

Farmers, Consumers Ask, 'Does The Risk Cup Runneth Over?'

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When environmentalists talk about pesticide exposure, they are usually referring to possible residue in our food. In fact, food is only one of many potential sources of pesticide residue in our environment. Both farmers and consumers, especially parents with small children, will benefit from the "risk cup" assessment of pesticide levels in our daily lives from ALL sources — not just agriculture.

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The Food Quality Protection Act (FQPA) established an entirely new set of guidelines for registering and reregistering pesticides. One of the new provisions of the FQPA requires EPA to consider pesticide exposures from food and non-food sources under the aggregate exposure provision in the law.

Before the FQPA, EPA assessed the total risk of a pesticide by adding the risk from all the foods it was registered for use on. EPA did not typically look at other exposures, such as drinking water, residential sources and other exposures in assessing the total risk. Now the FQPA requires EPA to conduct a comprehensive risk assessment for every pesticide active ingredient and evaluate all potential exposures.

Aggregate Exposure

In 1993 EPA changed its risk assessment policy when the National Academy of Sciences (NAS) released the report "Pesticides in the Diets of Infants and Children." The report recommended that the total exposure to pesticides from all exposures should be combined, including water and residential sources. Since the release of the report, EPA has conducted aggregate exposure risk assessments for some pesticides using the NAS recommendations.

The FQPA requires EPA to examine all exposures for every pesticide. The new law under section 408(a)(4) of the Federal Food, Drug and Cosmetic Act (FFDCA) states that for every tolerance there must be a decision "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures for which there is reliable information." The law also states that "...no harm will result to infants and children from aggregate exposure to the pesticide chemical residues..." So while EPA had already begun this process voluntarily before FQPA under its existing authority, the FQPA accelerates the process while including statutory protections for infants and children.

Before the FQPA, the focus was on food. After the FQPA, the focus is still on food, but additional exposures must now be considered. These include drinking water, chemicals that pesticides degrade into, children's outdoor residential exposures, and indoor exposures such as to termite or cockroach pesticides.

The Risk Cup

When adding all pesticide risks, EPA is using the analogy of a cup to demonstrate how it intends to evaluate acceptable risk under the FQPA. Here's how the risk cup concept works: For each pesticide active ingredient, EPA will determine the total level of acceptable risk. This is the level of exposure to a specific pesticide that a person could receive every day over a 70-year lifetime without significant risk of a long-term or chronic non-cancer health effect. This includes exposures from dietary and non-dietary sources. This total, or maximum, level of acceptable risk represents a full risk cup. This equals a pesticide's Reference Dose (RfD). Before the FQPA, the law only required food exposures to be in the risk cup.

"There is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."

Reference Dose

The RfD is calculated in the following manner: EPA requires pesticide registrants to determine through laboratory studies an exposure level below which no adverse health effects occur. For each active ingredient, studies establish a "no observed effects level" or NOEL. The NOEL is

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the highest dose that causes no effects. The reference dose is calculated from the NOEL using a 100-fold safety factor. In other words, the reference dose is 100 times lower than the dose that has no health effects on laboratory animals. For example if the NOEL is 10,000 parts per million. In this example, the risk cup is full when pesticide exposures reach 100 parts per million. This means that all pesticide residue tolerances, when added together, cannot exceed 100 parts per million. If a particular active ingredient was registered for use on 20 different crops, and the maximum residue level or tolerance for each was 5 parts per million, the risk cup would be filled by these 20 crops, and no new uses could be approved.

To determine when the risk cup is full, EPA will divide exposure into chronic and acute exposures, while factoring in other risk sources.

Chronic Exposure

A chronic exposure is daily, lifetime exposure to low levels of pesticides. While food and water are primary sources for chronic exposure, other sources may also be included. For example, janitors who use disinfectant products every working day may have chronic exposures. EPA is using the following formula to calculate chronic exposure: Chronic Dietary Exposure = Chronic Food Exposure + Chronic Drinking Water Exposure.

Acute Exposure

EPA will assess acute exposures separately. An acute exposure is defined as a single or one-day exposure and is the level of exposure to a specific pesticide that a person could receive in one day with no increase in risk. An acute exposure is a single exposure to a high-end dose of the same pesticide.

While EPA is required to consider exposures from multiple sources, it has admitted that it is highly improbable that people will treat their lawn and garden, spray for termites, swim in a pool, eat food and drink water

and be exposed to the same pesticide at maximum levels for all of those exposures in a single day. Plus, EPA believes that since residues decline over time, it is not appropriate to include residential pesticide exposures in acute exposure calculations at all. As a result, EPA will evaluate acute exposure as dietary exposures only.

Sources of Risk

EPA will perform risk assessments for pesticides assuming that people will be exposed to pesticides from the following four sources: 1) dietary 2) occupational 3) residential 4) drinking water.

Dietary Sources

To assess dietary risks, EPA will use the Dietary Risk Evaluation System (DRES) to combine available pesticide residue data with food consumption data. If EPA does not have residue data, they assume that residues are present on food at maximum levels. To evaluate what people are eating, EPA uses food consumption data from USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). The FQPA requires USDA to update the NFCS to reflect current consumption patterns, which is critical because the 1977-78 NFCS is not a good indicator of current eating habits.

To assess dietary risks, EPA assumes that residues are present on all food at the tolerance and that 100% of the entire crop has been treated. However, when data is available, EPA will refine its evaluation if percent crop-treated and actual residue information is available. All available information is combined and Monte Carlo techniques are used to evaluate risk. Monte Carlo techniques are a statistical methodology for reviewing exposures.

Occupational Exposures

Occupational exposure is worker exposure and includes pesticide mixers, loaders and applicators. EPA uses exposure data from the Pesticide Handler's Exposure Database, which contains dermal and inhalation exposure values. EPA estimates occu-

pational exposures using a variety of factors including the formulation, method of application, label rate of application, percent active ingredient and number of acres treated. Specific information allows EPA to lower occupational risk. For example, liquid formulations are less risky than wettable powders (wetable powders have a higher inhalation risk) and closed-system applications are less risk than air blast sprayers. Without data, EPA assumes that 100% of the crop is treated at the maximum label rate. Actual data allows EPA to lower its risk assessments.

Residential Exposures

Residential exposures occur when playing on a lawn, working in a garden, swimming in a treated pool, playing with a pet wearing a treated collar or touching surfaces that have been treated. EPA has limited data on residential exposures. Because of this, EPA issued a data call-in for new residential exposures in March 1995. As a result, the Outdoor Residential Exposure Task Force was organized to develop data in response to the data call-in. This data is expected to trickle into EPA early next year and to be finalized by the year 2000. Eventually, EPA will use this new information to develop a database similar to the Pesticide Handler's Exposure Database.

Drinking Water Exposures

A drinking-water assessment is required for all future human health assessments. It must include, at a minimum, why an assessment is not required. Every person drinks water every day. Because of this EPA will require a calculation of acute and chronic drinking-water exposure of both ground and surface water, but it needs more to evaluate all pesticides and metabolites. EPA will not estimate a national drinking water exposure. Pesticide detections from a specific region will not be averaged in with non-detects from other areas of the country to develop a national

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average. EPA believes this underestimates potential exposures.

EPA Decision Making

The FQPA became effective immediately when it was passed. There was no transition or phase-in period. This means that EPA lacked information it needed to make decisions demanded by the FQPA. Without data, EPA has developed default assumptions and will reserve a specific portion of the risk cup for the following exposures:

- 10% for drinking water exposure;
- 5% for indoor residential exposure;
- 5% for outdoor residential exposure.

This means that, for now, between 5% and 20% of the risk cup will be reserved for non-food uses. When EPA receives information, they will replace default assumptions with actual data.

What Aggregate Exposure Provision Means for Farmers

Based on the above information, how will the aggregate exposure provision affect farmers? First, EPA has been evaluating aggregate exposures for pesticides EPA deemed troublesome since 1993. The special review of the triazines is an example of the type of pesticides EPA thought fit into this category. Based on what has occurred so far in the triazine special review, farmers can expect little regulatory action. This is because the triazine special review has uncovered new data that dramatically lowers past risk estimates.

If the triazine special review is indicative of what farmers can expect from FQPA-mandated reviews of other pesticides, the impact will be minimal. As stated before, replacing theoretical maximum assumptions with actual data almost always lowers risk. If registrants are unwilling to develop data or cannot afford to, expect tolerance cancellations.

Second, persistent pesticides will be affected most by the aggregate exposure provision of the FQPA. This

means that for pesticides where residues show up in a lot of crops and in other applications that are also organophosphates, carbamates or B2 carcinogens.

“For pesticides where residues show up in a lot of places long after the pesticide was applied, expect some regulatory action.”

It is difficult to categorize which pesticides fall into this category. Persistent pesticides that are also either organophosphate or carbamate pesticides will likely feel some impact. For a list of organophosphate and carbamate pesticides, please contact AFBF for our earlier FQPA analysis on common mechanism of toxicity.

Other pesticides that may feel some impact are those with many applications and uses. One example of this type of pesticide is Lorsban. Lorsban is an insecticide used on a wide variety of crops with many home and garden applications. These uses include agricultural applications on apples and corn to Black Flag Ant Control System to Ortho Home Pest Insect Control to Lassie Take Charge Flea & Tick Dog Collar.

In total, it has more than 400-separate uses. It is moderately toxic, but not persistent. It is also an organophosphate pesticide, which brings other regulatory decisions into play. This requirement assumes that people (especially children) may eat food that may contain residues of Lorsban, roll in the grass that may have been treated with Lorsban and hug a dog that is wearing a Lorsban — impregnated dog collar. All of these exposures must be considered together.

Based on this, Lorsban would appear to face some crop and use cancellations. Detailed information on use patterns and residues permits a different conclusion. Pesticide use information reveals that Lorsban is never used on 100% of acres at maximum label rates. Plus, when residues

are found on food treated with Lorsban, they are always at levels far below the tolerance in a very small percentage of samples tested. While Lorsban is a pesticide that potentially raises many FQPA issues, detailed information satisfies many of those concerns.

Conclusions

The aggregate exposure provision of the FQPA highlights the fact that the new law is an information-intensive statute. Without data, farmers should be concerned. Growers who actively gather pesticide-use information will likely be rewarded for their efforts. Actual use information and residue data will make more room in the risk cup for other crops and uses to come in.

With data, farmers should be able to satisfy concerns. Farm Bureau's job is to help provide data to satisfy safety concerns while providing consumers in the U.S. and abroad with safe, affordable food.



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