

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Potential Nominees for Organophosphate Dialogue Committee (2 pages)	04/08/1998	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Thomas Freedman
OA/Box Number: 17544

FOLDER TITLE:

Food Quality Protection

2015-0274-S

wr10805

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Withdrawal/Redaction Marker

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E. Swartz

FAPA
Food — 29W

720-6158

4/17/98

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Geiston DPC

Senate 4/17/98

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FD - Delany

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\$420 million

FQPA



U.S. DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY

Telephone (202) 720-3631 Fax (202) 720-5437

FAX COVER SHEET

DATE: 13 April 98

NUMBER OF PAGES 4, INCLUDING COVER SHEET

PLEASE DELIVER TO: Tom Friedman, DRC

FAX NUMBER: () PHONE NUMBER: ()

FROM: OFFICE OF SCHEDULING

☐ MARY BETH SCHULTHEIS, DIRECTOR OF SCHEDULING

☐ JULIE EDDY, ASSISTANT SCHEDULER

☐ BILLY COX, BRIEFINGS COORDINATOR

☐ FRAN TROUT, TRAVEL ADVISOR

KATH PIRK

MESSAGE: Tom FYI Kull



DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 10, 1998

MEMORANDUM FOR THE VICE PRESIDENT

Subject: Food Quality Protection

We are writing in response to your memorandum of April 8, 1998, to inform you of actions we are taking to ensure smooth implementation of the Food Quality Protection Act ("FQPA"). We recognize that how we implement this Act will have important and far reaching consequences. We are confident we can assure the high standards of protection called for in this Food Quality Protection Act and preserve the strength of our Nation's agriculture and its farm communities.

We are committed to the principles you presented in your memorandum. You have our pledge that we will guide implementation by: applying sound science to all decisions; making our regulatory process transparent; providing appropriate reasonable transition mechanisms that will reduce risk but not jeopardize our nation's agriculture and its farm communities; and consulting with interested constituencies, including state, local, and tribal governments, growers, and consumers. We are also committed to achieving an unprecedented level of cooperation to eliminate unacceptable risks from pesticides.

While meeting the new requirements of the Food Quality Protection Act will be challenging, it also affords us tremendous new opportunities for creativity and partnership in finding common-sense ways to implement the law's requirements. We recognize that pairing strong public health standards with flexible implementation approaches has been a hallmark of President Clinton's and your approach to public health and environmental issues, and we look forward to working together to apply this approach here as well.

We will begin consulting with a broad range of interested parties on the issues you identified by establishing an advisory group under the Federal Advisory Committee Act, conducted through EPA's National Advisory Council on Environmental Policy and Technology. This group will be co-chaired by EPA Deputy Administrator Fred Hansen and USDA Deputy Secretary Richard Rominger. We are commencing this public process right away to ensure that consultation is consistent with meeting the tolerance reassessment deadlines established in the Food Quality Protection Act.

EPA and USDA will work together closely to identify qualified participants, representing farmers, other pesticide users, public health officials, pesticide companies, environmental groups, public interest groups, and state, tribal, and local governments. We will ask this group to help us

04/13/98 11:44 202 720 3437 USDA SECRETARY 0000

establish the framework for EPA's decisions on the first major -- and most widely used -- set of chemicals EPA is evaluating, organophosphates. We want to ensure that any decisions are predictable and easily understood by all interested parties. We expect the approaches pioneered by focusing on organophosphates can be applied broadly to all of our work in implementing the Act. We will also continue to seek advice from independent scientific experts, such as EPA's Scientific Advisory Panel. In addition, we have created a senior level working group -- reporting to both of our deputies -- to ensure close coordination between our agencies on these matters:

We will ask the advisory group to address these specific questions:

- What is the appropriate process for making pesticide tolerance decisions under FQPA, what documentation is necessary, and how do we ensure appropriate public participation and transparency?;
- What is the proper policy framework for deciding if there is adequate scientific information for making decisions on tolerance reassessments, when new information must be sought, when is it appropriate to use default assumptions and exposure scenarios, and what is the appropriate methodology for risk assessments?;
- How can we speed the pace of decision making to make available to growers newer and safer pesticides and new uses of registered pesticides that meet FQPA safety standards?;
- What are appropriate, common-sense strategies for reducing risk to acceptable levels while retaining those pesticides of the highest public value, including minor crop and integrated pest management needs? What are the opportunities for reasonable phaseout periods, market-based and targeted approaches and incentives, and cooperative partnerships to achieve these goals?; and
- What are the priorities in considering organophosphates, such as considering first those most likely to lead to exposures in children's foods?

EPA is also conducting a thorough review of its experience applying, reducing, or eliminating the ten-fold child-specific safety presumption called for by the Food Quality Protection Act. This review should provide specific recommendations for consistent scientific practices and procedures in evaluating child-specific risk issues. We also expect to consult with our advisory group on these issues.

We will keep you fully informed of our progress on all of these matters. We look forward to our continuing work together to guarantee Americans the public health protections they deserve, as well as the safe and abundant food supply of which our nation is so justifiably proud.



Dan Glickman

Secretary

Department of Agriculture



Carol M. Browner

Administrator

Environmental Protection Agency



U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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FAX COVER SHEET

DATE: 6 APRIL 98

NUMBER OF PAGES 4, INCLUDING COVER SHEET

PLEASE DELIVER TO: Tom Friedman, DPC Mary Smith, DPC
Mark Weatherly, OMB

FAX NUMBER: () PHONE NUMBER: ()

FROM: OFFICE OF SCHEDULING

☐ MARY BETH SCHULTHEIS, DIRECTOR OF SCHEDULING

☐ JULIE EDDY, ASSISTANT SCHEDULER

☐ BILLY COX, BRIEFINGS COORDINATOR

☐ FRAN TROUT, TRAVEL ADVISOR

MESSAGE: FU - Romney's talking points covered
during his meeting w/ Hansen.

Kurt

KEITH PATE

MEETING WITH EPA DEPUTY ADMINISTRATOR FRED HANSEN

FEBRUARY 25, 1998

PURPOSE: To establish a framework for working closer and more effectively with EPA on FQPA implementation.

ISSUE: Although Keith Pitts and Al Jennings have maintained close communication with the Office of Prevention, Pesticides, and Toxic Substances as well as the Office of Pesticide Programs, they are not being substantively involved in the development of policies and options. There is widespread concern in the agricultural community that the promised "process" has broken down and that FQPA implementation lacks transparency and predictability. Both USDA and EPA credibility are suffering.

TALKING POINTS:

- 1) The additional **10X safety factor** policy paper is scheduled for Science Advisory Panel review in March. As written, it is nearly impossible to identify the major policy directions and options that might be considered. Can the paper be recast to make the policy choices clearer? We have asked for recent examples of how the policy is being applied and would like an opportunity to review those examples.
- 2) **USDA must be made a full partner** in the planning, development, and analysis of policies and options. To this point, significant development work has gone on within EPA but has not been shared. Consultation with USDA on important issues must occur before public release. Effective implementation of FQPA will require the involvement of the agricultural community. EPA must provide USDA the time and information needed to adequately and meaningfully involve growers.
- 3) There are a number of **pesticide uses that are critical** to: the continued domestic production of many "minor crops"; IPM programs; and Pest Resistance Management Programs. Should EPA consider cancellation of these products, agriculture will need adequate time to transition to new pest management strategies. We need to work together to ensure that no commodity is left without effective pest management tools. EPA needs to publicly articulate its commitment to transition strategies that ensure major market disruptions will not occur.
- 4) Decisions on a number of issues will ultimately dictate the future availability of many pest management tools. Currently, EPA appears to be trying to make these decisions individually without the benefit of a clear and inclusive strategy. We believe **an overall strategy that links the many issues should be drafted** and major options analyzed. USDA and the agricultural community must be involved in the process.

5) Some of the issues that must be addressed and which might form the basis for future meetings are:

Assurances of EPA's use of best and most current data. USDA and grower groups are supplying current data on pesticide use and usage, residue levels in foods, and food consumption patterns. Is EPA committed to using the best and most current data in their risk assessments?

Appropriate use of USDA food consumption data in dietary risk assessment. EPA is using extreme high-end 99.9 percentile data in some risk assessments. It is not clear that this is the appropriate use of the data. At the extremes, the uncertainties in the data become large and it is not clear what they represent.

Drinking water exposures are sometimes based on old data and "worst case" models or analyses. For example, a recent carbofuran analysis used monitoring data from the early 1980s. The data do not reflect current levels which are reported to be lower because of EPA regulatory action in the mid-1980's

When food residue studies report "no detection", EPA assumes that residues are present at 1/2 the level of detection. There are many cases where these "no detects" drive the risk assessment and actually exceed the acceptable risk level. The recent study by the Environmental Working Group assumed the "no detects" were "zero". No-detects on imported produce could create a competitiveness issue for domestic growers of commodities for which a particular "no-detect" pesticide is no longer available.

Because certain commodities are consumed in such small quantities, especially by children, we would advocate a "de minimus" policy that would essentially exempt these commodities such as garlic, hops, wine grapes and mint from the "risk cup".

6) If American agriculture is to move away from current pest management technology such as the organophosphate insecticides, EPA must develop a transition strategy that accelerates the registration of new effective alternatives.

Emergency Exemptions under Section 18 were designed to be a "safety valve" but have become a bottleneck and a resource drain away from new products and uses under Section 3. The process needs to be reviewed and reformed.

IR-4 minor use registrations and tolerance petitions must be acted upon and expedited. Only one IR-4 petition has been cleared since FQPA was signed into law.

Experimental Use Permits and Section 3 registrations for new technology must be expedited. Current "crop destruct" policies are delaying new technology. Dimilin

for the control of the Rice Water Weevil is a current example. This product could replace carbofuran but must be tested on a large scale.

**MEMORANDUM FOR SECRETARY GLICKMAN
AND ADMINISTRATOR BROWNER**

CSQ

FROM THE

SUBJECT: FOOD QUALITY PROTECTION

In the Food Quality Protection Act (FQPA) of 1996, the Administration joined with a bipartisan leadership of the Congress and a broad array of agricultural, industry, and public interest constituencies to strengthen protection for all Americans from potential risks associated with the food they eat. The landmark protections established by this law, and in particular the new scrutiny given to potential risks to children, will ensure that Americans in the 21st century will continue to have the safest food supply in the world. These protections can be implemented while we maintain the significant growth in the net trade balance favoring United States agricultural produce that we have achieved in President Clinton's Administration.

The broad consensus supporting the FQPA's new protection for our families illustrates the fundamental premise of the law's sponsors and President Clinton's policies, that we can achieve higher standards of protection, especially for children, while preserving the strengths of our Nation's agriculture and its farm communities.

FQPA implementation presents complex scientific and regulatory issues. As with any major change in the law and the regulatory process, there have been concerns expressed by a range of constituencies about the manner in which the new law will be implemented. There is broad consensus supporting the strengthened protection of the public that Congress mandated in this new law. There is a corresponding anxiety, however, about potential uncertainty and disruption for those whose livelihood and practices are potentially affected as the Environmental Protection Agency (EPA) implements the new law.

Accordingly, on behalf of President Clinton and in accordance with my responsibility for implementation of Executive Order 12866 (Sep. 30, 1993), I would like to request that the EPA Administrator and the Secretary of Agriculture work together to ensure that implementation of this law is guided by sound regulatory approach, by the expertise of the Department of Agriculture (USDA), by appropriate input from affected members of the public, and by due regard for the protection of public health and the needs of our Nation's agricultural producers.

Implementation Principles.

In accordance with the provisions and policies of the FQPA and sound regulatory practice, EPA and USDA should work together as full partners to ensure that implementation of the law comports with the following four principles.

Sound Science.

Consistent with the provisions of the FQPA, EPA, and USDA should work together to ensure that all FQPA decisions follow the Clinton Administration's principles for sound regulation.

1. Regulatory decisions should be based on the best available science and data, using appropriate analytical approaches.

2. In determining risk levels permitted by the new law, EPA should avoid analytical approaches that overstate potential risk. The use of unwarranted default assumptions, or inappropriately conservative exposure scenarios, should be avoided.

3. Particular care must be exercised in applying the tenfold safety factor for risks specific to children. EPA and USDA should recognize the discretion given to EPA in the current law and should ensure that this discretion is exercised in a manner consistent with the intent of the Congress and the 1993 Report by the National Academy of Sciences concerning risks to children from pesticides. EPA and USDA should utilize external scientific review panels wherever appropriate.

Transparency.

In translating sound science into sound regulatory approaches, EPA and USDA should ensure that the decisions and positions of the two agencies are transparent to affected constituencies.

1. Approaches must be clearly and fully communicated in a manner that facilitates informed review by all affected constituencies.

2. Where there must be a selection among competing or alternative approaches or interpretations in implementing the law, alternatives should be fully presented and explained before moving forward.

Need for a Reasonable Transition

Implementation of the law will require transition to new pest management strategies for certain pesticide users. EPA and USDA should work together to address transition challenges in future years.

1. EPA does not intend any significant use cancellations in this growing season. If this should change based on new information, there should be immediate

2. To the extent permitted by law and consistent with public health protection, EPA and USDA should implement the FQPA in a way that ensures that affected pesticide users and other affected constituencies have the time, technical assistance, and resources they need for transition to new and effective pest management strategies.

3. EPA should facilitate transition to new and more protective pest management strategies by expediting approval of new products that may serve as effective and safe substitutes to pesticides that may present unacceptable risks under the FQPA. USDA should devote appropriate resources to research, and expand technical assistance in support of integrated pest management strategies.

4. EPA and USDA should review current operating budgets and identify, within 15 days, those additional appropriations resources that can and will be devoted to expedite new product approvals and expand integrated pest management strategies.

Consultation with the Public and Other Agencies

EPA and USDA should establish a more effective means of consultation with user groups, pesticide manufacturers, environmental and public health organizations, and others concerned about FQPA implementation.

1. Within 14 days, EPA and USDA should jointly establish a mechanism for seeking advice and consultation from affected user and other groups, following consultation with the Council on Environmental Quality (CEQ). All facets of FQPA implementation shall include ensure appropriate input from state and local agencies, Tribal governments, Members of Congress, and the public.

2. At critical points in the regulatory process, EPA and USDA should consult directly with relevant offices of the Food and Drug Administration (with respect to application of risk standards) and the Office of the United States Trade Representative (with respect to issues of concern from a trade perspective

* * * * *

CEQ should report to me on the implementation of this memorandum in 90 days, and periodically.

This memorandum is not intended to create any right, benefit, or trust responsibility,

substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, or any other person.

This memorandum will be published in the Federal Register.



U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

Telephone (202) 720-3631 Fax (202) 720-5437

FAX COVER SHEET

DATE: 4/9/98

NUMBER OF PAGES 2, INCLUDING COVER SHEET

PLEASE DELIVER TO: Tom Friedman /DPC

FAX NUMBER: () 456 7431 PHONE NUMBER: ()

FROM: **OFFICE OF SCHEDULING**

☐ MARY BETH SCHULTHEIS, DIRECTOR OF SCHEDULING

☐ JULIE EDDY, ASSISTANT SCHEDULER

☐ BILLY COX, BRIEFINGS COORDINATOR

☐ FRAN TROUT, TRAVEL ADVISOR

KEITH PITTS

MESSAGE: FYI 3 letters -

From: RANDALL BRINKHUIS
 To: GOLDMAN-LYNN
 Date: 4/3/98 5:21pm
 Subject: URGENT: EQPA Ltr to Clinton -Forwarded

Dr. Goldman,

I just received the following message forwarded to the OEM listserv by NRDC. You're probably aware of this effort already, but I thought I would forward it just in case. (The letter follows below, but I am not forwarding the text files since they are just formatted differently. In case you should find that they would be useful, please let me know.)

Randy Brinkhuis

>>> Jacqueline Hamilton <JHamilton@nrdc.org> 04/03/98 02:29pm >>>

Memo

To: Groups & individuals who care about children's
 pesticide exposure
 From: Erik Olson, Jacqueline Hamilton, David Wallinga
 Date: 04/03/98
 Re: Looming White House Pesticide Problem & Attached Letter

=====

The agribusiness, food, and pesticide industries (and their allies on the Hill) are applying substantial political heat to the White House and EPA regarding the implementation of EQPA, the new pesticide law. The White House is indicated that they intend to issue a directive to EPA that would essentially signal to Carol Browner to slow down in carrying out the new kids protection provisions and to take industry's arguments seriously. The White House is scheduled to brief some Hill staff Friday 4/3 on the draft directive, so the issuance of such a document may be imminent. We are extremely concerned about the White House signals, which could spell the beginning of the derailment of the 1996 law we fought so hard to get. We urgently need to counterbalance the industry political forces. Thus, attached is a letter to President Clinton that:

urges him not to cave in to industry; and,
 as a counterweight to industry arguments that EPA is
 overzealous, includes a detailed list of some of our
 fundamental problems with how EPA is being
 underprotective in implementing the law.

You will find the letter pasted below as well as attached as a text file and a Word file.

We need to get signatures from dozens of groups and individuals, especially doctors and scientists, on this letter. If you sign as an individual please say so and we will say that your title, affiliation, etc. are for identification purposes only. Be sure to give your name and affiliation or your group name exactly as you would like it to appear on the letter.

We need to act immediately if we are to have an effect on this potentially devastating White House action. (FYI, the letter will go out on plain paper rather than letterhead.) Please circulate this message to people that you think will support this letter, though please do not post it on bulletin boards etc. just yet. We hope to have the letter to the President by close of business Monday, April 6, so please e-mail or telephone your response to Jacqueline Hamilton as soon as possible. Phone: (202) 289-2362. If you have any questions or need more information, please call immediately. If you can't read the message for any reason, call so it can be faxed to you. Thanks for your quick turn-around on this important letter.

04/06/98 MON 16:43 FAX

003

April 3, 1998

President William Jefferson Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

We write to you as public health, medical, consumer, labor, environmental, and other citizen organizations to express our support for the principles you have enunciated for carrying out the Food Quality Protection Act of 1996. We also wish to note, however, our serious and abiding concern about the Environmental Protection Agency's actual implementation of this landmark law. In signing the FQPA into law, you said:

I like to think of it as the 'peace of mind' act, because it'll give parents the peace of mind that comes from knowing that the fruits, the vegetables, the grains that they put down in front of their children are safe. It's long overdue. The old safeguards that protected our food from pesticides were written with the best of intentions, but they weren't up to the job. This Act puts the safety of our children first. It sets a clear, consistent standard for all pesticide use on all foods for all health risks. It sets a standard high -- if a pesticide poses a danger to our children, it won't be in our food, period.

While we believe that both you and EPA Administrator Browner remain committed to these principles, we are troubled by some of the recent activities that may endanger the success of this new effort to protect the health of our children.

We understand that White House, EPA, and others in the Administration have come under increasing pressure from agribusiness and pesticide industry lobbyists and some members of Congress to slow and weaken implementation of FQPA, based largely on misinformation about EPA's present implementation plans and activities. Some in industry and within the Administration are asking for a White House directive that essentially would tell EPA to go slow in implementing the children's protection provisions in the law, and to take into greater account the industry's interests--a troubling, potentially unlawful, and fundamentally unjustified proposal. We believe that far from being overzealous in implementing FQPA, in some cases EPA has gone too far in accounting for industry interests, triggering the following major concerns about EPA's implementation to date, among others:

Failure to Vigorously Implement the Children's Protective Health Standard. FQPA embodies a new standard for pesticides in foods requiring that EPA find a "reasonable certainty of no harm" to children in order to issue a tolerance for pesticides in foods. As part of that requirement, Congress mandated that EPA use an additional ten-fold safety factor to protect children, as recommended by the National Academy of Sciences, to account for potentially higher pre- and post-natal toxicity and exposure for kids. Only if there are "reliable data" documenting the toxicity and exposure for children is EPA authorized to use a different safety factor. Yet according to the most recent available information, EPA has used the 10-fold children's safety factor for only 9 out of 91 tolerances issued since FQPA was enacted, despite frequent gaps in kids' toxicity and exposure data. In another 10 cases, EPA used a 3-fold safety factor. In other words, about 90 percent of the time, EPA is not using the Congressionally-mandated 10-fold children's safety factor. We urge EPA to make use of this mandatory kids protection safety factor whenever there are toxicity or exposure data uncertainties, as was implied by Administrator Browner's February 25, 1998 memo to Assistant Administrator Lynn Goldman.

Failure to Comply with the New Health Standard for Cancer-Causing Pesticides. EPA has on several occasions issued tolerances for pesticides that exceed the clearly-defined legal threshold for allowable cancer risk established by FQPA of one cancer per million people exposed.

The Use of Industry-Dominated 'Peer Review' and 'Stakeholder Meetings,' and Private EPA-Industry Negotiations.

We are troubled because many EPA informal and formal peer review and stakeholder involvement forums used to implement the new law are heavily weighted towards the

pesticide and agribusiness interests and their agents or consultants. EPA does not publicly disclose the economic interests of members of its peer review committees that could have a bearing on the potential bias of its members, such as consulting arrangements with industry interests. Moreover, EPA apparently often negotiates with industry in unannounced, private meetings in making tolerance and registration decisions. We urge that EPA assure that stakeholder and peer review meetings are balanced and publicly announced, and that there is full public disclosure of any industry or other economic ties of the members of any peer review panels.

Failure to Fully Implement the Aggregate Pesticide Exposure Requirements of FQPA. EPA has issued over 90 tolerances for pesticides in foods, yet for very few of these has the agency used data documenting exposure from multiple sources, particularly for children (such as from drinking water, drift, schools, playgrounds, living on or near a farm, indoor use, air exposure, etc.). Where such multiple exposure route data are lacking, EPA should use the best available information and should not remove the presumptive 10-fold safety factor for kids' protection. FQPA mandated this safety factor for just these types of situations where there are gaps in children's exposure data.

Lack of Aggressive Effort by USDA and EPA to Strongly Push Transition to Alternatives to Dangerous Pesticides.

EPA and USDA need to aggressively fund and implement major efforts to encourage pesticide users to shift to alternatives to dangerous pesticides. These efforts should include major funding commitments. They should make use of USDA extension services to advocate a shift to non-chemical alternatives and to using lower risk chemicals as an interim step toward truly sustainable agriculture. It also should include expedited EPA registration of new lower risk pesticides as part of that interim step towards non-chemical alternatives.

We truly appreciate your personal efforts and interest in protecting children from environmental contaminants, including pesticides. We urge you, therefore, to send the message within your Administration that you intend to aggressively carry out the children's protection and other public health reforms in the FQPA. We look forward to working with you to achieve these goals and to oppose efforts to weaken or slow the implementation of this law.

Sincerely,

CC: Vice President Al Gore
The Honorable Carol Browner, Administrator, EPA
Dr. Lynn Goldman, EPA Assistant Administrator
The Honorable Dan Glickman, Secretary of Agriculture
The Honorable Franklyn Raines, Director, OMB
All Members of the U.S. House and U.S. Senate

CC: RTPMAINHUB.WPXGATE.MULKEY-MARCIA, DCWSM03.DCADMIN1...

THE FOOD CHAIN COALITION

March 24, 1998

Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Dear Ms. Browner:

As organizations representing the U.S. food and agriculture industry, we are writing to express to you our deep concern regarding EPA's implementation of the Food Quality Protection Act of 1996. As you know, many of our organizations were supporters of the FQPA because we shared EPA's view that ensuring protections for infants and children, and making risk determinations and regulatory decisions based on sound science are worthy and compatible policy objectives. Regrettably, evidence to date suggests that EPA no longer shares an equal commitment to both objectives.

EPA has fostered the widespread perception that the Agency has already determined that certain pesticide tolerances must be revoked and that proposals to that effect will be issued soon. It appears such revocations will be proposed without benefit of proper use of "reliable and available" information, as provided in law, in order to fulfill a political agenda premised on the need to make adverse risk findings and demonstrate the "seriousness" of EPA's intentions to "take action." These initial decisions, driven more by an unnecessarily strict interpretation of the legal language than by thorough scientific evaluation, undoubtedly will establish precedents that will determine the outcome of future tolerance reassessments, reregistrations and registrations for years to come. Furthermore, the timeframe and manner in which the decisions are about to be made threaten to disrupt well-established Integrated Pest Management (IPM) and pest resistance management programs and create grave uncertainties for U.S. food and fiber producers, food processors and pest control businesses regarding the 1998 season and beyond.

The following points highlight some, but certainly not all, of our concerns.

Lack of Process Transparency & Consistency. EPA efforts to use numerous EPA-sponsored advisory committees to obtain stakeholder input has been inadequate. Consensus has not been developed regarding fundamentally new risk assessment methodologies required by FQPA, or the new procedures EPA must institute to avoid disrupting U.S. agriculture and pest control industries. The scientific basis for forthcoming EPA decisions remains unclear. Critically important risk assessment policies and procedures remain unresolved by the Agency such as determining common mechanism of action, cumulative risk, and many others.

Failure to Approve New Pesticides. Approving and making available to growers and other pesticide users new and safer pesticides and new uses of registered pesticides, which meet the new FQPA safety standards, to replace older pesticides, is the most effective means of immediately reducing pesticide risks with minimal disruption to growers. Yet, EPA's review and registration of new compounds and new uses for minor crops has ground to a virtual halt. In fact, at most one new IR-4-sponsored minor crop use has been approved since the enactment of FQPA. Agency resources should be immediately directed to approving additional pest management tools, particularly for use on minor crops, before the prospective loss of older pesticides.

Emergency Use Exemptions (Section 18's). As a new growing season approaches across most of the U.S., uncertainty abounds regarding prospects for swift EPA consideration of tolerances for emergency exemption applications. No response has yet been received from the agency to a 1997 grower proposal for streamlining the section 18 review process. And, a statutory deadline requiring that a final regulation on emergency use exemptions be published by August 1997 remains unmet. Uncertain or evolving EPA policies continue to make the Section 18 process unpredictable.

Disruptions to Agriculture and Pest Control. The U.S. Congress neither directed nor expected FQPA to result in major disruptions to U.S. agriculture and other activities that need pest control tools. Yet, EPA's prospective revocation of pesticide tolerances, without first seeking reliable and accurate data and adopting scientifically sound risk assessment methods, threatens to virtually eliminate the production of certain crops and management of certain pests in some regions of the U.S. Often, no known substitute pest control tools exist. How will EPA ensure that effective pest control tools are available to growers and other users during this interim period? Why is the EPA considering decisions that will dislocate U.S. food and fiber production, and increase our country's reliance on imported foods?

The Food Quality Protection Act of 1996 was considered "historic" by most of our organizations' because of our willingness to abide by EPA's "good faith" representations that the new law embodied many practices already employed by EPA, and that the law would be administered using sound science and available, credible data. The need to resolve these issues is urgent. We look forward to a productive dialogue with the Agency on these topics in the near future.

Sincerely,

American Bakers Association
American Soybean Association
Agribusiness Association of Iowa
Agricultural Retailers Association
Alliance of State Agribusiness Associations
American Agri-Women
American Crop Protection Association
American Dehydrated Onion & Garlic Association
American Farm Bureau Federation
American Frozen Food Institute
American Nursery & Landscape Association

American Society of Farm Managers and Rural Appraisers
American Soybean Association
American Sugarbeet Growers Association
American Sugar Cane League
Apple Processors Association
Arizona Agricultural Aviation Association
Arizona Cotton Growers Association
Arizona Crop Protection Association
Arizona Farm Bureau Federation
B & W Quality Growers, Inc.
Blackland Cotton & Grain Producers Association
California Beet Growers Association
California Canning Peach Association
California Cotton Ginners and Growers Association
California Cut Flower Commission
California Farm Bureau Federation
California Fertilizer Association
California Grain and Feed Association
California Grape and Tree Fruit League
California League of Food Processors
California Seed Association
California State Floral Association
California Tomato Growers Association, Inc.
Cherry Marketing Institute
Chocolate Manufacturers Association
Columbia Snake River Irrigators
Coors Brewing Company
Cranberry Institute
Florida Citrus Mutual
Florida Citrus Packers
Florida Farm Bureau Federation
Florida Fruit & Vegetable Association
Georgia Cotton Commission
Grocery Manufacturers of America
Grower - Shopper Vegetable Association of Central California
Idaho Crop Production Association
Idaho Eastern Oregon Seed Association
Idaho Grower Shippers Association
Illinois Farm Bureau
Illinois Fertilizer and Chemical Association
Illinois Milk Producers Association
Illinois Pork Producers Association
Illinois Specialty Growers Association
Imperial Valley Vegetable Growers
Independent Bakers Association
Louisiana Ag Industries
Louisiana Cotton Producers Association
Maine Food Processors Association

Maine State Pomological Society
Major Farms, Inc.
Maryland Grain Producers Association
Michigan Agribusiness Association
Michigan Christmas Tree Association
Midwest Food Processors Association
Minor Crop Farmer Alliance
Montana Grain Growers Association
National Alliance of Independent Crop Consultants
National Association of State Departments of Agriculture
National Agricultural Aviation Association
National Association of Wheat Growers
National Barley Growers Association
National Christmas Tree Association
National Confectioners Association
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Food Processors Association
National Grain Sorghum Producers
National Grange
National Onion Association
National Pasta Association
National Peanut Growers
National Pest Control Association
National Sunflower Association
National Watermelon Association
New York State Vegetable Growers Association, Inc.
North American Strawberry Growers Association
North Carolina Peanut Growers Association
North Dakota Grain Growers Association
Oregon Wheat Growers League
Oregon Potato Commission
Pacific Seafood Processors Association
Plains Cotton Growers, Inc.
Produce Marketing Association
Professional Grounds Maintenance Society
Professional Lawn Care Association of America
Sabroso Company
Snack Food Association
Society of American Florists
South Texas Cotton & Grain
Southern Cotton Growers, Inc.
Southern Rolling Plains Cotton Growers Association
Southeastern Cotton Ginners Association, Inc.
Southwest Peanut Growers Association
St. Lawrence Cotton Growers Association
Texas Association of Nurserymen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

TO: Keith Pitts

FROM: Gary Gory

COMMENTS: This should reflect our discussion
yesterday.

Number of Pages to follow: 3
Date: 4/9
Time:

Transmission Number: (202) 260-3684
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MEMORANDUM FOR THE VICE PRESIDENT

Subject: Food Quality Protection

We are writing in response to your Memorandum of April 8, 1998, to inform you of recent actions we are taking to help ensure smooth implementation of the difficult challenges posed by the numerous new requirements of the Food Quality Protection Act ("FQPA"). We recognize that how we go about implementing this Act can have important and far reaching consequences. We are confident that, through these efforts, we can assure the high standards of protection called for in this Act and preserve the strength of our Nation's agriculture and its farm communities.

We are absolutely committed to the principles you have presented in your Memorandum. You have our pledge that our implementation efforts will be guided by: the application of sound science as the fundamental bedrock for any decisions concerning pesticides; the need for transparency in our approaches to regulation; the appropriateness of reasonable transition mechanisms that will reduce risk while not jeopardizing our nation's agriculture and its farm communities; and the desirability of a thorough consultative process with interested constituencies, including state, local, and tribal governments, and grower, producer, and consumer groups. We are also committed to achieving an unprecedented level of cooperation among our departments as we continue work to eliminate unacceptable risks from pesticides.

While meeting the new requirements of the Food Quality Protection Act will be challenging, it also affords us tremendous new opportunities for creativity and partnership in finding common-sense ways to implement the law's requirements. We recognize that this kind of an approach has been the hallmark of President Clinton's and your approach to public health and environmental issues, and we look forward to working together to apply it here as well.

We are pleased to inform you that we are immediately commencing a broad-based stakeholder consultation process on the issues you identified. We are establishing an advisory process under the Federal Advisory Committee Act, housed at EPA under its National Advisory Council on Environmental Policy and Technology. The work of this group will be co-chaired by

Fred Hansen, EPA's Deputy Administrator, and Deputy Secretary Richard Rominger of USDA. It will build on the work of the broad-based public process we conducted in the Fall and Winter of 1996 to assist us in developing priorities in implementing the new requirements of the food safety law.

EPA and USDA will work closely together to identify qualified high-level participants, representing a wide range of interests, including farmers and other pesticide users, public health officials, pesticide companies, environmental and public interest groups, pest control experts, and state, tribal, and local governments. We will ask this group to provide extensive stakeholder involvement in establishing the framework for EPA's decisions on the first major -- and most widely used -- set of chemicals which we are evaluating, the organophosphates class. These decisions are of tremendous importance for the protection of public health and agricultural production, and public input will be key to developing a common sense and fair approach. We will ask the group for recommendations on the strategic direction for our tolerance reassessments to ensure that our approach is grounded in the best available science and leads to a decision process that is protective of public health and our nation's farmers and food supply, and that results in decisions that are predictable and easily understood by all interested parties.

We expect the approaches pioneered by focusing on organophosphates will be applicable more broadly to all of our work in implementing the new Act, and we will engage the group on broader questions as well. While we also plan to continue to seek advice from independent scientific experts, such as EPA's statutorily-created Scientific Advisory Panel, we will seek the perspective of the advisory group on the science policy issues -- such as questions concerning common mechanisms of action and cumulative risk -- that will underpin future decisions.

Among the specific issues we will ask for input from the advisory group are:

- What is the appropriate process for making these decisions, what documentation is necessary, and how do we ensure appropriate public participation and transparency?;
- What is the proper policy framework for deciding when there is adequate scientific information for making decisions on tolerance reassessments, when new information must be sought, when is it appropriate to use default assumptions and exposure scenarios, and what is the appropriate methodology for risk assessments?;
- How can we speed up the pace of decision making to make available to growers newer and safer pesticides and new uses of registered pesticides that meet new FQPA safety standards?;
- What are appropriate common sense strategies for reducing risk to acceptable levels while retaining those pesticides of the highest public value, including consideration of minor crop and integrated pest management needs? What are the creative opportunities for reasonable phaseout periods, market-based and targeted approaches and incentives, and

cooperative partnerships that can be employed to achieve these goals?; and

- What are the appropriate priorities in considering organophosphates, such as considering first those most likely to lead to exposures in children's foods?

We are commencing this public process right away to ensure that public consultation is not inconsistent with complying with the time frames for delivering the public health protections contemplated in the FQPA. In addition, we have created a high level working group -- reporting to each of our Deputies -- to ensure close coordination among our agencies on these matters.

You should also be aware that EPA is conducting a thorough review -- requested by the Administrator -- of its experience with applying, reducing, or eliminating the ten-fold child-specific safety presumption called for by the new Act. This review should provide specific recommendations for consistent scientific practices and procedures to be employed in evaluating child-specific risk issues. We also expect to consult with our advisory committee on these issues. We will keep you fully informed of our progress on all of these matters.

We look forward to our continuing work together to guarantee Americans the public health protections they deserve, as well as the safe and abundant food supply of which our nation is so justifiably proud.

Carol M. Browner
Administrator, Environmental Protection Agency

Daniel R. Glickman
Secretary of Agriculture

Paul Sohn

Table 6. Not Heat-Treatable Hazards

Evidence from outbreaks

Year	Product	Hazard	Cases	Cause	Source
1967	Orange juice	Virus (unidentified; other contaminants possible)	5200 (estimated)	Contaminated water added to orange juice concentrate	Schmelzer et al. 1967; Tabershaw et al. 1967
1969	Canned tomato juice	Tin	113	Nitrate in soil incorporated in tomato and corroded cans	Barker and Runte 1972
1984	Elderberry juice	Poisonous parts of plant	11		CDC 1984

Evidence from state investigations

1989	Orange juice	Virus		Ill food handlers	Personal communication with Pam Shillam, Colorado State health dept., January 17, 1997
1990	Guanabana juice	Toxic seed material	9		Personal communication with Dr. Hendricks, Texas State Health Dept., January 16, 1997

Evidence from recalls

Year	Product	Hazard	Cases	Cause	Source
1988	Fruit punch drink	Tin	2	Acidity of punch reacted with tin coating of cans (used wrong cans for packaging juice drink)	FDA recall data
1990-1991	Fruit juice and fruit drinks	Natamycin		Added as a preservative	FDA recall data
1991	Fruit drink	Sulfites		Inadvertently added	FDA recall data
1991-1992	Fruit drinks	Sodium hydroxide	3; 1 hospitalized (in 1992)	Sanitizing agent got into product containers during cleaning	FDA recall data
1990s	Fruit drinks	FD&C yellow #5 dye		Undeclared dye	FDA recall data
1991-1994	Fruit drinks	Glass			FDA recall data
1993	Orange juice	Milk		Filler lines not cleaned between milk and juice production	FDA recall data
1993	Orange flavored soft drink (with pear juice)	Copper	2	Cracks in heat exchanger allowed product to come in contact with copper pipe fitting	FDA recall data
1994	Lemon juice and grape juice	Sulfites		Added	FDA recall data

Year	Product	Hazard	Cases	Cause	Source
1995	Tomato juice	Salt		Undeclared	FDA recall data
1996	Apple-prune juice and prune juice	Lead	No illness; chronic hazard	Contaminated imported prune juice; possibly came in large drum	FDA recall data
1996	Fruit drink	Plastic	3 (complained of choking)	Plastic bags draped over side of bottle loading bin	FDA recall data