

**Revised Risk Assessment Methods for
Workers, Children of Workers in
Agricultural Fields, and Pesticides with
No Food Uses**

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Introduction

This policy addresses how the Office of Pesticide Programs (OPP) will conduct risk assessments for pesticides and pesticide risks that are not governed by the Federal Food, Drug and Cosmetic Act (FFDCA). A dichotomy has developed between how OPP assesses pesticide risks depending on whether a particular pesticide or an aspect of pesticide risk falls within the jurisdiction of the FFDCA. The Food Quality Protection Act of 1996 (FQPA) mandated consideration of certain risk assessment approaches in assessing pesticide risks under FFDCA section 408. Some of these approaches were based on emerging scientific information, while others pushed EPA to systematically take into account factors that previously had only been considered on a non-routine basis. Implementation of these techniques has required OPP to develop new or revised risk assessment techniques. This has been a lengthy process involving the drafting of numerous science policy papers through a transparent public participation procedure and dozens of consultations with the Science Advisory Panel (SAP). The end result is that what seemed novel, cutting edge, or even untested in 1996, has become standard risk assessment practice today. Certainly, challenges remain in adapting the principles of the FQPA to developing scientific knowledge. However, the state of the science since FQPA has advanced to the point that it is now possible to consider aggregate risks from the same pesticide used in agricultural, commercial and/or residential settings, cumulative risks from exposure to pesticides with common mechanisms of toxicity, and the unique risks posed to infants and children due to their potentially increased sensitivity to pesticides. Accordingly, EPA believes that “sound science” now calls upon it to consider such risk assessment factors for any pesticide risk assessment, whether or not it falls strictly under the jurisdiction of FFDCA section 408.

Taking this step at this time has important environmental justice ramifications. The principal group that has not been addressed using advanced risk assessment techniques is agricultural workers and their children who may accompany them to work. Agricultural workers are engaged in the family farm, or, more frequently, are migrant workers who receive few if any health benefits and often face language barriers. Agricultural workers, just like the general food consumer in the United States, can be exposed to pesticides from numerous non-occupational sources and are exposed to different pesticides having a common mechanism of toxicity. In addition, agricultural workers may have further exposure to these same pesticides in the course of their job. Such exposures could result in disparate health impacts to these workers, if not carefully evaluated and appropriately regulated. Although these occupational pesticide exposures are excluded for legal reasons from FFDCA section 408, as a factual matter, pesticide exposure is pesticide exposure. No scientific justification exists for distinguishing between otherwise identical exposures based on whether they occurred on-the-job or not. Further, children of agricultural workers may have additional exposures to pesticides related to their parents’ employment. Again, there exists no scientific reason for distinguishing these exposures from the types of exposures covered under FFDCA section 408. However, failing to extend risk assessment techniques where scientifically justified, can have significant environmental justice consequences. Importantly, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the primary regulatory authority for pesticide risks not covered by the FFDCA, does not exclude consideration of occupational pesticide exposures and otherwise gives EPA broad discretion in

making registration eligibility decisions. Thus, OPP believes the Agency's commitment to environmental justice compels it to act expeditiously, where consistent with statutory authority, to incorporate the risk assessment techniques developed in the implementation of the FQPA in assessing pesticide risks under FIFRA.

Background

Pesticides are licensed for sale and distribution under FIFRA. Tolerances, the limits for pesticide residues in or on food, are established under section 408 of the FFDCFA. The standard for registration under FIFRA is that a pesticide not cause "any unreasonable risk to man or the environment, taking into account the [pesticide's] economic, social, and environmental costs and benefits" (7 U.S.C. § 136(bb)). In contrast to the general risk/benefit standard imposed by FIFRA, FFDCFA section 408 applies a risk-only standard for tolerances in all but rare circumstances and also explicitly dictates certain approaches for how risks must be assessed. Specifically, these risk assessment approaches include: 1) the assumption of an additional 10-fold safety factor to protect children, which can only be revised or removed by specific information indicating a different factor is appropriate; 2) the requirement that all exposures to a pesticide be aggregated including food, water, and residential uses; and 3) the requirement to consider cumulative effects from pesticides and other substances with a common mechanism of action. The risk-only standard and the mandates concerning how risks should be assessed were added to FFDCFA section 408 by the FQPA in 1996.

The risk assessment mandates in the FQPA apply as a legal matter only to pesticide exposures coming within the jurisdiction of FFDCFA section 408. As such, they pertain to non-occupational exposures to food-use pesticides including exposures to such a pesticide from food and drinking water and from use of the pesticide in a residential setting. There is no explicit legal requirement under FIFRA to use, and EPA has not routinely used, the risk assessment approaches codified in the FQPA in assessing worker risks or in assessing risks from pesticides not applied to food crops (i.e., non-food use pesticides).

EPA has always assessed risks to pregnant women, including workers, separately from other subpopulations. However, since the passage of FQPA, EPA has not (under FIFRA) assumed an additional 10X uncertainty factor to protect infants and children in assessing worker risks. This includes child workers and non-working children brought to the agricultural workplace by their parents. Yet a March 2000 GAO report (*GAO/RCED-00-40 Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children* <http://www.gao.gov/new.items/rc00040.pdf>) states that at least 129,000 14-17 year-olds (workers under age 14 were not surveyed) were being hired to work in crop production in the United States, and that a significant percentage of farm workers with children age 5 and under occasionally took their children with them when they worked in the field (generally due to the absence of day care options).

Revised Methods

To provide a more comprehensive and consistent evaluation of potential risks of food use pesticides, non-food use pesticides and occupationally-related exposures, EPA intends to apply

risk assessment techniques developed in the implementation of the FQPA to any pesticide risk assessment, whether falling under the FQPA or not, so long as application of the risk assessment technique is consistent with good scientific practice and is not otherwise prohibited by law. Specifically, this will include use of an additional safety/uncertainty factor to protect children, and will also consider aggregate exposures to pesticides from multiple sources and cumulative effects which may occur from exposure to multiple pesticides with a common mechanism of toxicity. Moreover, risks will be explicitly reported for individuals who had not been explicitly considered, specifically, workers age 12-17 and young children taken into agricultural fields while their parents work.

Safety/Uncertainty Factors: While the basic process of pesticide hazard identification and dose-response analysis has generally remained constant (*Risk Assessment in the Federal Government: Managing the Process, NRC, 1983 and Science and Judgment in Risk Assessment, NRC, 1994*), safety/uncertainty factors have been applied differently to risk assessments since the passage of FQPA in 1996. Table 1 summarizes the different types of safety/uncertainty factors considered in risk assessments prior to 1996.

Table 1. Safety/Uncertainty Factors Historically Considered in Risk Assessments	
Safety/Uncertainty Factors	Purpose
Interspecies Extrapolation	To account for potential differences between the laboratory animals on which the toxicity was tested and humans – generally a 10 fold (10X) factor
Intraspecies Variability	To account for the potential differences among humans – generally a 10 fold (10X) factor
Subchronic to Chronic	To account for uncertainty in extrapolating from shorter duration toxicity studies to longer duration risk; this factor is used when chronic data are lacking
LOAEL to NOAEL	To account for the lack of a No Observed Adverse Effect Level (NOAEL) in a study (the factor is applied to the Lowest Observed Adverse Effect Level – LOAEL)
Missing Data	To account for uncertainty attributable to missing data determined to be important for the assessment of the risk of a given pesticide
Hazard of Concern	On infrequent occasions, a factor was applied to provide additional protection due to concerns raised by toxicity data

The interspecies and intraspecies factors were generally applied in all risk assessments relying on animal data. The other four safety/uncertainty factors were applied, in addition to the inter- and intra-species factors, on a case-by-case basis.

Passage of the FQPA changed this paradigm. The FQPA mandated that an additional 10X safety factor be applied to protect infants and children “to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and

children.” (21 U.S.C. §346a(b)(2)(C)). This additional factor can only be reduced or removed if there are reliable data showing it would be safe for infants and children. The children’s safety factor focused on completeness of the toxicity database and acknowledged the appropriateness of applying additional factors to address data deficiencies (the concern addressed by the existing factors for lack of chronic data, studies lacking NOAELs, and missing data generally). In calling attention to potential pre- and post-natal toxicity and the completeness of the exposure database, the FQPA emphasized the importance of using an additional factor infrequently applied in the past (hazard of concern) and expanded use of additional factors to a new area (exposure concerns). Further, the FQPA modified past practice by creating a presumption that an additional safety factor would be retained to account for uncertainty in quantifying risk to children, where previously EPA had only applied such factors in response to identification of a specific deficiency in the toxicity knowledgebase. (US EPA, *Office of Pesticide Programs’ Policy on the Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Setting Process* (February 28, 2002) <http://www.epa.gov/pesticides/trac/science/determ.pdf>).

In implementing the FQPA’s children’s safety factor, EPA has to date largely followed the narrow dictates of the FQPA as to how it generally assessed children’s risks under the FFDCA and FIFRA. Table 2 illustrates how safety factors have been used post-1996 in pesticide risk assessments.

Table 2. Differences in Use of Safety/Uncertainty Factors for Tolerance, Worker, and Non-Food Use Risk Assessments				
Safety/Uncertainty Factors		Factored into Tolerance Assessment	Factored into Worker Assessment	Factored into Assessments for Pesticides with no Food Uses
FQPA Safety Factor Considerations	Missing toxicity data	Yes	Study Dependent	Study Dependent
	Missing exposure data	Yes	No	No
	LOAEL to NOAEL	Yes	Yes	Yes
	Subchronic to Chronic	Yes	Yes	Yes
	Residual concerns as to children	Yes	No	No
Inter- and Intra-species Factor		Yes	Yes	Yes

EPA’s experience in evaluating children’s risks in safety decisions and tolerance risk assessments over the last 13 years has confirmed the need to systematically evaluate risks that the young (including infants, children, and fetuses) face from pesticides and the importance of a

robust toxicity and exposure database in ensuring that children's risks are adequately assessed. Further, there is no scientific basis to assume that the risks faced by children from exposure to pesticides would differ solely based on whether the exposure occurred from non-occupational sources or in the workplace (or from a food-use as opposed to a non-food use pesticide). Thus, in the future, EPA intends to use safety factors in FIFRA risk assessments (e.g., including risk assessments pertaining to workers and non-food use pesticides) to address children risks where the use of safety factors is scientifically appropriate given the adequacy and results of toxicity and exposure data.

Aggregate Risk Assessment: Aggregate risk assessments consider pesticide exposures from food, drinking water, and residential uses, by adding these exposures, if scientifically appropriate, to determine the total or aggregate risk from these sources (see OPP publication "*General Principles for Performing Aggregate Exposure and Risk Assessments*", 2001 <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>). Because workers are potentially exposed to pesticides through these different sources of exposure, as well as having pesticide exposure on the job, the lack of an aggregate assessment for workers may result in underestimation of their exposure and risk. In addition, some non-food use pesticides may result in residues in drinking water that could contribute to overall risk. An example would be a pesticide that was limited to use on turf and other non-food uses around the home. EPA can see no scientific reason not to aggregate such exposures. Therefore, EPA intends to aggregate, as scientifically appropriate, all potential sources of exposure, including residues in water, from non-food use pesticides, to determine the risks for all segments of the population, including workers and children in agricultural fields.

Cumulative Risk Assessment: Cumulative risk assessments consider pesticide exposure from multiple pesticides with a common mechanism of toxicity (i.e., a toxic effect produced through a common toxicity pathway). Because agricultural/commercial workers are potentially exposed both at work and outside of work to multiple pesticides sharing a common mechanism of toxicity, they may experience cumulative effects from these exposures. There is no scientific justification for not cumulating occupational pesticide exposures with non-occupational pesticide exposures solely because of the fact that an exposure occurred in the workplace. Also, there may be pesticides belonging to a common mechanism group, none of which have food uses requiring a cumulative assessment under FQPA, although this is expected to be a rare situation. Typically a food use exists for at least one pesticide belonging to a common mechanism group, so that the non-food uses associated with the pesticides in that group are included in the cumulative risk assessment. If this situation should occur, however, there is no scientific reason why non-food exposures from multiple pesticides with a common mechanism of toxicity should not be cumulated based solely on the fact that none of the exposures occurred through food. Accordingly, EPA intends to assess cumulative risks, as scientifically appropriate, to workers and children in agricultural fields for all pesticides determined to have a common mechanism of toxicity.

Proposed Changes to Risk Assessments

Occupational exposures in general:

Safety/Uncertainty Factor: EPA intends to consider the risks posed to infants, children, and fetuses (e.g., as a result of exposure to women of child-bearing age) from occupational exposure (including exposures due to their presence at the workplace) to pesticides taking into account the completeness of the toxicity and exposure databases for the relevant pesticide and the pesticide's potential for pre- and post-natal toxicity. Where there is uncertainty regarding safety due to adequacy of data or hazard concerns, EPA intends to apply safety factors to address that uncertainty as scientifically appropriate.

Aggregate: EPA intends to consider all potential sources of pesticide exposure to workers, aggregating these exposures as scientifically appropriate in assessing risks to workers.

Cumulative: EPA intends to consider worker exposure to multiple pesticides sharing a common mechanism of toxicity, cumulating these exposures as scientifically appropriate in assessing risks to workers.

Workers (age 12-17 years):

Based on an analysis of exposure studies that compared the exposures of farmworker children with adults, and also analyzing the current risk assessment approach from a mechanistic perspective by considering how the ratio of skin surface area to body weight correlate with differences in age, it is expected that workers ages 12-17 will have exposures similar to adults (University of California 1982, 1983a, 1983b, 1985, Phillips *et al* 1993). Therefore, a separate exposure assessment will not be required for this age group.

Children in Agricultural Fields:

Risks for young children taken into agricultural fields will be assessed using the same application rates and re-entry intervals as adult occupational post-application assessment. However, these assessments will differ from current worker assessments in the following ways:

- Toxicity endpoints and uncertainty/safety factors identified for children will be used.
- The contact and exposure factors (e.g., transfer coefficient, TC) may be different than for an adult worker, and will be chosen to reflect the specific use scenario.
- An incidental oral exposure component (e.g., hand-to-mouth, object-to-mouth, soil ingestion) will be incorporated if scientifically appropriate.

Aggregate and cumulative assessments will be conducted as scientifically appropriate.

Children and By-Stander Exposure near Agricultural Fields

In December 2009, OPP plans to consult the SAP on the potential for pesticide exposure to by-standers near agricultural fields due to volatilization. On November 4, 2009, EPA issued two Federal Register Notices (FRN) related to pesticide spray and dust drift. One notice is soliciting comments on a petition to protect children from pesticide drift, and the other is seeking comments on OPP's draft guidance for pesticide drift labeling. Pending the outcome of this SAP consultation, and comments received on the pesticide drift FRN, EPA intends to assess risks posed to infants, children, fetuses (as a result of exposure to women of child-bearing age) and adult by-standers near agricultural fields that may be exposed to pesticides via volatilization and/or drift. Pesticide risks will take into account the completeness of the toxicity and exposure databases for the relevant pesticide and the pesticide's potential for pre- and post-natal toxicity. Where there is uncertainty regarding safety due to adequacy of data or hazard concerns, EPA intends to apply safety factors to address that uncertainty as scientifically appropriate.

More specific guidance for conducting these assessments must be developed.

Pesticides with Only Non-Food Uses:

Safety/Uncertainty Factor: EPA intends to consider the risks posed to infants, children, and fetuses (as a result of exposure to women of child-bearing age) from exposure to non-food use pesticides taking into account the completeness of the toxicity and exposure databases for the relevant pesticide and the pesticide's potential for pre- and post-natal toxicity. Where there is uncertainty regarding safety, EPA intends to apply safety factors to address that uncertainty as scientifically appropriate.

Aggregate: EPA intends to consider all potential sources of exposure to non-food use pesticides, aggregating these exposures when scientifically appropriate in assessing risks.

Cumulative: EPA intends to consider whether exposure to multiple non-food use pesticides sharing a common mechanism of toxicity is likely, cumulating such exposures when scientifically appropriate in assessing risk.

Implementation/Policy Development and Data Needs

Some of the above proposed methodology changes can be implemented immediately, while for others, further research into available data, new techniques and data needs must first be undertaken and science policies developed. Consultation with the FIFRA SAP and request for public participation may be needed for new science policies. The proposed implementation strategy is summarized below.

Immediate Implementation

- Consistent application of safety/uncertainty factors among food use and non-food use pesticides, and worker risk assessments as scientifically appropriate and in accordance with legal requirements.

Longer Term Implementation (6 to 18 months)

- Development of exposure assessment methods for non-working children of workers in fields.
- Development of risk assessment methods for child workers (ages 12-17 years).
- Development of aggregate and cumulative exposure methodologies for adult workers and children.
- Development of risk methods to assess by-stander exposure near agricultural fields from pesticide volatilization and/or drift pending the recommendations of the SAP consultation and comments received on the pesticide drift FRN.

As these policies are developed, data needs may be identified including, but not limited to the following:

- the transfer of pesticide residues to children and youths present in pesticide-treated fields or orchards considering the different activities in which they may be engaged (e.g., working vs. not working),
- the extent to which youth under age 18 work in agriculture and the age distribution of these workers,
- the extent to which non-working children are taken into pesticide-treated fields, and
- the likelihood and extent of co-occurrence of exposure from work in agriculture settings (or presence in agricultural settings), in addition to food, drinking water, residential and other sources of exposure.

Effect of Policy

As a policy statement, this document is not binding on EPA, regulated parties, or the public. EPA retains the ability to deviate from this policy where circumstances warrant, and outside parties remain free to assert that risks for any given pesticide or any group of pesticides should not be assessed in the manner set forth in this policy.

References

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