Pesticide Regulation Issues: Living with the Delaney Clause

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Abstract

Pesticide use is regulated within a complex legal framework that includes the Federal Insecticide, Fungicide, and Rodenticide Act; the Federal Food, Drug, and Cosmetic Act; and other environmental laws. The framework includes risk-benefit rules for some decisions that permit full consideration of comparative performance, cost, and risks of a pesticide and its alternatives before decisions to permit or ban uses. The framework also includes risk-only standards, such as the Delaney Clause, that prohibit such comparisons and can have unintended and undesirable consequences by increasing health or environmental risks while increasing the cost of producing agricultural commodities.

Key Words: Delaney Clause, food safety, pesticide regulation

Concerns about potential health and environmental effects of agricultural pesticides and ways to reduce those effects have been important public policy issues for over three decades. Recently, questions about the safety of pesticides in food, particularly in children's diets, have been raised by "In Our Children's Food," a "Frontline" episode on the Public Broadcasting System, and the National Academy of Sciences (1993) report, *Pesticides in the Diets of Infants and Children.* There are a variety of issues associated with the Delaney Clause, which affects the food uses of pesticides classified as carcinogens. The resolution of these issues can affect the safety of the food supply and the availability of pesticides for agricultural uses, with important implications for agriculture in the Southern U.S. However, the Delaney Clause is one part of the framework of Federal pesticide regulation where risk-benefit standards govern some pesticide decisions and risk-only standards or other requirements govern other pesticide decisions.

Some decisions to restrict or ban uses of pesticides, made under this framework, might not only constrain agricultural production but also policies to reduce pesticide risks. The reason is that regulatory decisions that do not consider the risks and benefits of a pesticide as compared to its alternative practices could have unintended and undesirable consequences; such decisions could cause net economic losses (due to increased costs per unit of producing agricultural commodities) and, at the same time, increase health or environmental risks. Risk-benefit rules permit consideration of the risks and benefits of a pesticide and its alternatives and could help avoid such unintended consequences, but risk-only standards and other regulatory requirements prevent full consideration of risks and benefits. However, some changes proposed for the

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regulatory process would reduce the constraints on regulatory decision-making and allow greater consideration of risk and benefits of alternatives.

Legal Framework of Pesticide Regulation

Several Federal laws affect the use of pesticides, but the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) are the primary ones. FIFRA governs: 1) the registration of pesticides for various uses under Section 3 and 2) the suspension or cancellation of registered uses of pesticides under Section 6. A registration defines the crops on which a pesticide may be used and how it may be used (method of application, application rates, timing, target pests, pre-harvest and reentry intervals, etc.). FIFRA also allows States to register additional uses of a pesticide to meet special local needs, under Section 24(c), provided that U.S. Environmental Protection Agency (EPA) has not previously denied, disapproved, or canceled the registration of such uses. There are also procedures in FIFRA to allow the use of pesticides in special circumstances without a registration: emergency exemptions (Section 18), and experimental use permits (Section 5). FIFRA defines a risk-benefit rule for registration and cancellation decisions, because the decisions are to prevent "unreasonable adverse effects to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." However, 1988 FIFRA amendments require reregistration of pesticides against new safety standards and fees for maintaining registrations. If a registrant does not pay fees to maintain a label or provide data required for reregistration, the registration is suspended and ultimately canceled by the EPA without considering the impacts on agriculture or the risks of alternatives.

FFDCA regulates the presence of pesticide residues in food. A pesticide cannot be registered under FIFRA for a food use without residue tolerances under FFDCA, unless exemptions are granted. EPA sets tolerances and the Food and Drug Administration (FDA) enforces them. There are no tolerances for emergency exemptions, but EPA requires studies to show that levels of residues in food meet health standards before granting exemptions for food uses.

Section 408 governs tolerances for residues of pesticides used in producing raw agricultural commodities. Decisions to grant such tolerances can consider risks and benefits by weighing the need for an adequate, wholesome, and economical food supply against the need to protect consumers' health, which is narrower than the FIFRA risk-benefit rule. Section 409 requires food additive regulations (tolerances) for pesticides applied to processed food and animal feed products, processing equipment, and processing premises. The standard for Section 409 tolerances only considers risk: a reasonable certainty of no harm to consumers. The Delaney Clause prohibits section 409 tolerances for food additives that induce cancer in humans or animals, regardless of the benefits. Residues of pesticides applied to raw commodities can appear in processed food or feed products. In these cases, the "flow-through provision" of Section 402 allows the Section 408 tolerance to serve as the legal limit in processed food, and the Delaney Clause does not apply. However, EPA applies a concentration policy in these cases. Under this policy, a section 409 tolerance is required if the pesticide concentrates in processed food, even if residues do not exceed the section 408 tolerance. Theoretically, the residues could exceed the Section 408 tolerance if they concentrate. Also, if the pesticide is shown to induce cancer, EPA, under its coordination policy, revokes or denies the Section 408 and 409 tolerances. In these cases, the Delaney Clause affects pesticide use on raw commodities. In a case where there are two or more processed food or animal feed products from a raw commodity, concentration of a pesticide identified as a carcinogen in any one of them will result in the denial or revocation of the section 408 tolerance so that the pesticide could not be registered for use on the raw commodity. Conceivably, a pesticide could concentrate in one processed product and decline in others, but the section 408 tolerance would be denied or revoked.

Decisions under other environmental laws, such as the Clean Air Act, the Clean Water Act, or

the Endangered Species Act, can restrict or ban the use of registered pesticides, even though these laws are not specifically directed at pesticides. At times, these laws are much more visible than FIFRA. For example, the recently announced phase-out of methyl bromide is an action under the Clean Air Act, which did not consider benefits or the risks of alternative practices.

Risk-Benefit vs. Risk-Only Rules

I am not aware of anyone who has developed an "optimal" approach to regulating pesticides. However, many in academia, EPA, and USDA agree that full consideration of comparative pest control performance, costs, and risks of a pesticide and its major alternative practices is needed before deciding to cancel or restrict a pesticide's registration. The reason is to avoid decisions that simultaneously increase risk and cause net economic losses.[1] Obviously, uncertainties or errors in risk or benefit information could result in decisions that increase risk even if currently available information is fully considered.

Risk-benefit standards under FIFRA and FFDCA permit such comparisons, but, under a risk-only rule or regulatory requirement, EPA may be forced to ignore the comparative performance, cost, and risks of the alternatives to a pesticide. The resulting decision to ban or restrict a pesticide's use can have unintended and undesirable consequences; it could force greater use of alternatives that increase other risks not affected by the rule. The alternatives to the pesticide could be both less cost-effective in controlling pests and risker. Some health or environmental risks could increase while others decrease. How increases in some risks and decreases in others affect overall welfare is ambiguous, but such a result could conceivably decrease welfare, especially if combined with increased costs per unit of output.

When risk-benefit rules apply under FIFRA and FFDCA, EPA is permitted to use the decision-making process described above, but has not always done so. Traditionally, EPA's economic assessments have compared alternatives, but the risk assessments have not. As a result, EPA's decisions have had the potential of increasing risks. However, in recent years, EPA has modified regulatory decisions because of the risks associated with alternative practices. For example, some uses of EBDC fungicides were retained because of risks associated with alternative fungicides.

In cases where several alternatives of similar efficacy are available for a particular pest problem, full consideration of risks and benefits leads to the so-called "cluster" or "commodity" approach, which was discussed in the Administration's testimony on proposed pesticide policy and law changes (Browner, Rominger, and Kessler).[2] With this approach, the risks and benefits of all alternatives would be examined before making a decision on any one alternative. Currently, EPA is conducting an experimental "cluster" approach on planting-time insecticides used on corn, focusing on avian toxicity, but this approach has not yet been widely adopted. Other examples of cases suitable for a "cluster" approach include triazine herbicides used on corn and sorghum and pyrethroid insecticides used on cotton. This approach can help reduce risks cost-effectively by avoiding decisions that: 1) cause net economic losses while increasing environmental or health risks, or 2) increase the future economic benefits of higher-risk alternatives by removing lower-risk alternatives when several effective alternatives are available and net economic losses from banning any single alternative would be low. Such an approach would also help to identify cases where managing the use of a group of alternatives (for example, restrictions in the number or timing of pesticide applications) would reduce risk more cost-effectively than banning some of the alternatives. Removing alternatives can force increased reliance on remaining chemicals and encourage resistance to them, hampering the ability of farmers to reduce pesticide use. Also, some pesticides may fit well into an integrated pest management (IPM) program despite high health or environmental risks. Cancellation of such a chemical could result in an overall increase in pesticide applications and, conceivably, an increase in risk.

One adverse effect of a "cluster" or "commodity approach" approach can result if a

regulatory decision were delayed to obtain more information on risks and benefits of alternatives. The effect would be the additional exposure to risk that could have been prevented by an earlier decision, if the comparative information about alternatives did not change the decision. One approach to avoid this problem would be a temporary phase-down or phase-out. The Administration has proposed such authority when there is credible evidence of significant risks, but before all scientific questions are resolved (Browner, Rominger, and Kessler). It would seem that the decision could be reversed if further study lowered risk estimates or showed economic or environmental benefits to justify risks. However, identifying a chemical for phase-down or phase-out could trigger public concern, similar to that in the Alar (trade name of daminozide) controversy, even if the risk concern is not supported by further study. The result could be a de facto cancellation, if the public refuses to buy food treated with the pesticide. However, if public panic could be avoided, temporary phase-downs might be a useful way to reduce exposure to risks during an extended "cluster approach."

Ultimately, the best way to cost-effectively reduce risk is through the development and adoption of lower-risk pest control methods, including pesticides, that will be cost-effective enough to be used in place of currently-used, "riskier" materials. Farmers would then reduce risk by pursuing their economic interest. Such a change could render decisions to restrict or ban pesticides irrelevant in the long-run, but regulatory actions might be viewed as encouraging changes in practices. However, a major change in pest control and production practices could take years. For example, it took 25 years for corn farmers to fully adopt herbicides and could take many years for them to make other major changes in weed control practices (Osteen). On the other hand, the proportion of corn acreage treated with insecticides has decreased significantly since the mid-1980's to a level comparable to that in the 1960's. Changes in practices that fit well into current production systems could be adopted relatively quickly. As an example, pyrethroid insecticides were widely adopted by cotton producers in less than 5 years during the late 1970's as replacements for many organochlorine and organophosphate insecticides.

Public institutions can play a role in conducting research to develop alternatives, but many alternatives will have to be developed, produced, and marketed by private companies. To encourage the development and marketing of such methods, the registration process could be modified by developing screening procedures to eliminate unnecessary scientific tests or creating incentives to register "reduced-risk" pesticides or biological control methods. The Administration proposes to modify FIFRA to give priority to reduced-risk pesticides in the registration process and proprietary rights over toxicological and residue data supplied by registrants.

Delaney Clause Issues

The Delaney Clause is the best-documented situation where a risk-only standard can force pesticide decisions that increase risks or prevent decisions that reduce risks. Under current Federal law and EPA's concentration and concentration policies, different decision rules govern the registration of pesticides used in crop production, depending upon the characteristics of the pesticide. If the pesticide does not concentrate in a processed food or feed product (or there is no processed product), there is a risk-benefit rule for the raw commodity and processed products. If the pesticide does concentrate in a processed product, there is a risk-only, no-carcinogen rule.

The Delaney Paradox

Because different decision rules govern pesticide residues in food, depending upon whether or not a pesticide concentrates in a processed product, EPA asked the National Academy of Sciences to examine the issue and make recommendations about how to resolve potential conflicts. The National Academy of Sciences (1987), in *Regulating Pesticides in Food: The Delaney Paradox*, claimed that the registration of new and lower-risk pesticides could be blocked

even though they created a very small carcinogenic risk, while older materials, with higher carcinogenic risks, could remain on the market. This would be more likely to occur if an older material did not concentrate in processed food and a newer material did. Because of improvements in detection methods since the Delaney Clause was written in 1958, it is possible to find levels of possible or probable carcinogens estimated to cause only negligible cancer risks, but the Delaney Clause would prohibit their use anyway. As a result, the Delaney Clause could prevent reductions in risk by prohibiting the registration of materials with less risk than currently registered materials. While the no-carcinogen standard will likely reduce the number of pesticides available to agriculture and possibly cause net economic losses, there is no guarantee that the food supply will be safer. The Academy recommended a uniform rule for setting food residue tolerances in raw commodities and processed products, with a negligible risk standard to allow low levels of cancer risk. As a result, in 1988, EPA implemented a negligible risk or *de minimus* standard allowing a cancer risk of 1 in-a-million over a 70-year lifespan.

Estimating Cancer Risk

The importance of dietary cancer risks from pesticides as compared to other sources is an important controversy. The FFDCA, including the Delaney Clause, regulates food additives but not naturally incurring ingredients that could be more carcinogenic than pesticides. Ames argues that naturally occurring carcinogens, including "natural pesticides," in such foods as mushrooms, parsley, basil, parsnips, fennel, pepper, celery, figs, mustard, cabbage, broccoli, brussels sprouts, carrots, pineapples, and citrus juices may be much greater hazards than residues of man-made pesticides. Ames also argues that breeding varietal pest-resistance into food crops may create greater dietary cancer risks than the residues of man-made pesticides. He believes that focusing on cancer risks from pesticide residues in food may be diverting public attention and resources away from more important public health concerns such as smoking, alcohol, eating unbalanced diets, and AIDS.

The toxicological methods of identifying carcinogens and estimating cancer risk are controversial. EPA uses a different approach for estimating cancer risk than for other risks (U.S. General Accounting Office). EPA generally assumes there is a threshold dosage below which there is no risk. For cancer risk, EPA assumes that any dosage of a carcinogen has a risk associated with it. This might be valid for some substances, but a threshold approach could be more valid for others. The substance's mode of action in causing cancer must be considered when estimating cancer risk. If no effect can be shown from a low dose, the EPA approach is to extrapolate cancer risk from higher doses which do show adverse effects, using a "multistage linear model." Included is the maximum tolerated dose from long-term animal feeding studies, which is the dosage at which severe effects are observed. This dosage is included even though it may be much higher than the dosage to which people would be exposed in their diets. Ames argues that the maximum tolerated dose may promote cancer by causing cell proliferation, even though the substance does not cause mutations and would not cause cancer at low doses. Many other countries use a threshold model for cancer and do not include a maximum tolerated dose. If the cancer risk of a substance is described by a threshold model, the multistage linear model will overestimate cancer risk at the lower doses and show cancer risk for doses below the threshold when risk is actually zero.

The Ninth Circuit U.S. Court Decision

EPA was sued by the Natural Resource Defense Council over its use of the negligible risk standard. In 1992, The Ninth Circuit U.S. Court decided that EPA's standard was not acceptable and that a zero cancer-risk rule was required under current law. Clearly, the Ninth Circuit U.S. Court's decision has had a major impact on the debate over pesticide regulation.

Using the stricter, no carcinogen standard means that pesticide uses previously permitted under the negligible-risk rule could be banned and registrations for new pesticides that would have

been granted could be denied, no matter how small the measured cancer risk, how large the risks of alternatives, or how large the economic losses. An important impact of the Ninth Circuit U.S. Court Decision is that a legislative stalemate on resolving Delaney Clause issues would hurt agricultural interests more than before the decision. Agricultural interest groups now have a greater incentive to resolve Delaney Clause issues, because the potential cost to them of not changing the Delaney Clause is greater than before.

As a result of the decision, EPA has written a draft rule to revoke the section 409 tolerances for the materials and crops named in the court case: benomyl, mancozeb, phosmet, and trifluralin (Table 1). However, as of this writing, EPA has not proposed revocation of the section 408 tolerances on the raw commodities. If EPA follows its current policy, the section 408 tolerances will be revoked as well. Many other currently registered uses of pesticides will probably be affected by the interpretation if FFDCA is not changed; EPA released a list of 32 materials on a variety of uses in February 1993 (Table 1). The list could be expanded as studies are completed and show evidence for carcinogenicity and concentration in processed food or animal feed products.

Actions on the 32 listed pesticides would probably have greater proportional impacts on specialty crops, such as fruits, than on major field crops. As shown in Table 1, such actions would remove many registered fungicides and miticides for apples and grapes and herbicides for sugarcane.[3] Five of the 13 fungicides most widely-used on U.S. apples and 4 of the 12 most widely-used on U.S. grapes were listed (USDA, National Agricultural Statistics Service, 1992). The use of affected chemicals on corn, cotton, soybeans, or wheat and other small grains is either small or the net economic loss would be small because alternatives are available. The limited number of impact estimates show the potential for high proportional losses on apples, grapes, and hops, because alternatives are less effective or unavailable. Also, the reduction of alternatives could increase pest resistance to the remaining alternatives and increase losses, as demonstrated by the impact estimates for losing all miticides. In addition, financial losses may be concentrated in some regions. Fungicide use on apples and grapes is much higher in the east and south than in the west, so the eastern and southern production of those two crops would likely be more affected by disease control problems.

In May 1993, EPA revoked five Section 18 emergency exemptions and denied applications for other pesticides to be used on 10 crops in 16 States, based on the Ninth Circuit U.S. Court Decision. The actions reflected a new policy based on the logic that satisfactory progress could not be made toward registration, including the necessary tolerances, if the pesticide was a carcinogen that concentrated in a processed food or animal feed product. Hence, the Section 18 application should be denied or current exemption revoked. In the case of iprodione for use on apples in North Carolina, the exemption was granted only several weeks before it was revoked. Section 18's were also revoked for cyromazine on tomatoes and potatoes in Florida, fosetyl-Al on hops in Oregon, and triadimefon on tomatoes in California. So, the court decision can affect the registration of new materials and the granting of emergency exemptions, with particular importance for small acreage, high value per acre crops.

Resolving the Delaney Paradox

Currently, there are two major legislative approaches to resolve the Delaney Paradox. The Kennedy-Waxman Bills (S. 331 and H.R. 872) and the Administration proposals have negligible risk standards (risk-only) that would be applied to all residue tolerances in food. These proposals would require EPA to set tolerances based on a standard of a reasonable certainty of no harm to consumers of food, which is similar to the standard in section 409 of FFDCA with the Delaney Clause deleted. For some cases where alternative controls are not available, the Administration proposes transitional tolerances for a maximum of five years; risks and benefits to consumers would be considered in decisions to grant such tolerances, which is similar to the risk-benefit rule in Section 408 of FFDCA. The Administration also proposes a review of existing tolerances over 7 years to bring tolerances

Table 1 Pesticide registrations that could be revoked under the Delaney Clause

Commodity	Pesticide	Type a/	Use	Potential Net Loss	
			Percent of Acres	$ Millions	Percent of Crop Value
Apples	Metiram	F	--	--	--
	Maneb	F	--	--	--
	Captan	F	52	NA	NA
	Mancozeb	F	3	NA	NA
	Thiophanate	F	18	NA	NA
	Triadimefon	F	15	NA	NA
	Benomyl	F	9	NA	NA
	Oxyfluorfen	H	--	--	--
	Dimethoate	I/M	17	NA	--
	Dicofol	I/M	3	NA	--
	Propargite	M	27	16	1
	All miticides b/			100	7
Barley	Triadimefon	F	--	--	--
	Mancozeb c/	F	--	--	--
	Dicamba	H	8	NA	NA
Citrus	Benomyl	F	4	NA	NA
	Norflurazon	H	16	NA	NA
	Phosmet	I	--	--	--
	Dimethoate	I	9	NA	NA
	Methidathion	I	--	--	--
	Dicofol	I/M	18	NA	NA
	Propargite	M	11	1	<1
Corn	Captan	F	70-80	40-50	<1
Cotton	Oxyfluorfen	H	2	--	--
	Dimethepin	GR	4	2	<1
	Phosmet c/	I	--	--	--
	Acephate	I	8	28	<1
Figs	Propargite	M	NA	NA	NA
Grapes	Benomyl c/	F	11	NA	NA
	Mancozeb c/	F	13	NA	NA
	Triadimefon	F	18	NA	NA
	Captan	F	4	NA	NA
	Maneb	F	2	NA	NA
	Dicofol	I/M	3	NA	NA
	Propargite	M	40	10	<1
	All miticides b/			337	20
Hops d/	Propargite	M	100	80	95
Millet	Dicamba	H	NA	NA	NA
Oats	Mancozeb c/	F	--	--	--
	Dicamba	H	6	NA	NA
Peanuts	Alachlor	H	--	--	--
	Metolachlor	H	37	9	<1

See footnotes at end of table

Continued--

Table 1 Pesticide registrations that could be revoked under the Delaney Clause--Continued

Commodity	Pesticide	Type a/	Use	Potential Net Loss	
			Percent of Acres	$ Millions	Percent of Crop Value
Peppermint/ spearmint	Trifluralin c/	H	14	NA	NA
	Oxyfluorfen	H	3	NA	NA
Pineapple	Triadimefon	F	NA	NA	NA
Plums	Captan	F	33	NA	NA
	Propargite	M	17	6	4
Potatoes	Chlorothalonil	F	16	6	<1
	PCNB	F	--	--	--
	Linuron	H	6	NA	NA
Rice	Benomyl	F	36	NA	NA
Rye	Mancozeb c/	F	--	--	--
Sorghum	Alachlor	H	8	NA	NA
Soybeans	Oxyfluorfen	H	--	--	--
	Alachlor	H	12	40-70	<1
	Chlorothalonil	F	--	--	--
	Acephate	I	2	NA	NA
Sugarbeets	Metiram	F	NA	NA	NA
	Mancozeb	F	NA	NA	NA
	Maneb	F	NA	NA	NA
Sugarcane	Atrazine	H	59	NA	NA
	Simazine	H	NA	NA	NA
	Hexazinone	H	NA	NA	NA
	Asulam	H	50	NA	NA
Sunflower seed	Alachlor	H	5	NA	NA
Tomatoes	Captan	F	--	--	--
	PCNB	F	--	--	--
	Benomyl c/	F	4	NA	NA
	Lindane	I	--	--	--
	Permethrin	I	9	NA	NA
Wheat	Triadimefon	F	--	--	--
	Mancozeb c/	F	--	--	--
	Dicamba	H	13	NA	NA
	Methomyl	I	--	--	--

-- = Not significant
NA = Estimate not available
a/ F = fungicide, GR= growth regulator, H = herbicide, I = insecticide, M = miticide
b/ Potential impact if all miticides were lost due to regulatory action or resistance
c/ Pesticide and crop named in the Ninth Circuit U S Court Decision
d/ Dried hops are now classified as a raw agricultural commodity, so propargite on hops would be removed from this list

Sources Bridges et al , Ferguson and Moffitt, Kuchler and Ralston, Osteen and Kuchler, and various USDA/NAPIAP reports

in line with new standards. Pesticides identified as likely to exceed negligible risk would receive priority for tolerance review within 4 years after enactment. Tolerances would be revoked if registrants fail to complete testing or show that the statutory standard is met.

These proposals would be less restrictive than current practice where section 409 of FFDCA applies, but more restrictive where only section 408 applies. The proposed risk-only standards would resolve the paradox between section 408 and 409 tolerances and allow the registration of more pesticides than the no-carcinogen rule of the Delaney Clause. Since the proposals do not affect FIFRA, a paradox would remain in the registration and cancellation processes, because there would be risk-only standards for food-related risks and risk-benefit rules for many nonfood-related risks, such as worker exposure, toxicity to nontarget organisms, and noncancer-related dietary risks.

The Lehman-Bliley Bill (H.R. 1627) would allow risk-benefit comparisons for section 408 residue tolerances and expand the risk-benefit rule under section 408 to consider: 1) a pesticide's role in protecting humans or the environment from adverse effects on public health or welfare, and 2) risks to workers, the public, or the environment that would result from using the alternatives. H.R. 1627 would eliminate EPA's requirement for section 409 tolerances if the residues in a processed food did not exceed the section 408 tolerance, even after concentration. Requirements for other section 409 tolerances (pesticides applied directly to processed food, processing equipment, and processing premises) and the Delaney Clause would be unchanged. H.R. 1627 could allow more pesticides to be registered for food uses than the proposed risk-only standards. Additionally, the approach of H.R. 1627 would result in similar risk-benefit rules for many food-related and other health and environmental risks, especially for pesticides used before food processing.

A number of environmental groups oppose any relaxation of the Delaney Clause, so that a uniform standard would mean no carcinogens, at any level, in food. Currently there are no legislative proposals for this standard.

The EPA rule-making process could affect the impact of the Ninth Circuit U.S. Court Decision by reducing the number of cases where section 409 tolerances are needed. The food processing and pesticide industries argue that EPA could eliminate the concentration and coordination policies, because they are not consistent with the "flow-through provision" of section 402 of FFDCA, which allows the section 408 tolerance to serve as the maximum residue level in processed food (McCarthy). (This is also proposed in H.R. 1627.) If industry's argument were followed, EPA could allow some pesticides to concentrate in processed food without requiring a section 409 tolerance and thus avoid applying the Delaney Clause in those cases.

EPA has drafted a proposed rule for defining a raw agricultural commodity (RAC), which could reduce the need for section 409 tolerances and the cases where the Delaney Clause applies. The definition of a RAC in FFDCA is not clear. EPA's proposal is that if a treatment does not substantially alter the "structural integrity," the commodity can be viewed as a RAC. Under this proposal, a number of commodities traditionally classified as processed would be reclassified as RACs: dried fruits such as apricots, currants, figs, raisins, and prunes; raisin waste (an animal feed); dried ginseng; dried whole spices; dried unfermented (white) tea; and dried herbs. However, ground spices and dried fermented (black) tea would continue to be classified as processed commodities.

Other Risk-Only Rules and Regulatory Requirements

While FIFRA is generally viewed as allowing risk-benefit comparisons, pesticide registrations may be suspended or canceled without such a comparison. For example, during reregistration, EPA requires registrants to pay fees or provide data from toxicogical tests by particular dates. EPA can suspend uses if the deadlines are not met, regardless of the risks and comparative performance of alternatives. (This is not an argument that the law is wrong, but simply an

observation.) Between 1988 and 1992, the number of registered products decreased from about 45,000 to 20-25,000 (U.S. Environmental Protection Agency). Under the Administration's proposed policy, reregistration would continue; all pesticides uses would be reviewed every 15 years to make sure that registration information meets current standards.

Also, when EPA has identified risk concerns that could lead to restrictions or cancellations of a pesticide's registered uses through Special Review, a registrant may choose to voluntarily cancel some or all uses in order to reduce risks to an acceptable level. Registrants might choose not to support somes uses of a pesticide during registration or defend some uses during special review to avoid the costs. The registrant's decision could be based on a comparison of potential sales to the costs of supporting or defending a registration, which is not the same as comparing the relative performance, costs, and risks of the alternatives. EPA might be able to avoid this problem by examining the relative risks and benefits of alternatives before notifying the registrant of plans to initiate a Special Review of a particular pesticides.

Minor Use Pesticides

"Minor crops," such as fruits, nuts, vegetables, and other specialty crops, are particularly vulnerable to losing registrations in these two ways as compared to such "major crops" as corn, cotton, soybeans, and wheat. The reason is that minor crops create a relatively small market for pesticides and a small incentive for pesticide registration, even though the crop values and per-acre use of pesticides are often very high. Because major crops create large markets for pesticides, registrants have a much greater economic incentive to register pesticides for the "major uses."

A registrant might voluntarily cancel minor uses as a cost-effective way to reduce exposure to various risks and try to keep the major uses. EPA estimates the exposure to a risk from all sources, and eliminating some registered uses of a pesticide may reduce total risk to acceptable levels. The minor uses may be a source of high risk because of direct human consumption and high per-acre pesticide use, while the total value of the pesticide's sales for such crops are low.

The losses of pesticide registrations, whether through the reregistration process, revocations or denials of tolerances or emergency exemptions because of the Delaney Clause, or Special Review, have a disproportionate impact on the availability of pesticide registrations for minor crops. The losses of registrations could also cause economic losses to producers or consumers of these on these crops, because cost-effective alternatives are not available. Ultimately, the result could be lower production or higher prices for fruits and vegetables, which are often viewed as important components of healthy diets with a role in reducing cancer risks.

It is not unusual to estimate large benefits for minor crops and small benefits for major crops, even though major crops account for most of the use of a pesticide. The reason is that cost-effective alternatives are often available for the major crops but not for the minor crops. For example, the National Agricultural Pesticide Impact Assessment Program report, *The Biologic and Economic Assessment of Chlorpyrifos* (USDA, 1994), estimates that fruits, nuts, and vegetables account for 14 percent of the use of chlorpyrifos, but would account for over half of the net economic loss if that chemical were banned. In another case, *The Biologic and Economic Assessment of Propargite* (USDA, 1994) estimates that fruits, nuts, vegetables, and hops account for 53 percent of propargite use and 85 percent of the net economic loss if this chemical were banned. If cost-effective alternatives are available for a crop pest, high sales on a major crop do not translate into high net benefits for consumers and producers. Low sales on a minor crop can translate into high net benefits, if the pest is very damaging, crop value is high, and no cost-effective alternative to the pesticide is available.

Methyl Bromide

Other environmental laws, while not directed specifically at pesticides, can affect the use of pesticides. Actions can focus narrowly on a single risk-concern and ban or restrict a pesticide's use without comparing its performance, costs, and risks to those of the alternatives. The methyl bromide decision is particularly interesting because it will have widespread effects on agriculture, particularly minor crops, but was made under the Clean Air Act, not under FIFRA.

Methyl bromide is a fumigant with pre-plant soil and post-harvest uses, including quarantine treatments of exports and imports. The vast majority is used for preplant soil fumigation in California, Florida, and several other Southeastern States. EPA announced, on Nov. 30, 1993, a freeze of U.S. methyl bromide use and production at 1991 levels and a termination of use on Jan. 1, 2001. However, if future research can sufficiently reduce estimates of methyl bromide's impact on ozone depletion, its use and production could be permitted to continue. EPA took this action under the Clean Air Act after methyl bromide was classified as a Class I ozone depleting substance by the Parties to Montreal Protocol. EPA's action is more restrictive than those taken under the Montreal Protocol, which include a worldwide freeze on methyl bromide use and production at 1991 levels and further studies on methyl bromide's impact on ozone depletion before taking further action in 1995.

There were several issues of controversy. Agricultural interests argued that there are many uncertainties about the impact of methyl bromide on ozone depletion and the contributions of manmade and natural sources of methyl bromide to stratospheric ozone, so that it is unclear what effect EPA's action will have on ozone depletion. The availability and effectiveness of alternatives were also issues. EPA argued that effective alternatives could be found and registered by the year 2001, but agricultural interests argued that currently available alternatives are much less effective than methyl bromide and it is unlikely that new, effective alternatives could be found and registered by 2001.

The Biologic and Economic Assessment of Methyl Bromide (USDA, 1993) estimated that net economic losses caused by using currently available alternatives would exceed $1 billion per year, with tomato, strawberry, tobacco, and Florida vegetable production being particularly hard hit. International trade will be disrupted because methyl bromide is required as a quarantine treatment by many importing countries, including the U.S., to prevent the spread of exotic pests. Importing countries will deny entry to commodities grown in countries where these pests exist, unless effective alternative quarantine treatments are found. So, the cost of overestimating methyl bromide's impact on ozone depletion could be quite large.

The Clean Air Act does not permit the consideration of economic impacts or health and environmental risks associated with alternative treatments as FIFRA does. The use of less effective alternatives could increase non-ozone related health and environmental risks and cause significant net economic losses. Since EPA's action is much more restrictive than those taken by many other countries that are Parties to Montreal Protocol, use could increase in other countries to offset decreases in this country and reduce the effectiveness of the action in reducing ozone depletion. Among the major alternative pesticides that would be used in the U.S. are 1,3-D and metam-sodium. California has suspended use of 1,3-D because of health concerns, but studies are being conducted that could result in some uses of the chemical being permitted. However, EPA might conduct a Special Review because of cancer risks to workers, which could result in a restriction or cancellation of the registration. Metam-sodium received notoriety after a spill into the Sacramento River caused massive fisk kills. So, the action on methyl bromide could increase risks not directly affected by the Clean Air Act and cause net economic losses because the alternatives are less effective, unless cost-effective and lower-risk alternatives are made available by the phase-out date.

Effects on Agriculture in the Southern U.S.

Actions that restrict, phase-out, or ban the use of pesticides, whether by EPA or pesticide registrant, can impose constraints on agricultural production by removing or restricting pest control options. The result can be losses suffered by producers and/or consumers of commodities affected by the actions. Agriculture in the Southern U.S. is particularly vulnerable to financial losses from such actions as compared to other regions of the U.S., because of its relatively severe pest problems and high pesticide use. The region produces a large number of high-value, minor crops that are particularly vulnerable to losing registrations for pesticides, because manufacturers often do not register alternatives for small markets. Yield losses and higher production costs could result in the South losing market share to other U.S. regions or foreign countries. However, other regions could also be adversely affected. For example, crop production in California, Oregon, and Washington is particularly vulnerable to the loss of miticides.

Recently, I have been involved in three studies that help to demonstrate the vulnerability of Southern agriculture to impacts of restrictions on pesticide use. *The Importance of Pesticides and Other Cotton Pest Management Practices in U.S. Cotton Production* (USDA, 1993) showed generally heavier pesticide use in Southeastern and Delta States (the area from Virginia to Louisiana) than in States farther west. While it was estimated that the loss of individual materials generally would have little net economic effect, because effective alternatives are available, the loss of major groups such as pyrethroid, organophosphate, or carbamate insecticides; dinitroaniline, organic arsenical, substituted urea, or triazine herbicides; all seed treatments; or all desiccants and defoliants, whether through regulatory action or resistance, would reduce income and acreage in the Southeast and Delta States and encourage cotton production farther west.

The Biologic and Economic Assessment of Methyl Bromide (USDA, 1993) showed use to be concentrated in the Southeast, particularly Florida, and California. The largest production and net economic losses were on tomatoes, strawberries, tobacco, and Florida vegetables; Florida also incurred the largest production losses for tomatoes and strawberries. *The Importance of Fungicide in U.S. Leafy Green Production* (USDA, 1994), which includes collards, kale, lettuce, mustard greens, spinach, and turnip greens, showed that southern and eastern States were more likely to incur proportionally high economic losses than western States were, if certain individual fungicides or major groups of fungicides could no longer be used.

Conclusions

In conclusion, I wish to reiterate that full consideration of the comparative performance, cost, and risks of a pesticide and its major alternatives is desirable before making a final decision to restrict or ban pesticide uses; the reason is to avoid decisions that simultaneously increase health or environmental risks and cause net economic losses due higher costs per unit of output. The risk-benefit rule under FIFRA permits full consideration of risks and benefits of alternatives, while the narrower risk-benefit rule of section 408 of FFDCA weighs the adequacy of the food supply againsts consumers' health. But some risk standards and other requirements prohibit such comparisons. They include the Delaney Clause, reregistration data requirements, and some environmental laws such as the Clean Air Act. Decisions by registrants to voluntarily cancel uses do not necessarily account for comparative risks, costs, and performance of alternatives.

The Ninth Circuit U.S. Court decision invokes a zero cancer-risk standard for the Delaney Clause that is more restrictive than EPA's negligible risk interpretation. The zero-risk standard would increase the number of residue tolerances revoked or denied, but not necessarily reduce cancer or other health and environmental risks. However, EPA might be able to write rules that reduce the number of section 409 tolerances needed and the cases where the Delaney Clause applies.

The Administration and Kennedy-Waxman proposals to change FFDCA by using a negligible risk standard for all residue tolerances could result in fewer revocations of current tolerances or denials of new tolerances. With the new standard, EPA would be able to avoid many decisions that would prevent cancer or other risk reduction or cause unnecessary economic losses. The Lehman-Bliley Bill (H.R. 1627) would reduce the need for section 409 tolerances and increase the cases where a risk-benefit rule would apply in decisions to grant, revoke, or deny residue tolerances. The Lehman-Bliley Bill would expand the risk-benefit rule of section 408 of FFDCA to consider risks associated with using alternatives or risks associated with not controlling pests.

Ultimately, the best way to cost-effectively reduce risks is through the development and adoption of lower-risk and more cost-effective chemical and nonchemical pest control options. In this way, farmers will reduce risks by pursuing their economic interest. Such new alternatives would reduce net economic losses and the potential for adverse health or environmental risk effects from regulatory actions. The registration process could be modified to reduce barriers to the introduction of new alternatives in the marketplace.

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Endnotes

1. Throughout this paper, I assume two things: 1) less of a health or environmental risk is preferable to more, other things being equal, and 2) lower cost per unit of output (lower production cost or higher yield) is preferable to higher cost per unit of output (higher production cost or lower yield), other things being equal. So, decisions that increase a risk and cost per unit of output, other things equal, are inferior to the current situation and decrease welfare, while decisions that do the opposite are superior and increase welfare. The welfare effects of decisions that increase a risk and decrease cost per unit of output or vice-versa are ambiguous, without knowing more about social and political values concerning risks and economic effects. I use the term "net economic loss" or "economic loss" to indicate outcomes of decisions where cost per unit of output increases. Also, the net benefit of using a pesticide is the same as the net economic loss of banning its use. The aggregate economic gain or loss can be measured by the change in the sum of producer and consumer surplus or the value of yield loss plus cost change, depending upon estimated price and quantity changes. These measures implicitly assume that all financial gains and losses incurred by various individuals and groups, distributional effects, can be summed into one aggregate effect. While we economists can argue about issues of fairness and whether or not distributional effects can summed, I believe that the aggregate effect is a useful measure of the overall magnitude of yield and cost changes resulting from regulatory decisions.

2. A "cluster" approach considers the major alternatives for a particular pest problem on one or more crops. A "commodity" approach considers the major pesticides used on a particular crop and will include "clusters" for major pest problems on that crop. See *The Importance of Pesticides and Other Pest Management Practices in U.S. Cotton Production* (USDA, 1993) for an example of the benefit side of a "commodity" approach.

3. Dried hops are now classified as a raw agricultural commodity, so that propargite use on hops would be removed from the list of crops and chemicals affected by the Delaney Clause.