Moving Away from Pesticide Dependancy ■ The Community Pest Management Evaluation Toolkit ■ Zero Tolerance for Harm vs. The Hazards of Risk Assessment
Zero Tolerance for Harm vs. the Hazards of Risk Assessment

Selected amendments of the Pesticide and Food Safety Laws under the Food Quality Protection Act

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Commentary and Overview

It is not sound public policy to compromise with the health and safety of our ecosystem and the people that inhabit it—especially when there is a safer way. The reason: all is not well. We only need look at the level of contaminants that we put into the environment and the numbers of breast and prostate cancers, neurological and immune system diseases, reproductive problems and other chemically induced diseases.

The new food safety and pesticide law allows the continued introduction of pesticide poisons and contaminants into the environment. These are chemicals that we do not really need to maintain our quality of life and the productivity and profitability of our food production system. The compromises in the Food Quality Protection Act are a creation of politicians and those who promote or accept chemical use, not borne out of an assessment of whether toxic materials are needed in pest management. While many national environmental groups view the legislation as a good deal and indeed helped fashion it, NCAMP, U.S. PIRG, Citizens Clearinghouse for Hazardous Waste, Greenpeace, numerous grassroots groups and others opposed its passage.

The law has serious deficiencies, given what needs to be done to protect health and the environment and for the reasons outlined in the analysis below. The problematic provisions include the repeal of the Delaney Clause and its replacement with an uncertain risk assessment-based approach, the weakening of standards for so-called “minor use,” but widely used, pesticides, the preemption of state authority to set tougher food safety standards and others. The public and decision makers at every level need to understand the deficiencies in the new law and why their involvement in local pesticide policy and programs is needed. It is through local and state action that we can continue to replace unnecessary pesticides with alternative practices that achieve the goal we are all seeking—the safest possible and effective pest management.

At the same time, the law’s language may be used to put in place some improvements. It is here where we must focus our attention on the regulatory process and strive to improve the protection of children, look at the cumulative effects of pesticides, evaluate the combined effects of dietary and nondietary exposure, regulate endocrine disrupting effects, and consider the impact of full formulations of pesticides including inert ingredients.

However, when all is said and done, the new law does not embrace the standard that most parents embrace for their children: zero tolerance for harm. We do not need to poison our children with unnecessary pesticides and the law should reflect this.
An Analysis of Problem Provisions

Repeals the Delaney Clause: The Food Quality Protection Act most notably repeals the Delaney Clause and replaces it with a risk assessment-based approach to regulating cancer causing pesticides in food. In so doing, the Congress defines food in compliance with legal tolerances as “safe.” Residues of these toxic chemicals meet a risk calculation that can be as high as 2 in a million in cases where there would be “disruption to the food supply.” This risk calculation defines the safety standard in the law as a “reasonable certainty of no harm.”

Reduces health and safety requirements for most pesticides:
The law makes it easier to register pesticides defined as “minor use,” which includes all fruit, vegetable, nuts an ornamental crops and even portion of the major crops, such as grain, oats and rice. EPA has said about the minor use provision, “To the extent possible, EPA will waive data requirements or grant tolerance exemptions for minor uses.” The law does this in the face of viable alternative strategies in agriculture and urban pest management that do not require pesticides. Instead, the law adopts a definition of Integrated Pest Management (IPM) that does not establish pesticides as a last resort, but embraces them as integral to pest management.

Allows continued exposure to known hazards as a means of using up existing stocks of chemicals: The law codifies the unchecked EPA practice of allowing existing stocks of pesticides deemed too hazardous to remain on the market to be used up without warning to those exposed, a practice that accompanies EPA’s compromise approach to protecting health and safety.

Takes away state authority to adopt tougher food safety standards: While adopting a risk assessment approach to regulation, with all of its uncertainty and limitations (e.g. it does not consider synergistic effects of pesticides mixing and forming a more potent effect when added together), the legislation preempts states from adopting a more protective standard of safety.

Additional margin of safety for children undermined by risk assessment approach and limited data: The attention to children is weakened by a requirement to set more restrictive children’s standards based on “available” information, even though there is no mandate to collect the data necessary to protect this more sensitive population group.

Voluntary right-to-know programs do not work: The law establishes a voluntary pesticide residue notification program in supermarkets, which could serve to reduce consumer concern about pesticide use and exposure, as is typically the case with EPA statements and literature.

Occupational exposure and synergistic effects of pesticides not considered in risk assessment: Despite a requirement to consider other nondietary sources of exposure when setting food safety standards, these sources are restricted to non-occupational exposure. While aggregate exposure is to be considered if data are available, no requirement is imposed for considering the synergistic effects of pesticide (and pharmaceutical) mixtures.

Justification needed when EPA does not adopt residue level set by the Codex Alimentarius Commission: This creates another level of review for EPA to justify why its standard is different from one adopted by an international commission.

No explicit time frame for phase-in of new requirements in the law: With some exceptions (e.g. 3-year time frame for endocrine effects), the law allows flexibility while EPA develops new, long-term assessment practices. This means, given EPAs track record, that these complex new approaches to regulation may never be fully implemented.

Analysis of Positive Provisions

Focus on children: EPA has said, “When setting new or reassessing existing tolerances or tolerance exemptions under the new standard, EPA must now focus explicitly on exposures and risks to children and infants. EPA must, 1) explicitly determine that the tolerance, or exemption from tolerance, is safe for children; 2) consider the need for an additional safety factor of up to ten-fold to account for uncertainty in the data base relative to children unless there is evidence that a different factor should be used; and 3) consider children’s special sensitivities and often unique exposure patterns to pesticides.” The statute requires EPA to assess the risk of the pesticide chemical residue to children based on “available” information. Goal: Make sure that the information on children is available to EPA in a form that is considered valid by the agency.

Consider dietary and nondietary exposure, as well as varying sensitivities: EPA must consider other non-occupational sources of exposure when performing risk assessments and setting tolerances, including exposure from drinking water, non-occupational exposure, exposure from like pesticides that share a common mechanism of toxicity as well as other exposure scenarios. Included here is consideration of the “variability of the sensitivities of major identifiable subgroups of consumers.” The statute requires EPA to assess the risk of the pesticide chemical residue in this area based on “available” information. Goal:
Make sure that this information is available to EPA in a form that is considered valid by the agency.

Develop a screening program for estrogenic or endocrine system effects: Requires that the screening program be developed within 2 years and implemented within 3. Goal: Keep EPA to the deadlines with full public disclosure along the way.

Residue level can only be set if there is a detection capability: There must be a practical method for detecting and measuring the residue level of the pesticide before setting a tolerance. The tolerance level set must not be set below the level of detection.

Pesticide chemical is defined to include active and inert ingredients: Requires that the tolerance setting process take into account not just the active ingredients, but the inert, metabolites and degradation products, as well. Chemicals found on food, but not as a result of a “pesticidal purpose,” do not have to be considered. The Administrator may “except a substance from the definition of pesticide chemical or residue” if it is determined that it is better regulated under another provision. Goal: Ensure compliance and do not allow this provision to be used as a loophole.

Selected Provisions of the Food Quality Protection Act

TITLE I - Suspension—Applicators
Amends the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Subtitle A - Suspension
Sec. 103. Tolerance Reevaluation As Part of Reregistration
Amends Sec. 4(g)(2). Specific requirement that the Administrator no later than at the time of reregistration reassess the tolerance or acceptable residue of the pesticide in accordance with the standards in the act.

Sec. 104. Scientific Advisory Panel
Amends Sec. 25(d). Creates a Science Review Board to consist of 60 scientists to assist in reviews conducted by the Office of Pesticide Programs' Scientific Advisory Panel.

Sec. 106. Periodic Registration Review
(a) Existing stocks - Amends Sec. 6(a)(1). Existing stocks provision allows the continued sale and use of existing stocks of suspended or canceled pesticides as long as the Administrator determines that such sale or use is not inconsistent with the act.
(b) Registration review - Amends Sec. 3(g). Requires the adoption of regulations which establishes a periodic review of pesticide registrations; indicates that the goal shall be to review every 15 years.

Subtitle B - Training for Maintenance Applicators and Service Technicians
Sec. 121. Minimum Requirements for Training of Maintenance Applicators and Service Technicians
Adds Sec. 2(jj) and (kk). States may establish minimum requirements for training of maintenance applicators and service technicians (both new categories created with exemptions for antimicrobial pesticides, sanitizers or disinfectants), which “may” include instructions for safe and effective handling and use of pesticides in accordance with labeling, and instruction in integrated pest management. EPA is prohibited from establishing minimum standards for training.

Pesticide chemical is defined to include active and inert ingredients: Requires that the tolerance setting process take into account not just the active ingredients, but the inert, metabolites and degradation products, as well. Chemicals found on food, but not as a result of a “pesticidal purpose,” do not have to be considered. The Administrator may “except a substance from the definition of pesticide chemical or residue” if it is determined that it is better regulated under another provision. Goal: Ensure compliance and do not allow this provision to be used as a loophole.

TITLE II - Minor Use Crop Protection, Antimicrobial Pesticide Registration Reform and Public Health Pesticides
Amends the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Subtitle A - Minor Use Crop Protection
Sec. 210. Minor Crop Protection
(a) Definition - Adds Sec. 2(ll). Minor use is defined as the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where 1) the total U.S. acreage for the crop is less than 300,000 acres, as determined by USDA, or 2) the Administrator and Secretary of Agriculture determine, “based on information provided by an applicant for registration or a registrant,” the pesticide product is not sufficiently profitable to support the initial registration or continuing registration and (A) there is insufficient efficacious alternative registered pesticides available
(B) the alternatives to the pesticide use pose greater risks to the environmental and human health
(C) the minor use pesticide plays or will play a significant part in managing pest resistance, or
(D) the minor use pesticide plays or will play a significant part in IPM.

The minor use status continues until such time as the Administrator determines that the use may cause unreasonable adverse effect.

(c) Time extensions for development of minor use data - Amends Sec. 2(c)(2)(B). Under the data call-in and reregistration program, the Administrator may extend the deadlines for manufacturers to produce residue chemistry data until the final submission of data required for reregistration of the other uses of the pesticide. [Note: Since pesticide reregistration can drag out
indefinitely and EPA has a poor track record of meeting legislative deadlines and its own timelines, minor uses, which may not meet basic safety standards, can remain in use for an indeterminate amount of time.

To qualify for this status the following conditions must be met:

(A) the data to support other uses of the pesticide on food are being provided;

(B) the registrant provides a schedule for production of data and interim dates to measure progress;

(C) Administrator determines that such extension will not significantly delay the schedule for issuing a reregistration eligibility determination; and,

(D) Administrator determines, based on existing data, and the extension will not “significantly increase the risk of any unreasonable adverse effect on the environment.”

(d) Minor use waiver—Adds Sec. 3(c)(2)(E). Minor use waiver. “In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirement if the Administrator determines that the absence of such data will prevent the Administrator from determining

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.”

[Note: Without data that would otherwise be provided through the registration or reregistration process, the Administrator may not know enough to make a determination that the lack of data does not represent an unreasonable adverse effect.]

(e) Expediting registration—Amends Sec. 3(c)(3). Requires the Administrator to act expeditiously.

(e)(3) Adequate time for submission of minor use data—Adds 3(c)(3)(C). Minor use registration. If Administrator denies minor use waiver, clock on data submission does not start running until the denial decision is made.

(f) Temporary extension of registration for unsupported minor uses—Adds to Sec. 4(d)(3), 4(f)(3) and 4(e)(3)(A). The language in the act that generally applies to minor use extension is the following:

Administrator issues minor use extensions “unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns.”

“Administrator may deny, modify, or revoke the temporary extension. . . if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment.”

(i) Environmental Protection Agency minor use pro-

gram—Adds new Sec. 31. Environmental Protection Agency Minor Use Program. Establishes a minor use office in the Office of Pesticide Programs, with responsibility for coordinating the development of minor use programs and policies and consulting with growers regarding minor use issues and regulations. EPA must report within 3 years of the progress on minor use registrations and the effectiveness of the incentives.

(j) Department of Agriculture minor use program—

Adds new Sec. 32. Department of Agriculture Minor Use Program.

(a) In General—USDA is responsible for:

(1) carrying out the Inter-Regional Project Number 4 (IR-4) which utilizes public money to conduct testing for pesticide companies that are necessary to register pesticides;

(2) supporting IPM research;

(3) consulting with growers to develop data for minor uses; and,

(4) providing assistance for minor use registrations, tolerances and reregistrations with EPA;

(b)(1) Minor use pesticide data—

(A) Grant Authority—establishes a grant program to support development of data needed for minor use pesticide registrations, with the amount of the grant not to exceed one-half the cost of the project.

(b)(2) Minor use pesticide data revolving fund—

(A) Establishment—Establishes in the Treasury of the U.S. a revolving fund known as the Minor Use Pesticide Data Revolving Fund to carry out the minor use section. Authorizes to be appropriated $10,000,000.

Subtitle B—Antimicrobial Pesticide Registration

Reform

Sec. 221. Definitions.

Amends Sec. 2. Antimicrobial means a pesticide that is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or protection from bacteria, viruses, fungi, protozoa, algae or slime. Excludes (a) wood preservative or antifouling paint product, (b) an agricultural fungicide product, or (c) an aquatic herbicide product.

Sec. 222. Federal and State Data Coordination.

Adds Sec. 3(c)(2)(B)(viii). Administrator shall coordinate data requirements among the states and federal regulatory authorities, including test protocols, timetables, and standards of review and “reduce burdens and redundancy caused to the registrant by multiple requirements.” Within one year, the Administrator shall “identify and assist in alleviating future disparities between federal and state data requirements.”

Sec. 223. Label and Labeling.

Adds Sec. 3(c)(9). Labeling. Product manufacturer may
modify labeling of an antimicrobial pesticide to include relevant information on product efficacy, product composition, container composition or design or other characteristics that do not relate to any pesticidal claim or pesticidal activity. Notice must be made to Administrator who has 30 days to disapprove in writing with explanation. [Note: This is a major shift in the approval process, establishing self-regulation of aspects of the product label unless the Administrator disapproves within a relatively short time period.]

Sec. 225. Disposal of Household, Industrial, or Institutional Antimicrobial Products.
Adds Sec. 19(h)(2). Antimicrobial. Exempts antimicrobial pesticides not subject to the Solid Waste Disposal Act [Note: This includes most antimicrobials] from storage, disposal, transportation, and container design restrictions unless the Administrator finds that such restrictions are needed to prevent an unreasonable adverse effect on the environment.

Subtitle C – Public Health Pesticides
This section establishes a minor use act (with numerous amendments) for nonagricultural pesticides used in urban pest management that tracks the language pertinent to agriculture. Provides financial support for studies. Authorizes to be appropriated $12,000,000 a year. Public health pesticide is defined as “any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms that pose a threat to public health.”

Subtitle D – Expedited Registration of Reduced Risk Pesticides
Sec. 250. Expedited Registration of Pesticides.
Amends Sec. 3(c). Within 1 year, the Administrator shall develop procedures and guidelines for expedited registration for reduced risk pesticides. Any biological or conventional pesticide will be considered for expedited review. Application will qualify if one or more of the following is accomplished: (i) reduce the risks of pesticides to human health; (ii) reduce the risks of pesticides to nontarget organisms; (iii) reduce the potential for contamination of groundwater, surface water, or other valued environmental resources; and, (iv) broaden the adoption of IPM, or make such strategies more available or effective.

TITLE III – Data Collection Activities to Assure the Health of Infants and Children and Other Measures
Amends the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Sec. 301. Data Collection Activities to Assure the Health of Infants and Children.
The Secretary of Agriculture, in consultation with EPA and the Secretary of Health and Human Services, shall collect data on food consumption patterns of infants and children; pesticide residues;

Sec. 302 Collection of Pesticide Use Information.
USDA shall collect pesticide use information.

Sec. 303. Integrated Pest Management.
USDA and EPA shall implement research, demonstration and education programs to support adoption of IPM. Defines IPM as a “sustainable approach to managing pests by combining biological, cultural, physical and chemical tools in a way that minimizes economic, health, and environmental risks.”

Sec. 305. Pesticide Use Information Study.
Within a year, USDA and EPA shall deliver a report to Congress, including:
(i) an analysis of the quality and reliability of information collected by USDA, EPA and other federal agencies regarding the agricultural use of pesticides; and, (ii) an analysis of options to increase the effectiveness of national pesticide use information collection, including an analysis of costs, burdens placed on agricultural producers and other pesticide users, and effectiveness in tracking risk reduction by those options.

TITLE IV – Amendments to the Federal Food, Drug, and Cosmetic Act
Sec. 402. Definitions.
Amends Sec. 201(q) and (s) and adds (gg) and (hh). Defines “pesticide chemical” as any substance that is a pesticide within the meaning of FIFRA including all active and inert ingredients of such pesticide. Administrator is given authority to exempt pesticide residues found on raw or processed food that are not attributable to a pesticidal use in production, storage, processing or transportation of the food commodity. Allows Administrator to exempt from definition any substance that is “more appropriately” regulated under another provision of the Act.

Section 201(s) effectively repeals the Delaney Clause by severing pesticide residues from its definition. This is achieved by redefining “food additive” and “pesticide chemical residue” so that pesticide residues are always covered by Section 408 of the Federal Food, Drug and Cosmetic Act. The effect of these definitions is to make the Delaney Clause no longer applicable to pesticide residues concentrated in processed food.

Sec. 404. Adulterated Food.
Amends Sec. 402(a). Defines as adulterated any food that is defined as unsafe.
Sec 405. Tolerances and Exemptions for Pesticide Chemical Residues.
Amends Sec. 408. Any pesticide chemical residue is unsafe unless it has a tolerance or an exemption from tolerance; residue on processed food is not deemed unsafe despite the lack of a tolerance if the pesticide has been used in or on the raw agricultural commodity in conformity with a tolerance action, such residue has been removed to the extent possible in good manufacturing practices and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the raw commodity. Similarly, if an exemption is in effect for the raw commodity, it follows that the processed food tolerance is not needed.

(a)(3) Residues of degradation products- If the residue is present because it is a degradation product that itself is a pesticide chemical or pesticide chemical residue, such residue shall not be considered unsafe because of a lack of tolerance if:

the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than or of a greater significance than, any risk pose by dietary exposure to the precursor substance.

[Note: Burden is placed on Administrator to make finding rather than registrant to show safety.]

(b)(2)(A) Authority and standard for tolerance - General rule.

(i) Standard. Administrator may establish or leave in effect a tolerance for a pesticide residue if the Administrator determines that the tolerance is safe. [Note: This departs from a long history of not referring to pesticides as safe, defining any residue or outdated tolerance that is left in effect pending review as safe, and then in following sections defines a methodology for determining a legal tolerance as involving levels of risk and nonattainment to unknown hazard factors.]

(ii) Determination of safety- Safety is defined: “[T]here is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposure and all other exposure for which there is reliable information.” [Note: Reasonable certainty of no harm is applied to threshold and nonthreshold effects. In the case of nonthreshold effects, such as cancer effects (the inability to set a specific level at which a pesticide causes an adverse effect), reasonable certainty of no harm is defined as “negligible risk,” which is to be determined by quantitative risk assessment. The Committee Report said the following about the safety standard:

[b](2)(B) Tolerances for eligible pesticide chemical residues- Establishes a category of “eligible pesticide” for which the Administrator is unable to determine a threshold effect level (usually for cancer effects), the point at which the residue will not cause harm to human health.

(iii) Conditions regarding use- Tolerances for eligible pesticides can be set if, either: (i) the pesticide protects consumers from adverse effects that would pose a greater risk than the pesticide residue; or, (ii) the use of the pesticide is “necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) Conditions regarding risk- (I) the yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under the safety standard; and, (II) the tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect [Note: This allows a doubling of the risk]. After five years, the conditions that allow exposure (public health or economic disruption) must be reevaluated. If a change has occurred, the Administrator must issue a regulation to modify or revoke the tolerance.

(b)(2)(C) Exposure of infants and children- In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator: (i) shall assess the risk of the pesticide based on—
(b) Percent of food actually treated— in setting tolerances, the Administrator may consider available data and information on the percent of food actually treated with the pesticide chemical if the Administrator:
(i) finds that the data are reliable;
(ii) finds that exposure estimates do not understimate exposure for any significant subpopulation;
(iii) finds that if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietary exposed to residues above those estimated by the Administrator; and,
(iv) provides for periodic reevaluation of the estimate of anticipated dietary exposure.

(b)(3)(A) Detection methods. General rule— Tolerance cannot be established or modified [Note: A tolerance can be left in effect] unless the Administrator determines that there is a practical method for detecting and measuring the levels of the pesticide residue.

(b)(3)(B) Detection limit— Tolerance cannot be set below the limit of detection.

(b)(4) International standards— If the Administrator does not adopt the international standard set by Codex Alimentarius Commission, the Administrator shall publish for public comment a notice explaining the reasons for departing from Codex levels.

(n) National uniformity of tolerances
Preempts states and local political subdivision from setting more restrictive tolerances on pesticides; creates a petition process for states to seek an exception; state must show “compelling local conditions.”

(o) Consumer right to know— Within two years, the government will publish and distribute to large retail grocers [Note: This is a voluntary program; voluntary posting and notification programs have an historically bad track record], for public display: information on risks and benefits of pesticide residues; a listing of the action taken under subparagraph (B) of (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk about the risk allowed under subparagraph (A); and, recommendations to consumers for reducing dietary exposure to pesticide residues.

(p) Estrogenic substances screening program— Develop a screen for estrogenic pesticides within two years; within three years, shall implement the program.

(q) Schedule for review— 33 percent within three years; 66 percent within six years; 100 percent within ten years.

(q)(3) Publication of schedule— Not later than 12 months after the date of enactment, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to enactment. Failure to take action pursuant to the schedule established shall be subject to judicial review.