THE IMPACT OF THE FOOD QUALITY PROTECTION ACT ON FUTURE PEST MANAGEMENT OPTIONS

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Introduction

The Food Quality Protection Act of 1996 (FQPA) will bring a dramatic change to the regulation of pesticides under the Federal Insecticide Fungicide, Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA). FQPA amended both FIFRA and FFDCA and contains diverse provisions. These provisions range from new standards for setting tolerances on raw and processed food, and incentives for supporting minor uses of pesticides, to a revision of the definition of pesticides for certain medical uses, and explicit procedures for registering antimicrobial pesticides. FQPA went into effect upon signature by the President, so its impact was felt immediately.

The New Safety Standard

FQPA eliminated the application of the Delaney Clause of FFDCA to pesticide residues on processed food. By rewriting Section 408 of the FFDCA to reconcile the so-called "Delaney Paradox", Congress created a new uniform standard for pesticide residues on all food, both raw commodities and processed food. There is no longer a differential cancer risk standard for raw and processed foods, as there was under the Delaney Clause. The new "safe" standard directs EPA to assure that residues on all foods meet the standard of "...a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue...". In describing how this new standard is to be applied, Congress used the contemporary toxicology terms "threshold" and "nonthreshold" to provide flexibility to EPA in judging cancer and other toxicity risks. Thus, as EPA better understands mechanisms leading to cancer causation, it can apply the principal of a threshold toxicity dose as appropriate.

FQPA directs EPA to consider a number of factors in applying this new safety standard. In some cases, these factors represent the leading edge of scientific understanding, such as endocrine disruption. In other cases, Congress was merely clarifying an assumed standard, such as the completeness and validity of available data. In implementing the safety standard of FQPA, EPA developed the conceptual framework of the "risk cup" to describe the lifetime acceptable exposure to a pesticide. EPA's challenge in applying the new standard is to determine how the "risk cup" will be filled for each pesticide.

The centerpiece of the new safety standard is the special consideration given to the exposure of infants and children to pesticide residues in establishing, modifying, leaving in place or

revoking tolerances. These FQPA provisions pertaining to infants and children reflect the recommendations of the 1993 National Academy of Sciences report on the risks of pesticide residues in the diet to infants and children. In the absence of data that show no special health effects on infants and children, EPA is to apply up to an additional 10 fold margin of safety in setting or renewing a tolerance.

Aggregate exposure is another factor that EPA must address in establishing or renewing tolerances. Before FQPA, EPA focused on dietary exposure when setting tolerances. Now EPA must account for nondietary exposures from non-occupational sources, such as household use of a pesticide, and pesticide residues in drinking water.

Accounting for the cumulative exposure to chemicals with a common mechanism of toxicity is perhaps one of the greater challenges posed by the new safety standard. As EPA implements this new standard, they will be entering a new uncharted arena of regulatory toxicology. Establishing common agreement on what constitutes a "common mechanism of toxicity" is the first challenge. Subsequently, identifying the circumstances where multiple exposures will occur will be the next challenge. Finally, accounting for these exposures in risk assessment will be the final challenge.

EPA must now include endocrine effects in its safety determination. Congress recognized that endocrine disruption is a relatively new area of science, and directed EPA to develop a screening program in consultation with the Secretary of Health and Human Services. Congress provided a 3 year grace period for implementation of this requirement.

Approval of new uses of pesticides and new products by EPA has been slowed by the application of the new safety standard. This is an unintended consequence of establishing a more comprehensive safety standard for pesticide tolerances.

Tolerance Reassessment

Perhaps the greatest challenge of FQPA is the requirement that all tolerances and exemptions from tolerance be reassessed under the new safety standard over a 10 year period. There are approximately 9700 tolerances and exemptions that EPA must reassess. FQPA provides a specific timetable for the reassessment, namely 33% in 3 years, 66% in 6 years and 100% in 10 years. FQPA directs EPA to give priority to tolerances or exemptions that pose the greatest health risk. EPA announced late in 1996 that its first priority will be the B2 carcinogens, organophosphates and carbamates.

FQPA restricts the manner in which the benefits of pesticides can be used during tolerance reassessment. This provision is largely focused on pesticides identified as oncogens. Benefits can

only be considered if the use of the pesticide protects consumers from a risk that is greater than the dietary risk of the pesticide, and use of the pesticide is necessary to avoid a significant disruption in domestic production of a wholesome food supply. There are additional conditions placed on assessing the risk of such residues in order to qualify. Finally, any tolerance left in place under this provision must be evaluated after five years to assure that the original conditions for retaining the tolerance still exist.

EPA's use of default assumptions in the absence of data is a key issue in tolerance reassessment. Because the new safety standard has a far broader scope than previous requirements, EPA is attempting to account for exposure factors for which there is little or no data. This use of default assumptions has been a contentious issue from the outset because FQPA references the use of "available information" when accounting for aggregate and cumulative exposure. EPA has assumed the position that in the absence of data, they must be protective in their risk assessment.

The first application of the "cumulative exposure to chemicals with a similar mechanism of toxicity" will likely be the tolerance reassessment of organophosphate (OP) pesticides. EPA has received a recommendation from the independent International Life Sciences Institute that the organophosphates share a common mechanism of toxicity as represented by the inhibition of cholinesterase. The recommendation contains a number of caveats about relative dose for toxicity endpoints and appropriate target organs, and the need for more data. If EPA adopts the recommendation, it will most likely be applied to 39 OP pesticides, and will have a tremendous effect on the availability of OP insecticides. Bensulide is one herbicide that will be affected by this evaluation. It is not clear how EPA may apply this "cumulative exposure" factor to other groups of pesticides like the triazine herbicides. Determinations on the application of "common mechanism of toxicity" are pending.

Tolerance Reassessment and Minor Crops

The reassessment of tolerances will likely have considerable impact on pest management options for minor crops. Despite the provisions of FQPA that provide incentives to registrants to support minor uses, tolerance reassessment may override the benefits of these provisions. Registrants may not experience considerable economic gain for minor uses of their pesticide, but the minor uses may consume a substantial portion of the risk cup for the pesticide as the result of food consumption patterns. Registrants will likely make economic decisions when selecting which uses of a pesticide to retain during the tolerance reassessment process. An example of this issue would be insecticide use on pears. While pears represent a minor tree crop in the U.S., pears' contribution in the diet of infants and children is considerable. If the insecticide's risk cup is "overflowing", the registrant is unlikely to retain the pear use unless that use provides financial benefit compared to other uses

of the insecticide.

Will FQPA Affect Herbicides?

The extent to which FQPA affects herbicides will depend on individual chemicals. The occurrence of herbicide residues in harvested commodities will be one factor. Many herbicides are much less likely than insecticides or fungicides to leave significant residues on commodities at harvest. The propensity to leach into groundwater or move off the application site with runoff water, contributing residues to drinking water, will be another factor. Significant residential exposure may also be a factor for some herbicides that have considerable homeowner/landscaper usage. Whether the cumulative exposure factor will be applied to herbicides is unknown, but the triazine family of herbicides is one group for which "common mechanism of toxicity" may be applied. The contribution of endocrine disruption as a factor for herbicides is similarly unknown, but some herbicides have been tentatively identified as endocrine disruptors.

For a number of older herbicides, EPA had completed its reregistration prior to the passage of FQPA. EPA must now reexamine the tolerances for these herbicides to determine whether they meet the new safety standard.

Conclusion

FQPA's impact on pest management options remains uncertain as EPA learns how to apply the new safety standard in registering new products and reassessing old tolerances. The new standard will affect registrants' interest in retaining minor uses of pesticides or seeking new uses. How the factors that EPA must consider in applying the new standard will affect herbicide registrations is similarly uncertain, and will vary by chemical.