested in accordance with paragraph (2) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, or against whom a civil penalty is assessed under paragraph (8) of this subsection, may seek judicial review in accordance with section 16(a)(2) of the Act.

"(6) FAILURE TO PAY.-

"(A) If a person fails to pay an assessment of a civil penalty-

"(i) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with paragraph (5), or

"(ii) after a court in an action brought under paragraph (5) has entered a final judgment in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in paragraph (5) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States.

In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

"(c) CIVIL JUDICIAL ENFORCEMENT.-

"(1) IN GENERAL.-The Administrator may commence a civil action for a temporary or permanent injunction, and/or to compel compliance, and/or to assess and recover a civil penalty of not more than \$25,000 or the economic benefit of noncompliance, whichever is higher, for each day of violation, whenever such a person has violated or is in violation of a requirement or prohibition of this Act, or a regulation promulgated thereunder.

"(2) JURISDICTION.-Any action under this subsection may be brought in the district court for the United States for the district in which the violation is alleged to have occurred, or is occurring, or in which the defendant resides, or where the defendant's principal place of business is located, and such court shall have jurisdiction to restrain such violation, to require compliance, to assess civil penalties, to collect any fees owed the United States under this Act, and to award any other appropriate relief.

"(3) DETERMINATION OF PENALTY.-In determining the amount of a civil penalty, the court shall take into account the factors enumerated in subsection (c)(3) of this section.

"(4) MINIMUM PENALTY.-The minimum penalty the court must assess under this subsection upon a determination of liability is the amount of the economic benefit, if any, resulting from the violation, where such economic benefit is calculable.

"(d) CRIMINAL PENALTIES.-

"(1) Any person who knowingly commits any act prohibited under section 136j of this title shall, upon conviction, be punished by a fine of not more than \$50,000 for each day of violation, or by imprisonment for not more than 5 years, or both. If the conviction is for a violation committed after a first conviction of such person under this paragraph, the maximum punishment shall be doubled with respect to both fine and imprisonment.

"(2)(A) Any person who commits any violation under paragraph (2) of this subsection and in the course of or in connection with committing such violation knows at the time that he places another person in imminent danger of death or serious bodily injury, shall, upon conviction, be punished by a fine of not more than \$250,000 or imprisonment of not more than 15 years, or both. A person which is an organization shall, upon conviction of violating this subparagraph, be subject to a fine of not more than \$1,000,000. If a conviction of a person is for a violation committed after a first conviction of such person under this subparagraph, the maximum punishment shall be doubled with respect to both fine and imprisonment.

"(B) For purposes of this subparagraph-

"(i) the term "imminent danger" means the existence of a condition or set of conditions that could reasonably be expected to cause death or serious bodily injury unless the condition is remedied; and

"(ii) the term "serious bodily injury" means bodily injury which involves a substantial risk of death, unconsciousness, extreme physical pain, protracted and obvious disfigurement, or protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

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BACKGROUND ON JUDICIAL REVIEW ISSUE

The proposed amendment to section 16 of FIFRA would address problems that currently exist with the Act's provisions governing judicial review. The proposal would be of advantage to all litigants as it would clarify where and how judicial review of various decisions of the EPA should be made. It would thereby eliminate needless litigation. The proposal would also align the standard of review with the current movement to make proceedings under FIFRA less formal. Finally, the proposal would eliminate unnecessary language from the section.

The first problem addressed by the amendment is the current statute's failure to clearly state which decisions of the Administrator are reviewed by district courts and which are to be reviewed by courts of appeals. The current version of FIFRA deals with this question in two places. The first is in section 16(a) which provides that:

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

7 U.S.C. § 136n(a). Under the second provision, which is contained in section 16(b), the courts of appeals have jurisdiction to review decisions

issued by the Administrator following a public hearing.

7 U.S.C. § 136n(b). In large part, the question of which court reviews a particular decision of the Administrator turns on whether the decision was made following a "public hearing."¹ This question has caused uncertainty and given rise to unnecessary litigation.²

¹It is not clear why section 16(a) uses the language "following a hearing" while section 16(b) uses the qualifier "following a public hearing."

²See, e.g., Northwest Food Processors Ass'n v. Reilly, 886 F.2d 1075 (9th Cir. 1989); Humane Society of the United States v. EPA, 790 F.2d 106 (D.C. Cir 1986); EDF v. Costle, 631 F.2d 922 (continued...)

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The amendment would eliminate this uncertainty without changing what appears to be the intent of the current judicial review provisions in FIFRA. Those provisions assign to the courts of appeals the review of decisions that are made based upon a well-defined administrative record and of decisions that are committed to the discretion of the Administrator by law. This includes the review of EPA's regulations, registration decisions, and other similar actions. District court jurisdiction, on the other hand, extends to enforcement actions by the United States and the review of matters not within the discretion of the Administrator or for which review has not been assigned to the courts of appeals. The amendment would eliminate the uncertainty by specifying which decisions of the Administrator are to be reviewed by the courts of appeals.

Second, the proposed language explicitly states that all review will take place under the "arbitrary and capricious" standard rather than the "substantial evidence" standard presently contained in section 16(b). This is consistent with proposals to make the procedures for registration and other actions under FIFRA more akin to informal rulemaking procedures. The arbitrary and capricious standard is, of course, the appropriate standard for such rulemaking. See, 5 U.S.C. § 706(2)(A).

Third, much of the language of the current section 16 is unnecessary. For example, the present version of section 16(b) mentions how Supreme Court review of a court of appeals decision can be sought. This type of provision is not generally contained in other statutes and there is no reason to include it in FIFRA. The amended section 16 would accordingly be a more streamlined version which would make it easier to understand.

Fourth, the pertinent judicial review provisions in FIFRA can be consolidated into the proposed amendment of section 16. Presently there are at least three other provisions in the statute which deal piecemeal with certain aspects of judicial review: section 4(1), 6(c)(4), and 6(h); 7 U.S.C. §§ 136a-1(1), 136d(c)(4), and 136d(h). The proposed language of section 16 has been structured so that these additional provisions are

²(...continued)

(D.C. Cir.), cert. denied, 449 U.S. 1112 (1980); Louisiana v. Train, 392 F.Supp. 564 (W.D. La.), aff'd 514 F.2d 1070n (5th Cir. 1975).

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unnecessary and could be deleted. Accordingly, there should be less confusion over how to obtain judicial review.

Finally, the proposed amendment would require that all petitions seeking review of decisions of the Administrator which have a national impact be filed in the U.S. Court of Appeals for the D.C. Circuit. Having all such petitions resolved in one court helps to ensure that there is a uniform interpretation of the rules under FIFRA that are to be applied throughout the country. Some of the decisions of the Administrator, such as those granting primary enforcement to a state or involving challenges to the imposition of fines, only have local impacts. All of those decisions would be reviewed in the circuit in which the local impact would occur.

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TALKING POINTS RE: JUDICIAL REVIEW ISSUES IN FIFRA

- FIFRA currently provides that registrants, users and others can obtain judicial review of many of the decisions made by EPA under FIFRA. However, the judicial review provisions currently contained in FIFRA are confusing and somewhat difficult to apply. As a result they have led to unnecessary litigation and have probably discouraged some from seeking judicial review when it has been available. Streamlining the provisions would simply make judicial review easier for registrants and others who seek to challenge EPA's decision.
- FIFRA now provides that the question of whether jurisdiction to review a particular action is in the courts of appeals or district courts depends on whether the order involved was entered following a public hearing. The question of whether a public hearing has occurred has caused much uncertainty and confusion and has given rise to unnecessary litigation. It would be simpler to provide that judicial review of EPA's regulations, registration decisions, and other similar actions with a well-defined administrative record should take place in the courts of appeals. The district court would have jurisdiction to review only administratively assessed civil penalties as is provided for in other sections of the Act.
- Various aspects of judicial review are dealt with in FIFRA in sections other than section 16. Section 16 can be restructured so that it incorporates most of the other judicial review provisions. This will make it easier to understand how to obtain judicial review of EPA actions under FIFRA.
- Section 16 currently contains language that is unnecessary. For example, subsection (b) discusses how Supreme Court review of a court of appeals decision can be sought. This is an anomaly and is not contained in other environmental statutes. It can be eliminated without substantively changing the scope of judicial review available under FIFRA. The information on Supreme Court review is contained in other sections of the U.S. Code.

PROPOSED LEGISLATION:

REVIEW BY COURTS OF APPEALS.-Section 16(b) (7 U.S.C. 136n(b)) and section 16(c) (7 U.S.C. 136n(c)) are amended to read as follows:

"(b) **REVIEW BY COURTS OF APPEALS.**-

(1) **REVIEW IN THE DISTRICT OF COLUMBIA CIRCUIT.**-A petition for review of any of the following actions of the Administrator may be filed by any adversely affected person only in the United States Court of Appeals for the District of Columbia Circuit:

"(A) The promulgation of any regulations by the Administrator under this Act, or a final determination maintaining in effect a final rule under section 6(I)(5)(A)(iii) of this Act.

"(B) A final order of the Administrator canceling or suspending a pesticide registration in whole or in part or concluding that a pesticide registration should not be canceled or suspended.

"(C) A final order of the Administrator approving or denying an application for a pesticide registration.

"(D) A final order of the Administrator changing the classification of any use of a pesticide.

"(E) A final order of the Administrator responding to objections to a notice requiring changes in the labeling, packaging, or composition of a pesticide.

"(F) A final order of the Administrator denying a petition seeking to suspend or cancel a pesticide registration, to deny an application for a registration, to reconsider whether a registration should be suspended, or to change the classification of a pesticide.

"(G) A final determination of the Administrator to renew a pesticide registration under section 3(g)(4).

"(H) A final determination of the Administrator resulting in the expiration of a registration under section 3(g)(5).

"(I) A final order issuing or denying an emergency exemption to a Federal agency.

"(2) **REVIEW BY OTHER COURTS OF APPEALS.**-A petition for review of any of the following actions of the Administrator may be filed by any adversely affected person only in the United States court of appeals for the circuit in which the State in question is located or in which a hearing assessing a civil penalty occurred:

"(A) A final order following a hearing assessing a civil penalty.

"(B) A final order of the Administrator determining that a State shall have primary enforcement authority pursuant to section 26 of this Act.

"(C) A final order of the Administrator rescinding primary enforcement authority pursuant to section 27 of this Act.

"(D) A final order of the Administrator approving or disapproving a State certification plan for pesticide applicators pursuant to section 11 of this Act.

"(E) A final order approving or disapproving a State plan for the issuance of experimental use permits under section 5 of the Act.

"(F) A final order of the Administrator disapproving a State's registration of a pesticide or suspending a State's authority to register pesticides pursuant to section 24 of this Act.

"(G) A final order issuing or denying an emergency exemption to a State.

"(3) PROCEDURE.-Except as provided in paragraph (4) of this subsection, any petition for review under paragraph (1) or (2) of this subsection must be filed within sixty days of the final action unless the petition for review is based solely on grounds arising after the sixtieth day. Judicial review shall be in accordance with sections 701 through 706 of title 5 of the United States Code, and the challenged action shall be sustained unless it is found to be arbitrary, capricious, an abuse of discretion, or not in accordance with law. Actions of the Administrator with respect to which review could have been obtained under this subsection shall not be subject to judicial review in civil or criminal proceedings for enforcement.

"(4) IMMINENT HAZARD SUSPENSION.-Any petition for review under paragraph (1) of a suspension order or denial of a petition to reconsider suspension issued by the Administrator pursuant to section 6^c of this Act must be filed within ten (10) days of publication of the suspension order in the Federal Register, or, in the case of a challenge of the denial of a petition to reconsider suspension, within twenty (20) days of publication of the Administrator's order denying the petition for reconsideration. The commencement of proceedings under this paragraph shall not operate as a stay of the suspension order unless otherwise ordered by the court. The effect of any order of the court of appeals will be only either to stay or Agency as of the date the Administrator issued the suspension order.

Other information not available to the Administrator in issuing the suspension order under section 6(c)(1) may be introduced

solely through the procedures for reconsideration of a suspension order set forth in section 6(c)(4).

"(c) JURISDICTION OF DISTRICT COURTS.-The district courts of the United States are vested with jurisdiction over-

"(1) actions to enforce, and to prevent and restrain violations of, his Act; and

"(2) challenges to any other final actions that are not committed to the Administrator's discretion by law and which are not subject to review in the courts of appeals under subsection (a) of this section."

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 4329

FILE NO: 851

SPECIAL

5/6/96

LEGISLATIVE REFERRAL MEMORANDUM

Total Page(s): 6

TO: Legislative Liaison Officer - See Distribution below:

FROM: Ron PETERSON

R. Peterson

(for) Assistant Director for Legislative Reference

OMB CONTACT: Holly FITTER 395-3233 Legislative Assistant's Line: 395-6194
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Beverly BOYD 395-3445

SUBJECT: Environmental Protection Agency Proposed Report RE: HR1627, Pesticide Food
Safety Act of 1995

DEADLINE: 10:00 AM Thursday, May 09, 1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before
advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go"
provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

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FILE NO: 851

Please include the LRM number shown above, and the subject shown below.

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other. _____

_____ FAX RETURN of _____ pages, attached to this response sheet

5.6.96

Honorable Henry Waxman
House of Representatives
Washington, DC 20515

Dear Representative Waxman:

Thank you for your letter of March 5, 1996. I understand that action on H.R. 1627, legislation to amend the nation's food safety and pesticide laws, may take place in the near future. In anticipation of that action, I wish to reiterate our serious concerns about the legislation as currently drafted.

In testimony presented before the Health and Environment Subcommittee of the Committee on Commerce, representatives from the Environmental Protection Agency, the Food and Drug Administration and the Department of Agriculture indicated that we cannot support H.R. 1627 without significant changes. The testimony outlined a number of our concerns with the FFDCA portion of the legislation, including inadequate protection for infants and children, the expanded benefits considerations, the presumption accorded to Codex standards, and federal preemption of state and local standards. I have enclosed a copy of that testimony and a summary of our concerns. I would like to focus on one of the most important of those concerns here.

More specifically, the standards established in H.R. 1627 will not adequately protect the health of infants and children. While the legislation does include references to children's diets, it does not require a specific finding that pesticide residue levels are safe for infants and children nor does it expressly mandate Agency decisions to incorporate the key recommendations of the National Academy of Sciences study on Pesticides in the Diets of Infants and Children. Any legislation that intends to ensure safe food for all Americans must include strong provisions to protect children, our most vulnerable population. H.R. 1627 does not meet that test.

H.R. 1627 does not currently contain the provisions necessary to strengthen the nation's pesticide and food safety laws. In fact, key provisions of the legislation would weaken both FIFRA and FFDCA and jeopardize our ability to protect the public health. Although the Commerce Committee has jurisdiction over the FFDCA and not FIFRA, EPA believes that H.R. 1627 must be assessed as a whole. Even if our concerns about the FFDCA provisions are addressed we will continue to oppose H.R. 1627 if it does not strengthen current laws. Only through genuine efforts to preserve and strengthen our food safety laws will we be able to resolve longstanding problems and enhance public confidence in the safety of our food supply.

Sincerely,

DRAFT

Lynn R. Goldman, M.D.
Assistant Administrator

Need clearance per myograph

R. Conrad

<Date>

**Summary of Administration Concerns
H.R. 1627 - THE FOOD QUALITY PROTECTION ACT OF 1995**

On June 7, 1995, representatives of the Environmental Protection Agency, the Department of Agriculture, and the Food and Drug Administration testified before the House Committee on Commerce regarding H.R. 1627, the Food Quality Protection Act of 1995. In that testimony, the Administration indicated that it could not support H.R. 1627. This legislation does not adequately protect children, it greatly expands consideration of economic benefits when setting health standards for pesticide residues in food, and it does not provide fees to complete reregistration. While the Administration supports comprehensive legislative reforms to improve food safety and ensure that consumers are provided a safe, abundant and affordable food supply, we believe H.R. 1627 could actually hinder our efforts to protect public health. The following is a summary of our major concerns with H.R. 1627, as mentioned in testimony. The prepared testimony is also available for a more complete analysis of H.R. 1627.

KEY ADMINISTRATION CONCERNS

Federal Food, Drug and Cosmetic Act (FFDCA):

H.R. 1627 will not adequately protect the health of infants and children. The National Academy of Sciences 1993 report, Pesticides in the Diets of Infants and Children, concluded that current pesticide regulatory practices do not fully protect infants and children. While H.R. 1627 contains some brief language on this issue, it will not ensure that the recommendations of the NAS will be implemented.

H.R. 1627 weakens current law by expanding the kinds of economic benefits that can be considered when setting standards for pesticide residues in food, and by allowing these economic benefits to override risks to consumers and the environment. Pesticides that do not meet the bill's negligible risk standard could still remain on the market indefinitely if the risks are outweighed by the benefits considerations.

H.R. 1627 retains cumbersome, time-consuming hearing processes and establishes internally inconsistent procedures for actions on pesticide levels in foods.

H.R. 1627 contains very broad pre-emption language that would override state and local laws, including consumer right-to-know laws concerning the presence of pesticide residues in food, such as California's Proposition 65.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA):

H.R. 1627 replaces the existing procedures for removing risky chemicals from the market, which can already take years, with an untested and even more burdensome process. These changes attempt to shift the "burden of proof" for demonstrating a pesticide's safety from the pesticide producer to EPA, which would dramatically weaken current law.

H.R. 1627 does not extend authority to collect industry fees necessary to complete the legislatively mandated health and safety review of older pesticides - a major tool in managing the risks of pesticide use.

ADDITIONAL COMMENTS FROM ADMINISTRATION TESTIMONY ON H.R. 1627:

- Require specific Agency actions to incorporate key recommendations of the NAS report, Pesticides in the Diets of Infants and Children, when setting food safety standards. Requirements should include issuing a specific finding that legal limits on pesticide residues in food are safe for infants and children, considering all sources of exposures to a pesticide and its related compounds, and using more information on children's diets and exposures to pesticide residues.
- Clearly delimit the kind of benefits that can be considered when setting legal limits on pesticide residues in food, and set a limit on the maximum amount of risk that could be balanced against benefits.
- Set a time limit on any benefits considerations so that over time there is a transition to a purely health-based food safety standard.
- Streamline cancellation proceedings to allow for quicker resolution of pesticide risk concerns, and maintain the "burden of proof" in cancellation proceedings on the pesticide manufacturer.
- Extend EPA's authority to collect industry fees so that the review of older chemicals can be completed in a timely manner.
- Update penalties for violations under FIFRA and FFDCA so that they are better related to the severity of the offense and commensurate with other environmental laws, and strengthen EPA and FDA's ability to enforce food safety laws.

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COMMITTEES:
COMMERCE
GOVERNMENT REFORM AND OVERSIGHT

THE P. M. BOWLING
ADMINISTRATIVE ASSISTANT

Congress of the United States
House of Representatives
Washington, DC 20515-0529

HENRY A. WAXMAN
28TH DISTRICT, CALIFORNIA

March 5, 1995

The Honorable Carol M. Browner
Administrator, Environmental Protection Agency
401 M Street, S.W.
Mail code 1101
Washington, D.C. 20460

Dear Administrator Browner:

In the near future, H.R. 1627, "The Food Quality Protection Act of 1995," will likely be considered in the House Commerce Committee. This bill would amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

I am very concerned about the consequences H.R. 1627 could have on the presence of pesticides in the food supply. I am requesting that you share your views on this legislation with me, and would appreciate a response at your earliest convenience.

With every good wish, I am

Sincerely,


Henry A. Waxman
Member of Congress

OPTIONAL FORM 88 (7-90)

FAX TRANSMITTAL

To: <u>Henry A. Waxman</u>	From: <u>Robert Logan</u>
Dist. Agency: <u>202-225-5678</u>	Phone: <u>260-5431</u>
Fax: <u>202-225-5678</u>	Fax: <u>260-5431</u>
NSN 7540-01-010-7500	5010-101

GENERAL SERVICES ADMINISTRATION

4/6/10

U.S. Department of Agriculture
Office of the Under Secretary
Natural Resources and Environment
(202) 720-7173 - Phone
(202) 720-4732 - Fax

DATE: 7/23/96

TO: Elizabeth Dye

PHONE NUMBER: _____

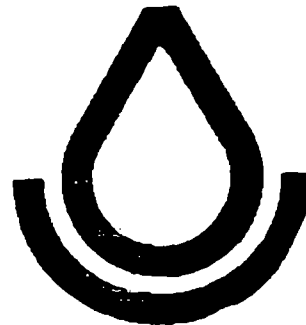
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DRAFT

Larry Elvorth

STATEMENT OF SECRETARY DAN GLICKMAN
ON HOUSE OF REPRESENTATIVES PASSAGE OF H.R. 1627
FOOD QUALITY PROTECTION OF 1996

~~July 22, 1996~~

Today's passage of bipartisan compromise legislation by the House of Representatives is a victory for farmers and for consumers. Strongly supported by the Clinton Administration, the Food Quality Protection Act (H.R. 1627), resolves the long standing problems posed by the Delaney clause, provides enhanced protection for infants and children, and includes common sense regulatory reform.

Farmers would benefit in two major ways from enactment of this legislation. The bill increases incentives for growers, particularly minor crop producers, to use new pest management tools. And, by strengthening pesticide laws, the bill would also positively impact consumers' confidence in the safety of the foods they purchase for their families.

The Clinton Administration urges swift Senate approval of this bill so that these improvements -- which benefit farmers and protect families -- can be signed into law.

#

OK -

NEEDS CLEARANCE

FROM OURS - WINE HOUSE PRESS

THE WHITE HOUSE
OFFICE OF THE VICE PRESIDENT

FOR IMMEDIATE RELEASE
WEDNESDAY, July 17, 1996

CONTACT: 202/456-7035

STATEMENT BY THE VICE PRESIDENT

Today, the House Commerce Committee took a major step toward improving food safety for all Americans by strengthening our laws regulating pesticides in foods.

The Committee bill meets goals President Clinton set forth early in his Administration: a strong health-based standard; enhanced protections for infants and children; and common-sense reform of regulatory requirements.

I commend the Committee for setting aside differences to address this critical issue. And I hope Congress and interest groups will respect the delicate balance of this bipartisan bill so that the President can sign legislation this year to improve food safety for all Americans.

##

25-4099

4/7/94

PESTICIDE AND FOOD SAFETY LEGISLATIVE PROPOSALS: COMPARATIVE SUMMARY OF KEY ISSUES

Three major proposals to amend the laws governing pesticides and food safety regulation are pending in the current Congress: the Administration's Pesticide and Food Safety Reform Act, (bill #), introduced [by request?] this week by [?]; the Pesticide Food Safety Act (H.R. 4091) introduced by Representative Waxman; and the Food Quality Protection Act (H.R. 1627, S. 1478) sponsored by Representatives Lehman, Bliley, Rowland et al. in the House of Representatives and Senator Pryor in the Senate. [NOTE TO REVIEWERS--THIS LEAVES OUT THE "ORIGINAL" WAXMAN KENNEDY BILL; PRESUMABLY ALL AGREE IT HAS BEEN SUPERSEDED BY NEW WAXMAN BILL?]

While all three proposals address some of the same issues, there are significant differences. The following discussion summarizes how each proposal addresses key issues in pesticide reform under both major pesticide regulatory laws. It does not reflect all provisions but focuses on 17 major points.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

Under the FFDCA, the Environmental Protection Agency (EPA) sets tolerances, or maximum legally permissible levels, for pesticide residues in food. The FFDCA is also the source of Food and Drug Administration (FDA) authority to monitor the food supply and enforce the tolerances set by EPA. The pending proposals address six major issues.

o STANDARDS FOR TOLERANCE-SETTING

Administration's Bill:

Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. This new uniform safety standard would replace the current standards in sections 408 and 409 of FFDCA and would be the basis for regulating pesticide residues in all types of foods, whether raw or processed.

The statute would specify factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations, risks from multiple sources of exposure, and risks from pesticides that have a common mechanism of action. EPA would also have clear authority to set multiple tolerances for residues in foods at different points in the food production and distribution chain, including at the farm gate and at the point of retail sale.

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Risk assessments would be performed utilizing the protective assumption that residues are present in foods at the applicable tolerance levels, except when reliable data permit exposure assumptions to be adjusted to reflect the percentage of a crop actually treated with the pesticide.

H.R. 4091:

Similar in approach to the Administration proposal in terms of setting standards to ensure the safety of all types of food, replacing current Sections 408 and 409, H.R. 4091 is more specific in terms of defining in statute how tolerances are to be set. The bill would require tolerances to meet a negligible risk standard, ensuring a reasonable certainty that pesticide residues will cause no harm to human health. In further defining how the safety standard should be implemented, the bill establishes specific numerical risk criteria for cancer and other non-threshold effects, as well as for threshold effects for which no effect levels can be established.

After enactment, no new tolerances could be established for potentially carcinogenic residues or any active or inert ingredient found to be "highly hazardous," as defined in the bill. Existing tolerances for these pesticides would be eliminated within five years of enactment: in certain limited circumstances, it would be possible to grant a three year phase-out extension, with use declining by 20 percent per year over the three years.

Tolerances could be established at three points in the food production and distribution chain: at harvest, at the point of retail sale, and after processing.

H.R. 1627:

This legislation would also amend FFDCA to establish a single negligible risk standard for tolerances for pesticide residues in raw and processed foods, but it is the least specific of the three proposals in defining what would qualify as "negligible." EPA is directed to take various factors and "reasonable assumptions" into account in tolerance-setting and is to define by regulation the factors and methods the agency would use in determining whether risks are negligible. If reliable data are available, the EPA would be required to base its exposure assessments on actual residues rather than assume residues are present at tolerance levels. Percent of crop treated data would also be used in calculating exposure.

Unlike the Administration's proposal and H.R. 4091, H.R. 1627 would allow risks that exceeded negligible to continue indefinitely, if they were outweighed by the benefits of the pesticide.

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o **SPECIAL PROVISIONS FOR INFANTS AND CHILDREN**

Administration's Bill:

The Administration's proposals for tolerance setting contain additional requirements that are directly responsive to the recommendations contained in the 1993 National Academy of Sciences (NAS) report on "Pesticides in the Diets of Infants and Children." Specifically, EPA would be required to consider unique aspects of children's diets and potential sensitivities to pesticide risks. EPA would issue specific findings that tolerances are safe for infants and children.

EPA would evaluate multiple exposures when establishing tolerances and apply additional safety factors and/or take other necessary steps to ensure safety for infants and children. More accurate data on children's consumption habits would also be developed and utilized in tolerance setting and reassessment.

H.R. 4091:

This bill requires EPA to fully account for potential susceptibilities of infants and children to pesticide risks and to ensure an ample margin of safety based on the consumption patterns of specified age groups as well as the general population. H.R. 4091 mandates use of an additional 10-fold safety factor unless complete exposure and toxicity data demonstrate that different safety factor will fully protect infants and children.

H.R. 1627:

H.R. 1627 does not specifically address children's diets and potential susceptibilities. S. 1478, introduced after the release of the 1993 NAS report, requires EPA, the US Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) to take certain actions based on the report. Both versions of the bill direct EPA to take into account "available information and reasonable assumptions" about variability in sensitivity to pesticide effects and the food consumption patterns of major identifiable subgroups of the population but do not mandate specific safety factors or age groups.

o **REVIEW OF EXISTING TOLERANCES**

Administration's Bill:

EPA would be required to review all existing tolerances and ensure that they meet the new standard within seven years of enactment. Fees would support both tolerance review and setting of new tolerances.

Special fast track provisions would require priority review of pesticides which, based on currently available data,

appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of such tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment. Pesticides subsequently identified as potentially not meeting the standard may be added to the fast track; similar time frames would apply for data submission and review.

H.R. 4091:

This bill contains a number of review provisions. A list of known or probable carcinogens would be published within 60 days, and updated every two years. Tolerances for these and other pesticides that are classified as "highly hazardous" would be terminated in five years, with a possibility of a three year phase-down extension as described above.

Within 6 months, a list would be published of active and inert ingredients for which there is limited evidence of carcinogenicity or which meet the criteria for "highly hazardous" specified in the bill. Within one year of publication of these lists, EPA would be required to take measures to inform the public of its exposure to pesticides on these lists.

Within one year after enactment, EPA would review all tolerances and exemptions as determine if they meet the standards for tolerances in the bill or lack the data needed to make such a determination. Tolerances found not to meet the standard would be revoked (or reduced to levels that do meet the standard) within one year of EPA's finding. Pesticides for which data are insufficient to make a determination would be put on a schedule for data development. Final determinations would be required for at least 30 percent of existing tolerances and exemptions within 2 years of enactment; 60 percent within 3 years; 90 percent within 6 years; and 100 percent within 7 years.

Within three years after enactment, EPA would publish a list of pesticides that are "hazardous," based on review of data submitted under new testing protocols that EPA is required to establish within one year of enactment.

Within four years after enactment, a review of the best available cancer data is required with respect to "all possible" human carcinogens to identify any that may be classified as "known or probable" carcinogens. Unless a petition demonstrating that the pesticide is not a "known or probable" human carcinogen has been filed and granted, the bill states that the pesticide "shall be a known or probable" carcinogen within the meaning of the FFDCA.

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Both the Administration proposal and H.R. 4091 require listing and review of pesticides that may qualify as "generally recognized as safe" (GRAS) to ensure that they are indeed GRAS. H.R. 4091 also requires review of existing methods of analysis within 180 days.

H.R. 1627:

While there is no tolerance review requirement in the FFDCA provisions of H.R. 1627, the bill would amend FIFRA to require a reassessment of tolerances whenever EPA has sufficient information to assess dietary risks, or in any event no later than the time the EPA makes a reregistration decision.

o TIME-LIMITED TRANSITIONAL TOLERANCES/ROLE OF BENEFITS IN TOLERANCE SETTING**Administration's Bill:**

EPA could grant time-limited transitional tolerances of no more than five years for a pesticide identified during the tolerance review process as not meeting the safety standard, if the loss of the pesticide would result in loss of direct consumer health benefits or significant disruption in domestic food production.

The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on tolerance sponsors to make the showing needed to support a time-limited tolerance.

H.R. 4091:

Like the Administration bill, H.R. 4091 would not permit benefits to be considered in setting any new tolerances. In exceptional circumstances, existing tolerances for pesticides identified as "known or probable" carcinogens or "highly hazardous to human health," for which there are no effective pest management alternatives, could qualify for a three year extension of the five year phase-out period required by the bill. A condition of this extension would be a reduction in use of at least 20 percent per year over the three year period.

H.R. 1627:

Unlike the other two proposals, H.R. 1627 would continue to permit tolerances that exceed negligible risk to be established and maintained, if benefits are found to outweigh risks, provided that EPA has assessed the extent of efforts to develop less risky alternatives. The types of benefits that EPA could consider in setting tolerances would include avoidance of greater risks to health or the environment resulting from inadequate pest control or use of alternative pesticides or means of pest control than would

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be posed by dietary exposure to the pesticide residue, as well as negative effects on the availability of an "adequate, wholesome, and economical food supply, taking into account regional and domestic effects." Effects on pesticide producers and marketers could not be taken into account.

o ENFORCEMENT AUTHORITIES

Administration's Bill:

FDA enforcement powers with respect to pesticide residues in food would be expanded to include new authorities to recall and embargo violative foods and to levy civil penalties for violations.

H.R. 4091:

While H.R. 4091 contains no similar FDA enforcement enhancements, it does, like the Administration's proposal, include provisions aimed at improving methods for monitoring and enforcement purposes.

H.R. 4091 provides that tolerance violations at the time of retail purchase would not be subject to penalties. New provisions allow any person to obtain judicial review of the adequacy of data supporting tolerances and require court revocation of tolerances unless the court finds the data to be adequate. EPA would have the burden of proof in these proceedings.

H.R. 1627:

This legislation contains no enforcement enhancements but does authorize \$12 million for increased monitoring of imported and domestic food for pesticide residues.

o PRE-EMPTION OF STATE TOLERANCE-SETTING AUTHORITY

Administration's Bill:

No provision.

H.R. 4091:

No provision.

H.R. 1627:

States and localities would generally be prohibited from establishing their own tolerances for pesticides first registered or reregistered after April 25, 1985, or for which there are other "qualifying federal determinations" that have been found to protect public health. States could petition for waivers based on compelling local conditions, if the waiver would not unduly burden commerce.

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**FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)
PROPOSALS**

FIFRA governs the registration and reregistration of pesticides by EPA for use. It contains a number of other pesticide regulatory authorities not directly tied to residues in food. FIFRA amendments relating to eleven major issues are found in the Administration's bill or H.R. 1627, or both. H.R. 4091 contains no FIFRA provisions.

o REGISTRATION "SUNSET"**Administration's Bill:**

Pesticide registrations would be required to be reviewed and renewed on an active ingredient basis every 15 years, to ensure they are in conformity with current scientific standards. Complete applications must be submitted to EPA by year 12 after registration or registration renewal. For the initial implementation of the 15-year cycle, the legislation would allow for grouping pesticides in a way that permits EPA to balance workloads and avoid skewed distributions in the numbers of pesticides that "come due" in any given year. Fees paid by registrants would support the sunset program.

H.R. 1627:

No provision.

o PHASE-OUT/PHASE-DOWN**Administration's Bill:**

Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements to avoid unnecessary dislocations.

H.R. 1627:

No provision.

o STREAMLINING LABEL CHANGES AND ESTABLISHING UNIFORM LABEL COMPLIANCE DATES ("LABEL CALL-IN" AUTHORITY)**Administration's Bill:**

Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that

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reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

H.R. 1627:

No provision.

o INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES

Administration's Bill:

EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided.

Also, EPA could grant special conditional registrations for biological pesticides posing low potential risks.

H.R. 1627:

No specific provision, except in the context of IPM research direction, as described below.

o PESTICIDE RISK AND USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT (IPM) PROGRAMS

Administration's Bill:

The statute would embody clear policy goals favoring reduced use and directing federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

The statute would authorize regional ecosystem-based reduced use pilot projects designed to reduce aggregate pesticide risks and provide a mechanism to focus research priorities. EPA and USDA would be mandated to work together to develop and make available comparative information on the environmental and health effects of pesticides and to identify the research, education and extension activities that are most promising in terms of meeting pest management needs and reducing use of pesticides that raise risk concerns.

The statute would require EPA to identify pesticides of regulatory concern for which there are limited alternatives. USDA would be required to use this information to focus its research and education efforts. The statute would require USDA, in consultation with EPA, to develop a research and extension plan for each commodity determined to have an "alternatives problem."

9

The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

H.R. 1627:

EPA and USDA are directed to research, develop and disseminate IPM techniques and other methods of pest control that enable growers to reduce or eliminate applications of pesticides that pose greater than negligible dietary risks, with special emphasis on crops considered critical to a balanced, healthy diet that are considered to be minor crops in terms of acreage.

o IMPROVED PESTICIDE DATA COLLECTION/RECORD-KEEPING**Administration's Bill:**

Following the model of the 1990 Farm Bill provisions, which applied only to restricted use pesticides, the legislative proposals would require record-keeping for all agricultural pesticide use.

H.R. 1627:

USDA is to coordinate with EPA in collecting pesticide use data through surveys and make survey results available for pesticide exposure assessments and benefits analyses. No new record-keeping requirements are established.

o PESTICIDE MINOR USES**Administration's Bill:**

Incentives for registering minor uses would include priority review and extended exclusive data use rights. In reregistration under amendments to FIFRA enacted in 1988, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

EPA, and the Department of Health and Human Services/Public Health Service (HHS/PHS) would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

H.R. 1627:

No provision.

10

o CANCELLATION AND SUSPENSION PROCEDURES

Administration's Bill:

Cancellation procedures would be amended to replace formal, trial-type proceedings before an Administrative Law Judge (ALJ) with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging suspensions would be replaced by a petition procedure and prompt judicial review.

H.R. 1627:

The bill would replace current FIFRA cancellation procedures with a process described as "informal rulemaking," but requiring many additional steps (including referral to an internal scientific peer review committee; pre-notice to registrants and the Secretaries of Agriculture and Health and Human Services; an advance notice of proposed rulemaking; a notice of proposed rulemaking; an informal hearing of up to 20 days duration; Scientific Advisory Panel (SAP) review and report, and possibly a public SAP hearing; a comment period on the SAP report; and a final rule or withdrawal of the proposed rule). Pesticides already in Special Review as of January 1, 1993, could continue to be dealt with according to special review procedures rather than these new cancellation provisions. Restricted use classifications would have to be made using the new cancellation procedures.

EPA would be authorized to issue suspension orders before issuing a proposed cancellation rule only in emergency situations. The Agency must proceed "expeditiously" to issue the corresponding cancellation proposal. ALJ proceedings are retained for suspension actions.

o ENFORCEMENT AUTHORITIES

Administration's Bill:

Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities and "whistle blower" and citizen suit provisions. Penalties for FIFRA violations would be significantly increased, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

H.R. 1627:

No provision.

o PESTICIDE EXPORT RESTRICTIONS

11

Administration's Bill:

Generally, the legislation would prohibit the export of pesticides not approved for use in the U.S., with certain limited exceptions.

Export of any pesticide to a country that has decided that it does not want to receive shipments would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns. Voluntarily canceled or withdrawn pesticides could be exported if the Administrator determines that there is no information indicating their use could pose significant health or environmental concerns. Other pesticides which do not raise health concerns (e.g., pesticides that may have been cancelled due to environmental risks) could only be exported to countries that specifically request them and only if the Administrator makes a finding that they have not been banned for any reason related to an adverse health effect.

Never-registered pesticides could only be exported if there were a U.S. tolerance in place, or if they had been approved in at least three countries that have sound regulatory systems and require independent review of scientific data as a condition of pesticide marketing. Analytical methods would also be required for all food use pesticides.

Export-related activities by EPA, including enhanced technical cooperation with developing countries to improve pesticide use and regulation, would be supported by fees from export producers. Additional provisions would require pesticide manufacturers to accept responsibility for sound product stewardship throughout the world, improve information on exports and make it publicly available, and otherwise enhance EPA's programs under Section 17 of FIFRA.

H.R. 1627:

No provision.

6 FEES TO SUPPORT FIFRA '88 REREGISTRATIONAdministration's Bill:

To address a shortfall in funds to support ongoing reregistration activities under FIFRA '88, the proposal includes authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

4/21/94

SUMMARY OF PESTICIDE AND FOOD SAFETY REFORM PROPOSALS

The Administration's pesticide/food safety legislative reform proposals require amendments to both the Federal Food, Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The laws would also be amended to recognize and require that changes under one statute be reconciled with appropriate complementary actions under the other statute.

The major elements of the proposals are summarized below.

1. FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

o Tolerance-Setting

Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. This new uniform safety standard would replace the current standards in Sections 408 and 409 of FFDCA and would be the basis for regulating pesticide residues in all types of foods, whether raw or processed.

The statute would specify factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations, risks from multiple sources of exposure, and risks from pesticides that have a common mechanism of action. EPA would also have clear authority to set multiple tolerances for residues in foods at different points in the food production and distribution chain, including at the farm gate and at the point of retail sale. Risk assessments would be performed utilizing the protective assumption that residues are present in foods at the applicable tolerance levels, except when reliable data permit exposure assumptions to be adjusted to reflect the percentage of a crop actually treated with the pesticide.

o Special Provisions for Infants and Children

Additional proposals for tolerance setting are directly responsive to the recommendations contained in the 1993 National Academy of Sciences Report on "Pesticides in the Diets of Infants and Children." Specifically, EPA would be required to consider unique aspects of children's diets and potential sensitivities to pesticide risks. EPA would issue specific findings that tolerances are safe for infants and children.

EPA would evaluate multiple exposures when establishing tolerances and apply additional safety factors and/or take other necessary steps to ensure safety for infants and children. More accurate data on children's consumption habits would also be developed and utilized in tolerance setting and reassessment.

o **Review of Existing Tolerances**

EPA would be required to review all existing tolerances and ensure that they meet the new standard within seven years of enactment. Fees would support both tolerance review and setting of new tolerances.

Special fast track provisions would require priority review of pesticides which, based on currently available data, appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of such tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment.

o **Time-Limited Transitional Tolerances**

EPA could grant time-limited transitional tolerances of no more than five years for a pesticide identified during the tolerance review process as not meeting the safety standard, if the loss of the pesticide would result in loss of direct consumer health benefits or significant disruption in domestic food production.

The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on tolerance sponsors to make the showing needed to support a time-limited tolerance.

o **Enforcement Authorities**

FDA enforcement powers with respect to pesticide residues in food would be expanded to include new authorities to recall and embargo foods containing violative pesticide residues and to levy civil penalties for such violations.

2. **FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) PROPOSALS**

o **Registration "Sunset"**

Pesticide registrations would be required to be reviewed and renewed on an active ingredient basis every 15 years, to ensure they are in conformity with current scientific standards. Complete applications must be submitted to EPA by year 12 after registration or registration renewal. For the initial implementation of the 15-year cycle, the legislation would allow for grouping pesticides in a way that permits EPA to balance workloads and avoid skewed distributions in the numbers of pesticides that "come due" in any given year. Fees paid by registrants would support the sunset program.

o **Phase-Out/Phase-Down**

Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements to avoid unnecessary dislocations.

o **Streamlining Label Changes and Establishing Uniform Label Compliance Dates ("Label Call-In" Authority)**

Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

o **Incentives for Development of Reduced Risk Pesticides**

EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided.

Also, EPA could grant special conditional registrations for biological pesticides posing low potential risks.

o **Pesticide Risk and Use Reduction and Support for Integrated Pest Management (IPM) Programs**

The statute would embody clear policy goals favoring reduced use and directing federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

The statute would authorize regional ecosystem-based reduced use pilot projects designed to reduce aggregate pesticide risks and provide a mechanism to focus research priorities. EPA and USDA would be mandated to work together to develop and make available comparative information on the environmental and health effects of pesticides and to identify the research, education and extension activities that are most promising in terms of meeting pest management needs and reducing use of pesticides that raise risk concerns.

- Call Bill Galston

- Endorse it quickly? —

- R's get credit

- Admin can get credit —

↳ but don't want to rub their face in it. —

Full com. Wed — by pass subcommittee —

— Markup Wed on Full com. —

— Send it to the floor the following week

Industry — Food Processors — Debbie Dunbar says...

Imppt. to Industry; Impt to public health. —

Fought for 14 years — v. partisan ~~time~~

— bipartisan compromise. —

→ Commerce Comt working together.

9:00-11:00 — Commerce comt. doing language. —

- announce it early afternoon

- want statements from industry. —

Wednesday — first statement

— call for Congress to pass it — get it
to ~~hearing~~ the President the following week. —

— Letter from the Administration —

↳ applaud Comt. for its work and endorse it. —

- Give up the Synhol preemption, —
protect the substance. —

The statute would require EPA to identify pesticides of regulatory concern for which there are limited alternatives. USDA would be required to use this information to focus its research and education efforts. The statute would require USDA, in consultation with EPA, to develop a research and extension plan for each commodity determined to have an "alternatives problem."

The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

o **Improved Pesticide Data Collection**

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Significant improvement over the previous draft — looking forward to see,

8:15 Waxman / Blubey / Dingell deal -

- No Delaney — pesticide residues in processed food
- NO 1,1-D-6 in statute
- No right to know labeling and — premarket benefits test

Delaney is repealed ~ hung issue

= great safety std. - reasonable certainty of no harm - 10⁶ will be in report language

- benefits perception - will only be used if

- ① you don't have any other choice -

- tests to qualify

- Adminis reviews w/in 5 years. —

- expedited review - just for special tolerances.

② good kids std - no special tolerance

-right to know - if you get special tolerance - Admin has to let grocery stores know - raw and process food. -

No FIFRA / CODEX override ~

- Presumption - general policy of presumption. -

tolerances set in safety std. - Prop 65 - and

eng warning labels. Not emphasis for special tolerances. -

- No special allowances -

- Urgent petition process. - 30 days - if no act. —

33% w/n 3 yrs.

100% w/n 10 yrs.

- Screening program - what pesticides have estrogenic. -

Chambers Bluff
and Carbon
~~Chambers Bluff~~

— v. class to
about all but safety
bill reforms practices

- Father was in Japan 1941
 - American taken & married 1941
 - So to fall out. marriage Wed.

Eu (my 7th grade)

...flaw next week

→ Praise bi-burner approval
Sister's

— Urg

5

o **Enforcement Authorities**

Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities and "whistle blower" and citizen suit provisions. Penalties for FIFRA violations would be significantly increased, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

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11:00 John Helly -

- Hickmont
- Lynn Goldman
- Burnett / FDA

Have draft. - Howard/Kearse/Danny met. w/several Ag groups tomorrow

- right to know pamphlet - some pending changes -

safe $\Rightarrow$ "reasonable certainty of no harm" - report language says
engulfable risk

1/20th of lifetime risk 2x standard

- benefits only to old "not new" (i.e. already registered)

- every 5 years after you get tolerance that based
on benefits

- right to know - requires in two years, every year after
that - agency publishes for display in grocery
stores - actions taken under B2B. -

Ag groups - understand this is not your bill $\rightarrow$ it's the bill -
May not confront in House - but bringing in column

Env Working App. $\leftarrow$ Mark Childress -

At Meigsbroff - NRDC - likely to have problems. -

Charlie Rawls -

Full comt -

3 days - file report -

7-10 days go to floor -

Get People know - who put this together what it represents -
- Don't want to make big deal about
how close it is

- time limit on benefits

Narrow scope

kids

estrogen

- Can have rat preemption - except which
B(2)B. - Also is states petition
Administrator - modeled on CA law -