

THE IWG's ROAD MAP

A SCIENCE-BASED, WORKABLE FRAMEWORK FOR IMPLEMENTING THE FQPA

I. INTRODUCTION AND OVERVIEW

When the Food Quality Protection Act (FQPA) was enacted in August of 1996, interested observers knew that it would significantly affect pesticide regulation. Among its major provisions, the law establishes a new “safety” standard for evaluating food-use pesticides—“reasonable certainty of no harm”—to replace the old “risk-benefit” standard. It requires the U.S. Environmental Protection Agency (EPA) to adopt a new process of "aggregate" risk assessment, which combines dietary risk with risk from other sources of exposure, namely drinking water and residential exposure. Further, it requires EPA to consider the combined risks of multiple chemicals that have a common mechanism of toxicity ("cumulative" risk assessment). The law also places a special emphasis on the protection of infants and children.

Farmers, food processors, pesticide producers, and others who sell or use pesticides understood that new principles of regulation would be applied, and their acceptance of them made adoption of the law politically possible. They further understood that if the new safety standard were applied in a reasonable manner, and if reliable data indicated real risks to public health, some pesticide uses might be lost. However, they did not anticipate, nor do they now accept, the adverse consequences to the production of food and natural fiber and the protection of public health that are threatened by the approach EPA has been taking in implementing the FQPA.

On April 8, 1998, in response to concerns about EPA’s implementation of FQPA raised by the agricultural community and their representatives in Congress, Vice President Al Gore directed EPA Administrator Carol Browner and Secretary of Agriculture Dan Glickman to implement the law in accordance with four principles: sound science in protecting public health, transparency, reasonable transition for agriculture, and consultation with the public and other agencies. These principles are similar to and consistent with the position of the Implementation Working Group (IWG)¹ on FQPA implementation and the IWG’s “Guiding Principles” presented at the beginning of this document.

¹ The IWG is a coalition of farm, food, pest management, and manufacturing organizations that have joined together to address and respond to the requirements of the FQPA and how it is being implemented.

The FQPA gives EPA significant discretion to decide on the policies to adopt for implementing the new law. The Agency can choose policies that will make it extremely difficult, or even impossible, to support pesticide tolerances, or it can choose, instead, policies that will allow the agricultural community to obtain and retain needed tolerances with reasonable investments in data, and still achieve health protection objectives. The IWG is gravely concerned that—given EPA’s current approach—the former outcome is likely. This "Road Map" presents the IWG’s views on how EPA can ensure a more balanced and workable implementation of the FQPA—as intended by Congress and by Vice President Gore’s directive. In addition, the IWG believes that its approach will result in a consistent, predictable, and streamlined process that will ultimately save time and Agency resources. Implementing the IWG recommendations will take no more time or effort than would otherwise be needed to put appropriate FQPA policies and procedures in place. Acting on the recommendations in this report will allow the Agency to make reasonable progress in meeting the August, 1999 deadline and to accomplish a rigorous tolerance reassessment program within the mandated ten year period.

The Road Map is organized as follows: section II presents the IWG’s general recommendations; section III discusses Congress’ intent; section IV discusses EPA’s implementation of FQPA to date; section V proposes an approach to aggregate risk assessment and the assessment of cumulative effects of chemicals with a common mechanism of toxicity; and section VI presents other important recommendations excerpted from detailed issue papers on key FQPA topics. Finally, the complete issue papers are in the back of this document.

II. IWG’s RECOMMENDATIONS FOR FQPA IMPLEMENTATION

EPA must change the way it has been implementing the FQPA. The kinds of changes the Agency must make involve both conceptual approaches and concrete choices. They involve both procedural and substantive changes. The IWG’s general recommendations to EPA are:

1. **Use sound science and reliable information, as intended by Congress, in fulfilling the FQPA mandate to protect public health from unacceptable risk of exposure to pesticides.** The FQPA changed the regulatory standard and risk assessment process for granting and revoking tolerances. It did not direct EPA to meet this standard by taking unrealistic approaches to evaluating toxicity or to assessing exposure.

2. **Acknowledge to Congress and the public that sound science requires good data and validated methodologies, which require time to develop.** Most of the unrealistic assumptions EPA has been using to reassess existing tolerances could be replaced by real data. Many studies and surveys are already under way, sponsored by registrants, grower groups, and government agencies; additional studies are needed. EPA should not make final tolerance reassessment decisions before these new data can be taken into account and the Agency has adopted validated methodologies to conduct risk assessments under the new standard.

3. **Do not use unrealistic default assumptions in the tolerance reassessment process.** While conservative default assumptions may be appropriate for screening-level assessments, particularly for new chemicals that typically have limited use patterns initially and for which water monitoring data are not available, they are not appropriate for tolerance revocations of existing products. In the absence of “reliable” information, EPA should give users and registrants the opportunity to develop such data. For non-dietary exposure (which includes all exposures not on “food”), the law expressly requires EPA to use “reliable” information [FFDCA § 408(b)(2)(A)²], a provision that clearly makes the use of default assumptions (or unreliable model estimates) inappropriate.

4. **Determine whether to apply additional uncertainty factors on a chemical-specific, case-by-case basis, considering the weight of all available and reliable scientific evidence.** EPA should exercise the discretion provided in the law. The FQPA does not require the Agency to use an across-the-board additional 10-fold uncertainty factor to provide extra protection for infants and children. When considering whether to retain an additional uncertainty factor, EPA should focus on the completeness and reliability of the data on developmental and reproductive effects, and on whether there is evidence of special sensitivity of infants and children to the pesticide that is not addressed sufficiently by the existing studies and the normal uncertainty factors. (EPA should look at the type and severity of any observed effect, the steepness of the dose-response curve, information on the mechanism of action and on structure-activity relationships, and biological plausibility with respect to humans.) EPA should also consider dropping or

² All sections of law noted in this document refer to the Federal Food, Drug, and Cosmetic Act (FFDCA), unless stated otherwise.

reducing the standard 10-fold interspecies uncertainty factor when well-designed and toxicologically relevant human studies are available.

5. **Use the most relevant toxicity endpoints in the tolerance reassessment process.** The selection of toxic effects or endpoints in regulating pesticides has taken on even greater significance because of the FQPA requirement to consider the combined risk of pesticides having a common mechanism of toxicity. When EPA assesses the risk posed by a pesticide to a specific population subgroup as a result of a particular exposure scenario, EPA should use end points from the available toxicity studies that are most relevant to that scenario in terms of the duration of the study, the route of exposure, and the mode of administration of the substance. EPA also should note the potential for overestimation or underestimation of risk from using end points from less appropriate kinds of studies. Furthermore, EPA should consider the severity, adverseness, and reversibility of the effect in question. For example, in the case of cholinesterase-inhibiting chemicals, the “toxicity” end point most often used to set the no-observed-effect levels is, in fact, an indicator only of exposure, not a toxic effect.

6. **Establish a deliberate, consistent, and transparent decision-making process.** This includes regulatory and risk management policies and procedures, risk assessment-related policies and procedures, data requirements, test guidelines, and data evaluation procedures. Vice President Gore’s memorandum directs the Agency to “ensure” that its approaches to decision making are clearly communicated and explained to the public. This is commendable, but does not go far enough. EPA’s approaches to date have been characterized by inconsistency, unannounced changes in established practices, lack of explanation, and absence of meaningful opportunities for public review and comment. EPA should provide adequate notice and comment opportunities for major policies, procedures, data requirements, and methodologies. The Agency should provide an analysis concerning the potential consequences of alternative approaches. This does not mean that the Agency should stop making decisions while it improves the openness of its process. It does mean that EPA should begin immediately to inform the public about major policies—current and proposed—concerning tolerance review and reassessment and request comment on these policies. Also, for individual chemical reviews, EPA should establish schedules and procedures that give registrants and users full opportunity to bring relevant hazard and exposure information to the Agency’s attention before major decisions concerning such chemicals are made (e.g., changes in the reference dose).

7. **Give higher priority to making sound scientific decisions than to completing final tolerance reassessments by statutory deadlines. Use the authority provided in the law [FFDCA § 408(g)(1)] to make “preliminary” decisions on tolerances and delay effective dates for a reasonable period of time to allow data development.** The FQPA does not require EPA to make decisions so quickly that it cannot give registrants the opportunity to obtain needed data and then base final decisions on what the data show.
8. **Revoke only those tolerances that pose actual unacceptable risks, and take steps to avoid removing uses that pose only a theoretical risk based on worst-case assumptions.** Congress did not intend the FQPA to cause the unnecessary termination of uses and products that have acceptable levels of risk and histories of safe use. Unless EPA changes its approach to implementing the law, this outcome is a virtual certainty. Some other unintended consequences could occur; namely adverse and unfair trade implications for American growers, and adverse health implications (especially for people with low incomes) caused by higher costs of healthful foods.
9. **Do not revoke tolerances unless tolerance reassessments are based on actual use and usage information.** The Agency should work with the U.S. Department of Agriculture (USDA), growers, and others to identify sources of use and usage data, to ensure that such data represent the complexity and variability in pesticide use both within and between cropping and use regions and seasons, and to incorporate this information into exposure assessments. The Agency should have a clear understanding of how and why products are used.
10. **Propose policies and methods for risk allocation and make them available for public review and comment.** The Agency has yet to determine how it will allocate risk among competing uses of an individual chemical or multiple chemicals when the aggregate or cumulative risk is determined to be unacceptable. It will be difficult to decide which uses to keep among competing agricultural needs of a single chemical (or competing agricultural and residential needs), or among different chemicals with a common mechanism of toxicity. For example, what if a chemical has some uses that presumptively pose, at most, a low dietary risk, because the application method (e.g., seed treatment, dormant orchard spray, or soil incorporation of nonsystemic products) inherently results in low or nondetectable residues? Should EPA exempt such uses from the risk assessment as a matter of policy?

How should the Agency treat a chemical that has very low aggregate risk on its own, but falls into a class with other chemicals that collectively produce an unacceptable cumulative risk? Should such chemicals be distinguished from each other? Although EPA leadership has stated that it would like to involve registrants and users in this process, no proposed policies or guidance have been made public. Also, if registrants and growers wish to reach agreement on uses to be retained or dropped, antitrust questions will arise. Has EPA sought guidance from the Department of Justice on how these issues will be addressed and what industry may expect?

11. **Allow adequate time for pesticide users to make a reasonable transition to alternative products and practices when existing product tolerances are revoked.** For many uses few, if any, practical alternatives are currently available. In order to minimize disruption to agricultural production, EPA should work with the USDA to determine appropriate transition periods, and with registrants on relabeling and channel of trade issues.
12. **Redress the current resource imbalance between tolerance reassessment and new chemical/new use registration and accelerate the pace of making decisions on new products and uses. EPA should adopt an incremental risk approach to evaluating Section 18s.** The Agency has been devoting the overwhelming proportion of its pesticide program resources to tolerance reassessment and Section 18s, and has neglected the review and approval of new chemicals and new uses of registered chemicals, including those in the “reduced risk” category. This is a misguided policy that will delay the normal action of market forces to change the mix of pesticides from older products to newer, often safer products. EPA should reconsider its recent rejection of an incremental risk approach to evaluating Section 18 risk that was proposed to the Pesticide Program Dialogue Committee (PPDC), and adopt such an approach.

III. WHAT DID CONGRESS INTEND?

In determining whether EPA is implementing the FQPA in a reasonable way, it is critical to consider the context in which the law was passed. It was passed unanimously by both Houses of Congress *without* meaningful subcommittee, committee, or floor debate on the key new tolerance provisions, but *with* assurances from the Administration that the Agency’s approach to implementation would not be significantly different from existing practice. The

FQPA is the only major environmental legislation in the past 20 years that has been enacted without debate on its final form among the affected constituencies and without controversy, at least superficially.

The “Food Chain Coalition,” whose members include virtually all major organizations of farmers, food processors, food sellers, and pesticide manufacturers, urged prompt passage of the FQPA, and their approval clearly made the Act’s passage politically possible. Congress certainly intended to end application of the Delaney clause to avoid unnecessary losses of important pesticides, and Congress intended to change the regulatory standard, provide added protection for children, and require aggregate risk assessments. But the IWG³ does not believe that Congress intended the kind of wholesale revision of regulatory policy and practice that now threatens to disrupt the production of food and natural fiber.

It is not conceivable that Congress would have set an August 1999 deadline for reassessing one-third of the existing tolerances if it knew that EPA would try to meet that deadline by adopting a series of unrealistic default assumptions, resulting in substantial losses of critical pesticides instead of obtaining and using sound scientific data.

Congress added provisions specifically designed to ease the regulatory burden on minor crop farmers. Thus, Congress did not intend that many of the pesticides those farmers rely most heavily upon would become highly vulnerable candidates for tolerance revocation. Nor is it likely that Congress intended for the new product and new use registration process to bog down to the point that even “reduced risk” applications are taking many months to schedule and two years to review, or for EPA to devote the majority of its product registration resources to reviewing Section 18 applications.

It is apparent that key Congressional framers of the FQPA share the IWG’s concerns about EPA’s implementation of the law as intended by Congress. In a letter of March 10, 1998, to EPA Administrator Carol Browner, Chairman Tom Bliley and Ranking Member John Dingell of the House Commerce Committee questioned whether EPA’s FQPA implementation to date has been consistent with Congress’ intent on important matters such as the use of sound science versus unrealistic default assumptions, the application of the extra safety factor for infants and children, and the transparency and consistency of the decision-making process.

³ IWG membership includes most of the membership of the Food Chain Coalition, plus additional organizations.

IV. EPA's IMPLEMENTATION OF FQPA TO DATE

A. EPA's Missed Opportunities

The IWG believes that EPA's implementation of the FQPA to date has diverged greatly from what Congress intended and the Administration promised. As described in the following examples, the Agency has developed unduly narrow legal interpretations of key provisions of the law and unrealistic technical positions that have combined to result in the current threat to the efficiency and productivity of the agricultural community.

- ?? The Agency could have continued the balanced approach to application of the 10-fold uncertainty factor for assessing risk to children that it took in the first year of implementation. This approach was presented to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in September 1996, and was endorsed by that panel. Late in 1997, however, EPA apparently decided to apply the 10-fold factor in almost every case. The Agency presented a new position to the SAP in March 1998, that is inconsistent with its 1996 position. In its report of May 5, 1998, the SAP strongly urged EPA to clarify its latest position and to resubmit it to the SAP for further evaluation.
- ?? The Agency could have adopted an incremental approach to implementing the requirement to establish tolerances for Section 18s, with virtually no increase in risk, as recommended by a subcommittee of the PPDC. Instead, EPA has rejected that recommendation. Under FQPA, EPA has given Section 18 requests the same full-scale treatment as requests for permanent tolerances, using valuable resources that could have been applied to registration and reregistration projects, delaying decisions on emergency use, and generating great uncertainty among farmers and state officials. The Agency has said that Section 18s will not become a serious resource drain or diversion in 1998. This may be true for actions that are simple "repeats" of 1997 decisions. It is not yet clear what will be the result of new actions, or with repeat actions if the facts in 1998 are not identical to those of 1997.
- ?? The Agency could have developed guidance through a public notice and comment process defining the terms *available* and *reliable* information to mean real data, as the IWG believes Congress intended. Instead, it has not developed any explicit guidance on these critical terms, apparently not even for internal use by EPA staff, and has relied on unrealistic default assumptions in the absence of data. The use of such assumptions almost always produces exaggerated risk estimates,

especially when several conservative assumptions are used in combination.

- ?? The Agency could have used the authority that Congress put in the law to make initial findings on whether a tolerance is “safe” and then required registrants to develop the necessary data to make a final finding. Instead, it has ignored and failed to discuss publicly the provisions of law that give it this authority [FFDCA § 408(g)(1) and 408(f)].

- ?? The Agency could have acknowledged that it would be impossible to base final tolerance reassessments on sound science and reliable data and still meet the August 1999 deadline. Instead, it appears to be concentrating much more on meeting that deadline than on developing appropriate FQPA regulatory policies.

B. Changes in EPA’s Approach to Data

The IWG supports the basic principles underlying the FQPA: a new safety standard; protecting children; and assessing the risk from aggregated exposures to a single chemical as well as from cumulative exposure to multiple chemicals with a common mechanism of toxicity. These are laudable legislative goals and sound principles for regulation. However, they can only work well in practice if good scientific data are available and new risk assessment methodologies are adopted. A critical problem with EPA’s implementation of the FQPA to date is the Agency’s decision to rely on unduly conservative default assumptions and safety factors in the absence of real data. The result is risk assessments that grossly overstate risk and, thus, unnecessarily threaten the availability of important crop protection products and the health benefits that result from an affordable, abundant, and wholesome food supply.

EPA appears to have changed its approach to obtaining and using the data it needs to make good decisions. The FQPA added to the FFDCA a new section, 408(q), that requires EPA to reevaluate tolerances on a schedule. That schedule calls for the first third of the existing tolerances to be reevaluated by August 1999. In order to meet this deadline, EPA is accelerating science reviews of the food-use pesticides that it has categorized as having high risk potential (including all organophosphate and carbamate insecticides and all active ingredients classified as probable human carcinogens) and a number of other compounds on which reregistration reviews were well along when the FQPA was enacted. In the course of reregistration and tolerance reevaluation, EPA has created new data requirements and new toxicity evaluation endpoints,

and is dealing with exposure scenarios it has never before used in tolerance evaluations.

Before the FQPA was enacted, when EPA wanted new data, it first announced the data requirement, then allowed registrants sufficient time to gather the needed information, and only then reached conclusions about what the data showed. But EPA appears to have concluded that it cannot meet the FFDCA § 408(q) deadlines if it waits to perform the reevaluations until guidance is developed, and users and registrants have had sufficient opportunity to gather and submit the necessary information. Instead, EPA has decided that its initial reevaluations will have to rely heavily on a variety of *assumptions* about (a) the toxicity of pesticides; (b) the nature, level, and duration of exposure to pesticides; (c) the effects of aggregate exposure to single pesticides; and (d) exposure to multiple pesticides with common mechanisms of toxicity. These varied assumptions include: the results of mathematical modeling that tries to predict human drinking water exposure; the use of a few worst-case surface water findings (e.g., storm runoff) to characterize distribution nationwide; estimates regarding the extent of pesticide use nationally; a wide range of assumptions about residential exposure; and additional safety factors based on the premise that if newly required studies were performed they might indicate high risks. A common feature of these assumptions is that they are highly “conservative” or “risk averse.” Moreover, assumptions are being created (and modified) on an ad hoc basis during the course of data reviews and risk assessments, so that it is impossible for users and registrants to know in advance what data to gather or the probable results of EPA’s reviews.

Most of these assumptions are not required by law. In most cases, the law simply requires the Agency to “consider . . . available information” on various kinds of exposure and toxicity factors. EPA is treating worst-case assumptions as “available information,” presumably out of a perceived need to be extremely risk averse in order to satisfy the FQPA’s safety standard, and in spite of Congress’ clear intent for tolerance decisions to be made on the basis of “reliable information.”

With rare exceptions, the kind of detailed information on exposure that is now necessary to make the FQPA work well has not previously been required for assessing pesticide risks, and thus is not yet available. These newly important types of information include, for example, data on detailed actual use and usage (as contrasted with label information), market basket residues in food, drinking water monitoring, and precisely measured levels of exposure in and around residences. In the absence of real data, reliance on unduly conservative safety factors and default assumptions threatens to cause the revocation of tolerances

for uses that almost certainly will be shown to be safe when the data become available.

In the case of “aggregate exposure” and “common mechanism of toxicity,” the law has introduced concepts never used before by EPA or any other agency in a regulatory process. There is no scientific consensus on how they should be used. Development of a broad scientific consensus on how to apply the concepts of aggregate exposure and common mechanism will take a significant amount of effort. The process requires careful thought, intellectual give and take, and open discussion.

The Agency has attempted to generate consensus by asking the International Life Sciences Institute (ILSI) to conduct workshops on these and related issues, bringing together scientists from government, academia, and industry. This is a commendable approach. So far, however, the early results of these workshops have confirmed the view that the issues are extremely difficult and not susceptible to easy resolution.

Unfortunately, EPA appears to have made a preliminary conclusion, based on what we believe is a misinterpretation of the report of the 1997 ILSI workshop on organophosphates, that all such compounds must be regulated as a group, since they all inhibit cholinesterase. The IWG believes that this is an oversimplification of the workshop results. See both written and oral comments to the SAP meeting in March 1998. Further, in its May 8, 1998 report, the SAP concluded that EPA has not yet developed a “workable strategy” for “determining whether or not a group of pesticides act with a common mechanism of toxicity.” The Agency should acknowledge that there is no consensus methodology for assessing the cumulative risks of organophosphates. Until EPA develops a methodology and subjects it to peer and public review, the Agency should continue to regulate individual pesticides on an individual basis.

The law does provide a mechanism for obtaining sound scientific data, and including these data in the evaluations of whether products pose unacceptable risk and, thus, must be taken off the market. FFDCCA § 408(f) expands EPA’s authority to issue data call-ins, rules, and orders when necessary to obtain data to “support the continuation of a tolerance or exemption,” and section 408(g)(1) provides authority to postpone the effective date of a tolerance regulation at the Administrator’s discretion. Most of the unduly conservative safety factors and assumptions EPA is using now to reassess existing tolerances could be replaced by reliable data. Even without EPA mandates, many studies and surveys are already underway, sponsored by registrants, grower groups, and federal and state government agencies. However, EPA has declined, so far, to

take advantage of its authority under the law to require additional data, and apparently plans to make the first round of tolerance reassessment decisions before these new data can be taken into account.

C. EPA's Current Approach

Although the recommendations in this report apply to all classes of compounds, this section highlights organophosphates since EPA appears to be giving special attention to these pesticides.

Until Vice President Gore's memorandum of April 8, 1998, it was apparent to the IWG that EPA was planning to issue a large number of tolerance reassessment decisions in 1998 and 1999, and that these reassessments could result in the revocation of a very large number of tolerances for organophosphate insecticides. The evidence for this was abundant. Agency leaders had openly said so in many formal and informal settings. Furthermore, a February 5, 1998, internal staff "briefing document" indicated that EPA was giving serious consideration to the radical approach of proposing in mid-1998 to revoke all the tolerances for all the insecticides in this category, and then take final revocation action against all of them in mid-1999, unless registrants would voluntarily give up enough uses so that the risk (calculated using worst-case assumptions) would be low enough for EPA to conclude that it was acceptable.

EPA has recently disavowed the "revoke all tolerances" approach and, in fact, has stated that it does not plan to take any action that would result in termination of significant uses in 1998. Furthermore, in response to Vice President Gore's memorandum of April 8, 1998, EPA Administrator Browner and Agriculture Secretary Glickman have pledged to guide FQPA implementation by:

applying sound science to all decisions; making our regulatory process transparent; providing appropriate reasonable transition mechanisms that will reduce risk but not jeopardize our nation's agriculture and its farm communities; and consulting with interested constituencies . . .

EPA and USDA have initiated the public consultation provision of their pledge by establishing a new, broad-based Tolerance Reassessment Advisory Committee (TRAC). They have committed to seeking this committee's advice on a variety of critical FQPA implementation issues, including the appropriate decision-making process, the adequacy of scientific information and the use of

default assumptions, the pace of decision making on new pesticides and new uses of existing pesticides, the most appropriate strategies for balancing risk reduction and retaining important pesticides, and priorities for consideration of organophosphates.

The list of issues outlined in the EPA/USDA response to Vice President Gore implies that EPA has not yet developed proposed policies on these critical matters. If that is a mistaken implication—and EPA does indeed have preliminary positions—the Agency should offer its initial proposals for consideration by the TRAC, and refined proposals should then be subjected to public notice and comment. This Road Map contains the IWG’s position on the important FQPA implementation issues. IWG members will bring these positions to the attention of EPA and USDA in various ways, including the TRAC meetings.

Although the IWG has high hopes that the TRAC will result in a more science-based, workable implementation of the FQPA, we remain concerned about EPA’s position on the important issue of the use of available and reliable data. EPA leaders have continued to maintain that they have “all the data they need” to reassess these tolerances, that their files are “data rich,” and that they use “scientifically reviewed models,” not unrealistic assumptions. Unfortunately, for many critical components of tolerance reassessment, real data simply are not available. The IWG can only conclude, therefore, that EPA intends to meet the statutory requirements of “available” and “reliable” information by the use of worst-case assumptions to make a case that the risk is too high. The further implication is that EPA does not intend to allow registrants, farmers, food processors, and others sufficient time to provide additional data that could demonstrate that the Agency’s worst-case predictions are gross overstatements of risk.

If EPA continues to use this approach, it will inevitably lead to the revocation of large numbers of tolerances for many pesticides and uses. It is instructive that the Agency’s recent commitment to avoid significant use cancellations was limited to the 1998 growing season. Any approach that involves large-scale tolerance revocations will have a number of potential negative consequences. For example, it will pit grower groups, food processors, and pesticide manufacturers against one another in a desperate scramble as pesticide companies seek to retain profitable, large-acreage uses, and growers and processors of minor-use food crops, as well as proponents of non-food uses of these products, seek to preserve the uses most important to them. If a large number of tolerances are revoked in 1999, it may result in extremely costly disruptions of fruit and vegetable production and major problems with pest outbreaks in field crops.

In addition to these obvious impacts of a large-scale revocation strategy, a number of other serious negative consequences, as described below, would result.

- ?? Many of the insecticides that are targets for tolerance revocation are critical components of integrated pest management and resistance management programs. Such products are not normally used prophylactically, but are used when necessary in response to serious cyclical pest infestations and when field scouting shows that economic thresholds have been exceeded. Removing them from the market would hamper growers' capability to control pests in the most economic and biorational manner, and could even result in the use of alternative pesticides more frequently and at higher volumes. Because of the comparatively broad spectrum efficacy of products being considered for tolerance revocation, for many crops or regions it may be impossible to "replace" current pest control capability with alternative products, and certainly not in a cost-effective manner. The many "ultra" minor crops, for which only one or two pesticides may be registered, would be extremely vulnerable.

- ?? Many of the insecticides that are targets for tolerance revocation also are critical to public health uses, such as mosquito control programs. Even if EPA were to exempt these uses from cancellation, in many cases manufacturers could not economically produce only the small volumes required by these uses.

- ?? There are similar implications for the availability of pesticides for use in termite, ant, and roach control programs, and for other home and garden uses. Product sales for these uses also are small in relation to agricultural uses and—even though they are often a higher value per unit of volume—may not be able to cover costs of production.

- ?? There would be potentially serious impacts on foreign trade. Presumably, many of the revoked tolerances would be for pesticides used on imported food products. These commodities would become illegal to import, aggravating economic relations between the United States and exporting countries and potentially raising General Agreement on Tariff and Trade (GATT) and North American Free Trade Agreement (NAFTA) "trade irritant" issues. In cases where residues on imported crops are not detectable, foreign growers could gain an advantage if they were willing to use the pesticide and gamble that the residues would avoid detection. Similarly, keeping import

tolerances in effect for uses canceled in the United States would seriously disadvantage American farmers.

EPA's current approach would also have major impacts on the development of new products. The unpredictable nature of EPA's decisions on risk assessment policy will make it extremely difficult for manufacturers to predict how EPA is likely to evaluate new chemicals. This will have a negative influence on the willingness of companies to continue the new chemical development process, which requires long lead times and investment of tens of millions of dollars. If manufacturers can no longer reasonably predict how and when EPA will evaluate new chemicals, they are likely to be reluctant to invest as readily in new products. The result not only could be bad for the future of safe and effective pest control, but also could threaten the economic viability of some manufacturers, with consequent impacts on the jobs of chemical workers and on agricultural production in the United States.

As this document goes to print in mid-June 1998, it is unclear whether EPA will moderate its approach to tolerance reassessment in a way that will avoid the negative consequences outlined above. To do so, the Agency must follow through on both the letter and spirit of its response to Vice President Gore's directive of April 8. It is clear to the IWG that this will require the Agency to make fundamental changes in its implementation of the FQPA.

V. THE IWG'S PROPOSED APPROACH FOR AGGREGATE RISK ASSESSMENT

The IWG recognizes that no situation is "typical" when it comes to assessing the risk of pesticide chemicals. However, in order to give substance to the recommendations outlined in this document, the IWG believes it would be helpful to demonstrate how EPA could approach tolerance reassessment under FQPA consistent with those recommendations. A critical component of this approach is recognition of the FQPA requirement that the non-dietary exposure components of an *aggregate exposure assessment* must be based on "reliable information." As a general rule, this means that EPA cannot make an adverse tolerance reassessment decision on the basis of information that is unreliable for human exposure assessment purposes (whether or not it is useful for other purposes), such as the following:

- ?? Unrealistic default assumptions (such as many of the assumptions in the residential exposure Standard Operating Procedures);

- ?? Results from models that have not been validated or shown to reliably predict residue levels relevant to human exposure, including, but not limited to, models:
 - ?? That are unreliable predictors of human drinking water contamination levels, or
 - ?? That were developed for other purposes (e.g., to “screen” pesticides to determine whether they may pose a problem for fish and aquatic organisms in water near treated fields), and have not been validated for human exposure;
- ?? Water monitoring data that are not representative of water that is used for human consumption (drinking water);
- ?? Monitoring results from testing that was not conducted with good quality control; or
- ?? Monitoring or modeling values that have been selectively chosen to yield unrealistically high values.

Instead of trying to use unreliable information to conduct a hypothetical aggregate exposure assessment, EPA should set out to gather reliable information and, once that information is obtained, use it in an aggregate exposure assessment. Of course, if a conservative screen or set of assumptions shows that there will be *no* significant exposure to a pesticide by a particular route (e.g., by drinking water or through residential exposure), EPA does have the discretion to make a favorable tolerance reassessment decision without requiring additional data.

For the purpose of this example, let us assume that a food use chemical has no residential uses (if the product had residential uses, additional steps would be added similar to those outlined below for drinking water exposure). The chemical has a modern standard, dietary residue database available. Here is how the aggregate exposure assessment for this chemical would work:

1. The Agency would conduct a dietary (food) exposure assessment based on existing dietary data (using reasonable assumptions for use and usage, anticipated residues, treatment of non-detects, food consumption, etc.).
2. At the same time, EPA would put the chemical through appropriately conservative drinking water screens/default assumptions.

- a. If the chemical "passed" a Tier 1 screen (i.e., the results showed that any drinking water risk was negligible and the resulting aggregate exposure would be acceptable), EPA would conclude that the pesticide does not pose a drinking water concern and would not further consider water exposure in the risk assessment.
 - b. If the chemical did not "pass" the Tier 1 screen, EPA would determine whether there was sufficient reliable information to conduct a full drinking water exposure assessment at the time.
3. If there is sufficient reliable information on drinking water exposure, EPA would conduct a drinking water exposure assessment, combine the dietary and drinking water exposure assessments into an aggregate exposure assessment, and proceed to Step 5 below.
4. If there is not sufficient reliable information, EPA would make an interim tolerance reassessment decision based only on dietary information, and proceed to Step 5 below. EPA would also take action to obtain reliable information on drinking water exposure, including, for example, using its data call-in authority to require registrants to submit such information.
5. If the aggregate risk *is* acceptable, EPA would make a favorable tolerance reassessment decision. If the aggregate risk *is not* acceptable, EPA would take appropriate steps to reduce the risk to acceptable levels, such as:
 - a. allowing the registrant, in consultation with growers, to make label changes, take other steps to mitigate exposure, and/or drop uses, and collect data to show the effectiveness of such mitigation measures;
 - b. revoking selected tolerances and delaying the effective dates of the tolerance revocations, if necessary, to provide sufficient time for a workable transition to other products; and/or
 - c. revoking selected tolerances, but delaying effective dates to give registrants and users an opportunity, and sufficient time, to develop additional information (this would be appropriate when analyses, including extrapolation from prior experience with other pesticides, indicate that additional information, such as market basket residue surveys and/or more precise use and usage information, would be likely to demonstrate acceptable risk).

- d. After receiving any additional information provided for in Step 5c, EPA would reassess aggregate risk. If the risk is acceptable, the Agency would lift the tolerance revocations. If the risk is unacceptable, it would allow the tolerance revocations to become effective.
6. If, under Step 4 above, EPA received sufficient reliable information showing that there is human drinking water exposure, EPA would combine the dietary and drinking water exposure assessments into an aggregate exposure assessment, and proceed as in Step 5. In most instances, it will not be necessary to delay the effective dates of tolerance revocations to develop additional dietary exposure information, because registrants and users could obtain such information during the time reliable information on drinking water exposure is being developed. In certain circumstances (e.g., reliable information on drinking water is developed in a very short period of time), EPA should delay the effective dates of tolerance revocations to permit development of additional information on dietary exposure, when such additional data are likely to demonstrate acceptable risk.

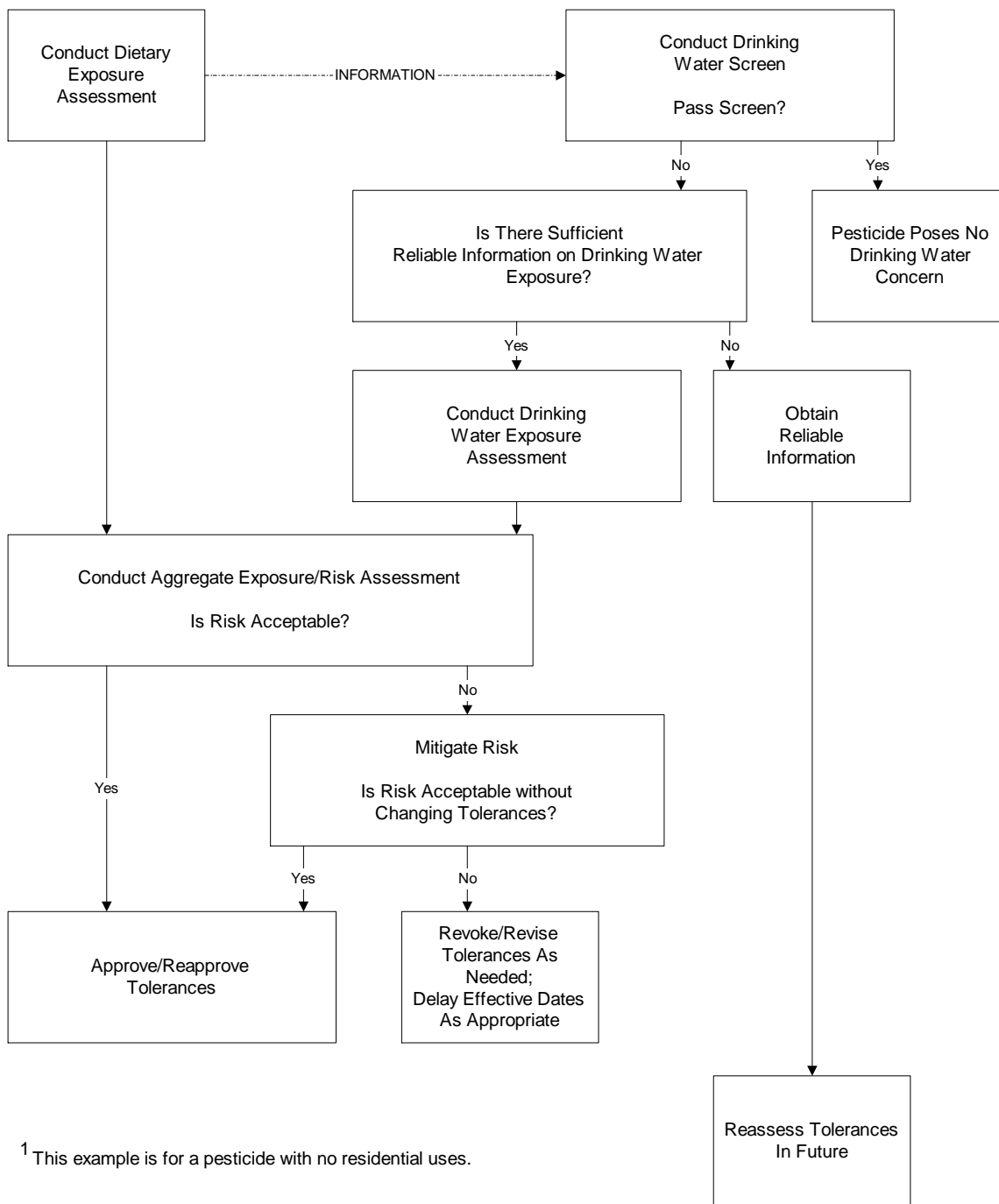
Throughout the process described above, EPA would give registrants and users reasonable opportunities to participate in the development of exposure and risk assessments and of risk reduction alternatives.

See Figure 1 for a schematic representation of the steps outlined above.

The above process would cover the aggregation of risk for a single chemical. For *multiple chemicals* that may have a *common mechanism of toxicity*, EPA must first resolve the scientific and policy issues concerning the possible cumulative risk from multiple chemicals that may be in the same general class, but that have significantly different characteristics (e.g., toxicity end points, reference doses, routes of exposure, time between dosing and maximum effect, duration of effect, reversibility of effect, pharmacokinetics, and other related factors), before regulating them under the FQPA's cumulative effects provision. Furthermore, any assessment of multiple chemical risk must be based on accurate and realistic data on use and concurrent exposures, not simply on label uses. Once EPA has developed the policies and received the data needed to conduct a valid aggregate assessment of multiple chemical risks, the Agency should follow a modification of the process recommended above for single chemicals.

FIGURE 1

PROPOSED APPROACH TO AN AGGREGATE ASSESSMENT ¹



¹ This example is for a pesticide with no residential uses.

VI. ADDITIONAL SPECIFIC RECOMMENDATIONS

Issue Paper I - The FQPA Additional Uncertainty Factor

- ?? The magnitude of an uncertainty factor should accurately reflect a sound scientific judgment that is based on a case-by-case evaluation and weighing of the evidence for or against the possibility of additional susceptibility of infants or children that is not already addressed by the available toxicological studies and covered by the basic uncertainty factors. Factors that should be taken into account include, but are not limited to, the type and severity of any effect observed in developmental and reproductive studies, the steepness of the dose-response curve, information based on mechanism of action and structure-activity relationships, relevant data from other studies such as chronic feeding studies, and biological plausibility with regard to relevance to humans.
- ?? It is not necessary to use an across-the-board additional 10-fold uncertainty factor to assure safety for infants and children.
- ?? In the case of a pesticide with a complete and reliable data base (one that contains all the studies required by 40 CFR Part 158) showing no evidence of increased susceptibility to developmental and reproductive effects, there is no justification for using an additional uncertainty factor over and above the usual 100-fold uncertainty factor that is currently applied to the no-observed-adverse-effect levels (NOAELs) derived from animal studies.
- ?? If the existing database of required studies is incomplete or unreliable or if existing studies raise concerns about developmental or reproductive effects that might be relevant to humans and have not been adequately assessed, an additional uncertainty factor of up to 10-fold might be applied.
- ?? An additional uncertainty factor should only be applied to an endpoint that is relevant to protection of fetuses, infants, and/or children.
- ?? No additional uncertainty factor should be imposed merely because EPA has recently added a new kind of study to the list of requirements that apply to a particular category of pesticides (e.g., developmental neurotoxicity) or required a registrant to replace a previously accepted study (e.g., to respond to revised guidelines).

Issue Paper II - Choice and Use of Endpoints in Risk Assessments of Cholinesterase Inhibitors

- ?? For any given exposure scenario, EPA should use endpoints from the available toxicity studies that are most relevant to that scenario being reviewed, in terms of the duration of the study, route of exposure, and mode of administration of the substance, and should note the potential for overestimation or underestimation of risk from using endpoints from less appropriate kinds of studies.

- ?? A cumulative risk analysis of a group of chemicals should deal only with the toxic effects that all the chemicals in the group have in common. EPA should not normalize different chemicals on the basis of their overall reference doses (RfDs).

- ?? If EPA decides to use a measure of exposure such as blood cholinesterase (ChE) inhibition as an endpoint for regulation in lieu of a higher adverse-effect endpoint, EPA should:
 - ?? Acknowledge that inhibition of blood ChE is not adverse in itself;

 - ?? Acknowledge that use of such a measure of exposure as an endpoint has the effect of adding a safety factor; and

 - ?? Consider the built-in safety factor when deciding whether any additional safety factor is needed to protect the health of infants or children, and what the overall safety factor should be.

- ?? EPA should not use the threat of regulating on the basis of blood ChE inhibition endpoints as a way of putting pressure on registrants to develop and submit data on other endpoints. For example, if EPA wants data on ChE inhibition in peripheral tissues, EPA should announce what testing is required and allow registrants a reasonable period to perform the studies. More generally, EPA should propose for notice and comment any new kinds of toxicity testing that it thinks are needed for sound evaluation of categories of compounds (e.g., those that are found to inhibit blood ChE).

Issue Paper III - Dietary Exposure

- ?? In reassessing existing tolerances, if additional exposure information is needed to better characterize exposure or to support a tolerance in view of recent reinterpretations of data or new FQPA requirements, EPA should inform registrants of the kinds of information that are needed and allow registrants an opportunity to generate the data before modifying the tolerances, unless EPA is aware of scientifically valid data showing that the use of the pesticide under the existing tolerances would pose a significant dietary risk during the period needed to gather the new data and explains why no action against such risk was taken earlier.
- ?? If specific data are known to be required, EPA should, in conformance with FFDCA § 408(f) and FIFRA § 3(c)(2)(B), issue a data call-in. If necessary, EPA should use its FFDCA § 408(g)(1) authority to allow the tolerances in question to remain in effect while the data are being developed.
- ?? For samples in either field residue trial data or monitoring data, with residues below the limit of quantification (LOQ), EPA should not presume that the residue is present at the LOQ. One-half of the LOQ would be a reasonable general default for most samples known or presumed to have been treated, and registrants should be allowed to develop evidence and arguments supporting another value or range of values. For certain uses such as dormant orchard treatments, some seed treatments, and some soil treatments, it would be reasonable to expect no residues in crops and to treat less-than-LOQ samples as having no residues at all.
- ?? If there is no indication that the dietary residues of a pesticide cause adverse effects in humans, EPA—in reassessing the tolerances for that pesticide—should, as a policy matter, avoid taking adverse regulatory action that is based to any extent on risk associated with residues that are so low they cannot be measured by reasonably sensitive analytical methods.
- ?? EPA should adopt a clear, well-explained, and sensible approach to dealing with outlier values in both consumption surveys and residue sets that is consistent with the approach set forth in the February 1998 presentation to the SAP and take whatever other steps are needed to avoid the domination of assessments by unreliable individual values.

- ?? EPA should revise its system for calculating risk to eliminate the compounding of unlikely events. Until EPA develops or obtains validated methods that better reflect actual exposure values, rather than very improbable values, and makes other adjustments to account for overestimation of exposure and toxicity, what EPA calls the 99.9th percentile exposure level is well beyond that level and is an unsuitable basis for regulatory action.

Issue Paper IV - Drinking Water Exposure

- ?? EPA should state publicly that it construes the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408 as saying that drinking water exposure is not part of dietary exposure, but instead is “other exposure” to be included in aggregate exposure if EPA has reliable information about such drinking water exposure.
- ?? EPA should abandon the idea that GENEEC, PRZM/EXAMS, or SCI-GROW screening models can be the basis for regulatory action. Specifically, EPA should acknowledge that the FQPA neither requires nor allows EPA to assess drinking water exposure, or risk, using unreliable information derived from irrelevant worst-case methods. EPA’s duty is to consider the “reliable” information that is available; it cannot rely on unreliable information to take action against a tolerance.
- ?? EPA should abandon the practice of combining worst-case exposure values for food and water in assessing risks from aggregate exposure.
- ?? EPA should abandon the misleading use of the term “drinking water level of concern” and adopt a more neutral terminology for the value, such as “screening value for drinking water,” that more accurately reflects the nature of the initial tier and does not suggest that exceeding the screening value indicates a risk.
- ?? EPA should revise its approach to be more consistent with the reasonable approach the Agency has long taken under the Safe Drinking Water (SDWA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
- First, EPA should consider what is known about a pesticide’s toxicity as well as the likelihood it will be found in drinking water before requiring quantitative analyses of risk. EPA should make maximum use of existing monitoring data, environmental fate data, and use-pattern information to reach sensible interim conclusions about potential exposures and the need for more refined exposure assessments. For instance, if a product’s acute

toxicity is very low, EPA should not require an acute drinking water exposure analysis. If a product binds tightly to soil, or is not persistent in the environment, EPA should not require a drinking water exposure analysis, and should presume that the pesticide will not be found in drinking water at levels warranting any regulatory concern, unless existing monitoring data show otherwise.

- Second, if EPA’s Office of Water has not found reason to issue or propose a primary drinking water regulation for a particular pesticide under the SDWA, and if the Office of Pesticide Programs (OPP) has not regulated the pesticide under FIFRA in order to protect drinking water, it would be reasonable for OPP to presume that there is no urgent problem with residues of this pesticide in drinking water. In this case, OPP should give this presumption appropriate weight in setting priorities for data-gathering and in deciding on the scope of monitoring requirements. This presumption should also be a major consideration in resolving issues about whether or not it is necessary to include drinking water exposure in assessments required by the FQPA.

?? EPA should take steps to improve its water exposure assessment capabilities.

?? As a Tier 1 screen, EPA should replace GENEEC with a regression model that links the mobility potential of a pesticide to actual watershed monitoring data on registered products. A Tier 1 screen should discriminate usefully between pesticides that may produce significant human exposure via drinking water and those that clearly will not.

?? EPA should work with stakeholders to develop needed screening, modeling, and monitoring approaches that allow the Agency to focus on those pesticides that may pose actual problems. OPP staff should concentrate less on performing some sort of FQPA drinking water assessment for each pesticide and more on developing better screening techniques and better ways to gather reliable information on those pesticides for which it is most needed.

?? EPA should work with the United States Department of Agriculture (USDA) and the United States Geological Survey (USGS) to conduct surveys of actual drinking water consumption to establish a population baseline on drinking water exposures to pesticides.

Issue Paper V - Residential Exposure

- ?? EPA should acknowledge the statutory requirement that before residential exposure is included in an aggregate assessment there must be reliable information to characterize the exposure, and should provide guidance for applying that principle.
- ?? EPA should use notice-and-comment procedures to formulate and issue guidance on how it expects to use reliable residential exposure data in the conduct of aggregate exposure assessments.
- ?? With the possible exception of the estimates that rely on applicator exposure data from the Pesticide Handlers Exposure Database (PHED), the Agency should use the exposure estimates obtained from the current draft *Residential Exposure SOPs* only as a screen to determine whether more data and/or higher-tier exposure assessments are needed. The Agency should not assert that the post-application estimates or non-PHED applicator estimates are “reliable information” suitable for use in aggregate risk assessments, or otherwise are sufficient to show that a pesticide use causes a certain actual amount of exposure or poses a certain level of risk that warrants action against a registration, registration application, or tolerance. It may be possible to refine some of the post-application models in the *Residential Exposure SOPs* enough to allow the estimates they produce to be used as reasonable worst-case exposure estimates, but it is unlikely that they can yield information about the likely *distributions* of exposure that the Agency will need to properly characterize residential exposure for FQPA purposes.
- ?? The *Residential Exposure SOPs* should be revised to make the screening estimates meaningful for purposes of identifying needs for further data or higher-tier assessments. EPA should revise the *Residential Exposure SOPs* to replace “best judgment” assumptions with available data whenever possible. The document’s post-application exposure estimates now rely heavily on “best judgment” assumptions, rather than currently available data.
- ?? EPA should issue improved guidance on how higher-tier residential exposure assessments are to be conducted and what kinds of data would be useful in such assessments.
- ?? EPA should follow the *HED SOP 97.2* guidance that the aggregation of different residential use patterns must be based on scenarios that have a reasonable probability of occurring, and should provide guidance for applying that principle in a variety of scenarios.

?? EPA should address distributional analysis of aggregate exposure in revised SOPs on aggregating exposure and risk.

Issue Paper VI - Aggregate Exposure

?? Issue a rule construing the statute to preclude both (a) including exposure from a non-dietary route in its aggregate exposure assessments if it lacks reliable information on the exposure from that route, or (b) using the lack of such information as a basis for an additional safety factor.

?? Announce that, to the extent it might be required to consider non-dietary exposure for which reliable information is lacking, it will use its FFDCA § 408(g)(1) authority to delay implementation of the effective dates of any tolerance revocation rules that might result from such consideration, while reliable data are developed.

?? Continue to make short-term estimates of non-dietary exposure to make decisions about which pesticides clearly present no problems and which ones require further data generation. In particular, EPA should:

?? Develop better, more realistic first-tier screens for residential exposure and drinking water exposure. In this area, making fewer extreme assumptions, putting more focus on real-world situations, and placing less emphasis on compounding various worst-case inputs will be very helpful.

?? Commit to use existing information (such as water monitoring information, residential testing measurements, and toxicity and fate information), even if it is not representative of all situations or has deficiencies, to help make exposure estimates for near-term use.

?? Announce that, while it lacks reliable exposure information about the actual amount of drinking water or residential exposure on a number of pesticides, it has enough information to know that when better data become available the data almost certainly will show that actual exposure is much lower than the existing screening models predict.

?? Give registrants guidance on how to generate reliable information based on modeling, monitoring, and testing. EPA should work with registrants and the user community to develop and agree upon better methods, and to develop reliable information and data, so that sound, long-term assessments of aggregate exposure can be made.

- ?? Move to the use of probabilistic modeling to better characterize the distribution of exposure from non-dietary as well as dietary routes and to prevent the overly conservative assessments that result when a series of individually conservative values are combined.
- ?? Publish its aggregate assessment policies as proposed rules, with explanations of the approaches selected and identification of issues, give interested parties an adequate opportunity to provide comments, and issue final rules that discuss major comments and explain why they were or were not adopted by the Agency.

Issue Paper VII - Common Mechanism and Cumulative Effects

- ?? Allocate necessary resources and allow the time needed to develop appropriate criteria for identifying pesticides with a common mechanism of toxicity and appropriate exposure and risk assessment methodologies;
- ?? Implement a fair and open risk assessment process that includes notice and comment opportunities concerning the procedures to be followed, as well as the specific decisions that are made as a result of using those procedures;
- ?? Allow the time needed to develop data and information to refine FQPA risk assessments; and
- ?? Take the steps needed to ensure the development and implementation of an equitable and balanced process to make FQPA regulatory decisions regarding groups of chemicals as well as decisions on individual pesticides that flow from grouping decisions.

Issue Paper VIII - FQPA Legal Issues

- ?? Aggregate exposure assessments may include only those non-dietary routes of exposure for which there is reliable information.
- ?? Use of an additional safety factor for protection of infants and children is required only when necessary toxicological information is missing or when existing information shows there is unaddressed uncertainty about potential pre- or post-natal toxicity.
- ?? Congress intended that EPA rely upon anticipated residue levels.
- ?? Congress intended that information regarding the percent of the food actually treated be utilized in EPA risk assessments.

- ?? EPA is expected to continuously review tolerance decisions as new data become available.
- ?? The Administrator is authorized to delay the effective date of tolerance revocation or modification rules.
- ?? The Agency must engage in notice and comment rulemaking in establishing its policies applicable to tolerance setting determinations.