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Food Safety Reforms and Production Agriculture

by

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This nation benefits from being home to the world's most efficient food production system. In 1951, the average U.S. citizen spent 23% of his or her paycheck to put food on the table. Today, American consumers spend only an estimated 11% of their disposable income for food.

Over the past forty years, the cost of food for American consumers has dropped significantly because of the efficiency of our farmers and ranchers and their access to modern production tools and methods. One of the critical tools used by producers to enhance their ability to produce the world's most abundant, most affordable food supply is pesticides.

Most dictionaries define a "pesticide" simply as a chemical used to kill a pest. In practical terms, "pesticide" must be defined more broadly. Agricultural producers use a wide variety of chemical and biological agents in combination with an ever-expanding array of management methods and integrated strategies to control pests in a safer, more efficient manner. The result is that the U.S. food supply, guarded by some of the most stringent and exhaustively analyzed pesticide risk assessment standards of any nation, is not only the most abundant and most affordable in the world, but also one of the safest and most wholesome.

Despite the comprehensive nature of the current pesticide regulatory scheme, the general public perceives the U.S. food supply as less than safe because scientific analysis can identify pesticide residues in raw and processed agricultural commodities. Unfortunately, even though analysis also shows that the level of pesticide residues sometimes found in foods is substantially lower than levels determined to be safe through scientific research, the perception persists because the public believes — or is led to believe — that agricultural producers apply heavy doses of dangerous pesticides or other chemicals with little or no regard for the impact on human health or the environment.

Older Americans remember the post-World War II notion of "better living through chemistry." In hindsight, many members of the scientific community and of the commercial sector, as well as federal policy makers, implemented this concept with a zeal that permitted the widespread use of some chemicals of noted benefits, but with potential human health or environmental risks. In the late 1950s and early 1960s, the worm began to turn.

In 1962, Rachel Carson published her book, Silent Spring, which focused on her perception of society's indiscriminate use of and reliance on chemicals, particularly pesticides. Her work touched off a firestorm of public anxiety over the use of pesticides, particularly the insecticide DDT. Within ten years, this public

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While only a rough estimate, EPA officials have indicated it can take from four to eight years to remove a pesticide product from the market because of the lengthy review, rulemaking, public comment, and judicial process provided for by law.

Regulating Pesticides to Ensure Safe Use

According to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a pesticide is defined as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance . . . intended for use as a plant regulator, defoliant, or desiccant . . . ." This legal definition applies whether the product in question is a chemical or biological agent.

FIFRA, unlike most other environmental statutes, was designed by Congress to operate on a principle of examining a pesticide's risks versus its benefits. When EPA, the federal agency charged with responsibility for enforcing FIFRA, determines that the risks (whether to human health, the environment, or both) associated with the use of a pesticide outweigh its benefits, EPA can:

- restrict the use of the pesticide;
- temporarily suspend the use of the pesticide while new data is gathered and analyzed;
- cancel its use entirely depending on the nature of the risk;
- in the case of a new pesticide or new use, refuse to register the pesticide product in the first place.
FIFRA was enacted in 1947 to protect users of pesticide products, primarily agricultural producers, from false pesticide claims and dangerous chemicals. In the early 1970s, when Congress moved the function of pesticide regulation from the U.S. Department of Agriculture (USDA) to the newly created EPA, FIFRA became an environmental protection statute covering a wider range of issues, with emphasis on consumer and environmental protection. This new role was finalized with the 1972 enactment of FIFRA amendments which are the foundation for the current statute and regulations.

Through FIFRA, EPA regulates the manufacturing and use of pesticides. Until EPA registers a substance as a pesticide, the substance cannot be sold as a pesticide within the United States. The registration process includes an exhaustive and thorough review of data from a comprehensive battery of health and environmental tests, detailed information (referred to as the “label”) about the crops on which the pesticide is registered for use, and information on how often and when it may be used. Once a pesticide is registered, EPA’s regulatory system (which includes cooperative arrangements with other federal and state public safety and environmental agencies) uses a substantial array of tools, including cancellation or suspension procedures to remove the product from the market and fines that can be levied for the misuse or mishandling of pesticides, to ensure the pesticide product is used according to the approved label.

Another frequently raised regulatory question involves the export of pest control products. There are pesticides produced in the United States for use in other countries that are not registered for domestic use. An example would be a fungicide manufactured for use on bananas, a commodity for which there is no domestic commercial production.

If, however, the exported pesticide is for use on a crop that could find its way into our food supply — say, for example, bananas — the manufacturer of the pesticide must obtain a food tolerance from EPA, which is discussed in the “Food Safety” section below. Although this tolerance is established under a different statute, EPA sets the maximum residue tolerance level using the same rigorous scientific criteria for analyzing risk assessment data as is used in FIFRA to examine the human health risks of a pesticide for which a domestic use registration is sought. If an exported pesticide does not have an approved residue tolerance, foods containing residues of that pesticide are barred from importation to the United States.

Food Safety: FFDCA’s Impact

As a key element of the federal government’s overall effort to protect consumers from unsafe foods and other products, such as food additives, Congress in 1938 enacted the Federal Food, Drug, and Cosmetic Act (FFDCA). Congress has amended the FFDCA numerous times since its original enactment. Under this statute, EPA has the mandate to establish safe limits on pesticide residues in food. These maximum legal limits are known as “tolerances.”

The FFDCA does not govern the use of pesticides, which falls under the jurisdictional authority of FIFRA. The FFDCA, however, does impact the use of pesticides because it provides that, for any pesticide product that may be used on or near crops, livestock, and other foodstuffs, the resultant residues that may appear in our foods cannot exceed a safety level determined by an EPA scientific review of human health data.

One of the critical aspects of FFDCA that agricultural interests have been working to reform is the so-called Delaney Clause, which regulates carcinogens in food additives. The Delaney Clause goes far beyond the general, scientifically accepted parameters of safety. It effectively requires that any pesticide with a residue that concentrates during processing and shows any level of cancer risk cannot be used on foods. It is an emphatic “zero-risk” tolerance.

The Delaney Clause was enacted in 1958 during a time when scientific technology could identify residues at a parts-per-trillion level. Today’s technology can detect residues at a parts-per-quadrillion level, and parts-per-quadrillion technology soon will be readily available. The advances in science’s ability to detect residues of potential carcinogens and/or other potential toxic effects, coupled with the Delaney Clause’s “zero-risk” standard, often preclude the chemical industry from bringing new pest control products to market, products that could be safer than some currently being used.
The fundamental problem is a statutory provision written with insufficient flexibility to allow scientific risk assessment to progress. In the late 1950s, laboratory methods could identify, with a high degree of scientific reliability, the presence of chemical residues in foods that represented a cancer risk of 1/10,000 to 1/100,000 of a percent. At that level of risk, one perhaps can understand why a zero-risk standard made sense. Because, however, today's technology can provide scientists the potential ability to identify risk down to 1/1,000,000,000 of a percent, there are legitimate concerns about blocking advancements in food safety.

Consider that the average American faces a 25% chance of contracting some form of tumor, carcinogenic, or oncogenic. Now consider a pesticide residue that raises the potential of causing one additional incident of cancer in a population of one million. The person's risk level is raised to 25.000001%.

As a society, we have an interest in and preoccupation with identifying the risks that threaten our health and well-being. This is how we know, for example, that eating a particular fruit treated with a specific chemical raises the potential risk of an additional incident of cancer by .000001% (one millionth percent). What is often missing from this preoccupation with identifying risks is a meaningful comparative analysis of other types of risks we face, risks we willingly accept as part of our day-to-day lives.

For example, 1982 data from A.C. Upton's research on the biological effects of low-level ionizing radiation indicated that, while the public perceived the risk from pesticides to be high, the number of deaths actually caused by pesticides ranked substantially lower than accidental deaths related to smoking, alcohol, motor vehicles, swimming, aviation, bicycles, hunting, home appliances, power mowers, and skiing, among other things. The fact is the vast majority of Americans readily accept and/or adjust their lives to manage the risks posed by these various activities.

An issue for many people is the debate between "scientific risk" versus "regulatory risk." Scientific risk is described as the best estimate of the true risk permitted by the available data. Regulatory risk is the estimate of risk allowable to assure public safety. According to a report by the Council for Agricultural Science and Technology (CAST) called Pesticides, Cancer, and the Delaney Clause, each of these risk estimates is appropriate for its purpose, but calculations of regulatory risk should not be mistaken for scientific risk assessment, or vice versa.

For the food industry, setting priorities on risk hazards based on scientific analysis is a primary concern. In its report, CAST cited the desirability of using scientific risk assessment to compare the possible hazards from pesticides with the possible hazards from other naturally occurring compounds:

We (Americans) are ingesting in our diet at least 10,000 times more by weight of natural pesticides than of man-made pesticide residues. These are natural "toxic chemicals" that have an enormous variety of chemical structures, appear to be present in all plants, and serve to protect plants against fungi, insects, and animal predators. Though only a few are present in each plant species, they commonly make up 5 to 10% of the plant's dry weight. . . . Plants commonly produce very much larger amounts of their natural toxins when damaged by insects or fungi. For example, psoralens, light-activated carcinogens in celery, increase 100-fold when the plants are damaged by mold and, in fact, can cause an occupational disease in celery-pickers and in produce-checkers at supermarkets.

In theory, the Delaney Clause prohibits a pesticide residue that raises cancer risk by a negligible amount, regardless of the pesticide's potential benefits. The point is that there are many factors, from the foods we eat to the environment in which we live to our genetic makeup, that contribute to each person's potential reaction to risks inherent in his or her environment. The strong case made for reforming the Delaney Clause boils down to making certain that society's concerns about the exposure to potential risks to health or the environment posed by the use of pesticides are balanced with the concrete benefits that pesticides provide, such as a stable food supply and control of disease-bearing or destructive pests.

The irony of the Delaney Clause as it currently stands is that, if federal food safety officials are forced to abandon FIFRA's risk/benefit principle, society's health risks will increase because of
declines in the availability of pesticides intended to enhance and assure the variety and affordability of foods identified by the National Academy of Sciences (NAS) and the Surgeon General as essential to a healthy diet. Specifically, NAS and the Surgeon General have stated that a diet rich in fruits and vegetables and related food products significantly reduces the risk of heart disease and many forms of cancer.

If supplies of these products decrease or the costs associated with providing them to the market increase because of farmers’ inability to control a yield-robbing pest, consumers will be paying much higher prices if they can afford to include them in their diet in the first place. This is particularly true of low-income families who statistically face the highest health risks because of insufficiencies in their diets.

**Legislative Reforms**

Reforms to enhance food safety relative to pesticide use center on key provisions of FIFRA and FFDCA. FFDCA reform proposals revolve around amending the Delaney Clause through enactment of a flexible standard based on the concept of “negligible” or “de minimis” risk. In addition, there will be considerable debate over two other concepts: creating nationally uniform standards in setting tolerances, and benefits consideration.

Regarding FIFRA, some of the key issues involve streamlining FIFRA’s current cancellation and suspension provisions, reviewing/enhancing the ongoing re-registration of “old” chemicals, and addressing the relatively new issue of minor use pesticides.

**Cancellation and Suspension**

Cancellation and suspension generally go hand in hand. These two FIFRA provisions are the primary tools EPA uses to address health or environmental safety concerns about a pesticide that already has been registered and is in use. When cancellation procedures begin, EPA determines that sufficient evidence exists to review a pesticide and to ensure that it has a complete understanding of the pesticide’s risks. While a product is in cancellation review, it is allowed to stay on the market. If, however, it determines that the pesticide poses an “imminent hazard” during cancellation review, EPA can invoke its suspension authority and immediately remove the product from the market and prohibit its further use until safety concerns with the product can be reviewed and addressed.13

Critics of current cancellation and suspension provisions, ranging from the chemical industry to the environmental community, complain the procedures simply take too long to work. While only a rough estimate, EPA officials have indicated it can take from four to eight years to remove a pesticide product from the market because of the lengthy review, rule making, public comment, and judicial process provided for by law. Over the past few sessions of Congress, several bills have proposed eliminating burdensome, time-consuming cancellation procedures to provide for a more efficient, streamlined process.

Many advocates of cancellation reform, however, believe that enhanced suspension authorities also are needed to allow EPA to move more quickly to remove dangerous pesticides from the market and, in turn, reduce the identified risk posed to society. While users and manufacturers of pest control products agree there is a rational argument for some adjustment of the suspension authority, they are highly concerned that EPA too readily would use enhanced suspension authority by always choosing to suspend pesticides over cancelling them.

This concern is founded on the difference in standards between suspension and cancellation EPA must meet before acting under either authority. With cancellation, EPA must follow prescribed notification and rulemaking procedures and provide scientifically valid data to show that a product would cause an “unreasonable adverse effect” on the environment or human health.14 As mentioned earlier, the product would remain available for use while the cancellation proceeding was under way.

Using suspension, which provides for immediate removal of the product from the market, EPA does not need to provide prior notice or any justification other than declaring, in its own judgment, the presence of an imminent hazard before taking action.15 Yet, suspension can cause severe disruptions in production, marketing, and processing of agricultural and food products.

**Re-registration**

Re-registration, the process of expanding and reviewing the relevant health and safety data of pesticides registered before tougher health and environmental standards went into effect, has been a persistent — and largely unresolved — problem surround-
Minor Use Pesticides

Regulation of minor use pesticides is another issue which is an outgrowth of re-registration and will be a key debate topic during FIFRA reform proceedings. By rough definition, this category of pesticides describes products that are registered for uses on certain crops, chiefly fruits, vegetables, and specialty crops, that make up a small or "minor" percentage of the pesticide's total use.

The producers of these crops face severe economic problems if a product is cancelled or suspended from use because, in many cases, they do not have alternative pest control tools to replace the lost pesticides. Their concern, however, is not so much that EPA will suspend or cancel a particular use, but rather that EPA will require expensive tests for continuing a minor use. The cost of these tests, compared with the revenue potential of the product, is leading many manufacturers to conclude that it makes little economic sense to meet EPA's request.

For example, if EPA decides, after a review of the data pertaining to chemical "x," that the registration needs additional detail and further analysis to fill gaps in the EPA's understanding of the chemical's risk to human health, it can require the registrant to conduct certain tests to provide the missing data. Because these tests — which are required even for a chemical with a single use — can cost from several hundred thousand to several million dollars, the company then must decide which uses of the product it will test. If a particular use does not provide sufficient economic return, the company may choose to drop the chemical's registration for that use to minimize research costs.

The bottom-line business decision most companies will be forced to make is to seek re-registration of chemical "x" for major uses — in other words, the uses that will pay the bills — and drop the minor uses. This in turn leaves minor crop producers without a necessary pest control agent. Even worse, it could require a producer, whose crop is hard hit with a major infestation, to use an alternative product that is more dangerous and less efficient.

Specific Legislative Proposals

To address these and many other related issues, various legislative proposals have been introduced in the 103d Congress. With regard to food tolerance levels and general FIFRA reforms, there is H.R. 1627 with over 200 co-sponsors in the House, and its companion bill S. 1478, now sponsored by eleven senators. Both bills are supported by a broad-based coalition of over 230 farmer and commodity groups, food processing industry companies, and food product wholesalers.

H.R. 967 with over 113 co-sponsors in the House, and S. 985, with forty co-sponsors, both address the minor use pesticide issue and are supported by a coalition of grower and commodity groups impacted by the loss of minor use pesticides.

On the other hand, most of the environmental interests have voiced their support for H.R. 872. This legislation also seeks to reform FFDCA's Delaney Clause, but differs from the Food Chain Coalition package in that it does not aim any reforms at FIFRA. While this may seem paradoxical for a package supported by the
environmental community, the actuality is that H.R. 872, and its Senate companion S. 331, propose critical changes to FFDCA that would have a serious negative impact on production agriculture.

First, H.R. 872 and S. 331 would eliminate any consideration of pesticide benefits. We all recognize that pesticides pose risks. But with those risks in mind, it is equally important to weigh those risks against how the use of a particular pesticide will benefit society through the control of other risks, whether to health, the environment, or the economics associated with a healthy diet.

Second, neither bill contains provisions to assure national uniformity in the mechanisms used to set pesticide residue tolerances. Good, validated science at the federal level should preclude the need for states or localities to get involved in additional regulation and enable state and local governments to make wiser use of tax dollars, resources, and personnel.

Third, the bills would establish a “bright line” standard of 1 x 10 to the minus 6 (one in a million) for carcinogen levels, effectively repeating the mistake made twenty-five years ago when the Delaney Clause enacted the bright line standard of “zero” for carcinogens. If ever there was a case for making certain我们 do not repeat the mistakes of the past, it is represented by the example of the Delaney Clause. We need to let scientists and regulatory officials do their job under the guidance of narrative, flexible standards. To put it another way, Congress often errs whenever it decides to include specific numbers in legislative solutions to complex problems. We must prevent a repeat of recent events which led the Ninth Circuit to conclude that current bright line standards give no recourse to the EPA administrator if he or she seeks to make rational policy decisions.

Finally, these bills effectively give FFDCA control over FIFRA. While this may seem to be a petty jurisdictional argument to some, the reality is that the competition between oversight committees with respective jurisdiction over FIFRA and FFDCA (the House Agriculture Committee and the House Energy and Commerce Committee) helps ensure development of a balanced, systematic, and scientifically justified food safety policy and avoids allowing any one particular segment of society to use fear-mongering to establish policy.

**Additional Issues Relevant to the Legislative Process**

Last June, NAS released its long-anticipated report, *Pesticides in the Diets of Infants and Children*. During lengthy hearings before several congressional committees and subcommittees, members of the NAS panel who studied this issue testified that some legislative action could force the regulatory process to adjust the parameters of pesticide registration and tolerance setting. Most of the panel’s recommendations for improving EPA’s understanding of the risks pesticides may pose to children’s diets, however, could be implemented through administrative action.

Of particular interest to farmers and food industry representatives was the NAS panel’s assertions that we do not have a food safety crisis in America, that our food supply is safe, and that we do not need to reinvent the wheel with respect to food safety policies. Their bottom-line recommendation simply is to improve the collection, analysis, and consideration of data pertinent to the diets of children. I anticipate there will be a bipartisan effort to include provisions addressing the NAS recommendations in any package of pesticide reforms.

A final element to consider is the general reform package proposed by the Clinton administration. I am encouraged that the proposal put forth by USDA, EPA, and Food and Drug Administration (FDA) officials recommends replacing the outdated Delaney Clause with a new scientifically based standard for detecting carcinogens in our food supply. I am also encouraged that the Administration avoids codifying science into law and instead suggests the use of a narrative, flexible standard which allows EPA to move forward with improved scientific technology and knowledge to assess accurately the risks and benefits of pesticide use.

With only a general outline available at this time, the Administration’s proposal lacks sufficient detail for critical, decisive analysis and comment. Despite fears that some within the Administration are aiming for the outright elimination of pesticides from producers’ arsenals of pest management tools, most agricultural interests look forward to working with USDA, EPA, and FDA officials to shape these concepts into specific, detailed proposals that will enable Congress to consider carefully the tough issues surrounding food safety policies.

Producers and consumers alike have a major stake in this debate. It must be waged with reason and common sense against a backdrop of sound science, without the emotional rhetoric and special-interest politics that have sidetracked food safety issues too often in the past.

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**Notes**

4. Among other criteria, EPA requires, as part of the tolerance-setting process, that there be a verifiable laboratory test to identify the presence of the pesticide residue in a raw commodity or food product. 21 U.S.C. § 346a(d)(1). With respect to re-importation of food products with pesticide residues, see 21 U.S.C. §§ 321(b), 331(a), 342(a)(2)(B), 346a (1988).
10. Id. at 9.
11. Id. at 12 (emphasis in original) (quoting Bruce N. Ames et al., *Ranking of Possible Carcinogenic Hazards*, 236 *Sci.* 271, 272 (1987) (footnotes omitted)).
14. 7 USC 136d(b) (1988).
26. See *Hearings, House Comm. on Agriculture* 36-52 (citing the findings and recommendations of the NAS report).
27. See *Hearings, House Comm. on Agriculture*.