SFIREG Issue Paper: Pesticide Impurities in EPA Registered Pesticides

Background

On January 24, 1996, EPA published in the Federal Register (FR) a "Statement of Policy Regarding Toxicologically Significant Levels of Pesticide Active Ingredients; Notice of Availability and Request for Comments", 61 FR 1928, Docket OPP-00424. Comments were accepted until March 25, 1996. Prior to the FR notice, EPA had released a draft "Pesticide Regulation (PR) Notice 96-?", titled "Toxicologically Significant Levels of Pesticide Active Ingredients", December 8, 1995, 730 0 96 001. The draft PR Notice addressed cross-contamination of active ingredients in pesticide products by contaminants that are also pesticide active ingredients.

According to the 1996 FR Notice regarding the draft PR Notice, "EPA's current policy is that any level of an impurity that is also an active ingredient in another pesticide is considered "toxicologically significant" and must be reported to EPA." There was language in the draft PR Notice which would change EPA's definition of "toxicologically significant" levels of active ingredients to a risk-based standard. The draft PR notice was eventually finalized and became Pesticide Regulation (PR) Notice 96-8.

Many years later, on August 14, 2007, EPA posted a FR Notice requesting comments on PR Notice 96-8, EPA-HQ-OPP-2007-0814-0001. The docket appears to be still open, and there is no evidence that any comments were received.

PR Notice 96-8 provided further interpretation of 40 CFR 158.167 [currently §158.340], "Discussion of formation of impurities"; and also 40 CFR 158.175 [currently §158.350], "Certified limits".

PR Notice 96-8 states, "EPA requires all impurities of toxicological significance to be reported and accepted as part of product registration (40 CFR 158.167). EPA also requires that registrants propose upper certified limits for toxicologically significant impurities in technical grade active ingredients or products produced by an integrated system (40 CFR 158.175), and may require upper certified limits for other impurities. At the time EPA promulgated these regulations [i.e., 40 CFR 158.167 and 40 CFR 158.175] it did not set quantitative criteria for determining whether an impurity is toxicologically significant."

A contaminant is defined as an active ingredient that is not on the product's confidential statement of formula or listed in the discussion of impurities. A toxicologically significant level is the concentration at or above which EPA would consider the contaminant to be toxicologically significant. The toxicologically significant levels apply to all registered products that are sold or distributed, regardless of whether the container is nonrefillable (i.e., "packaged product") or refillable (i.e., "bulk product.")

Issues identification

The Oregon Department of Agriculture (ODA) was notified by another Oregon state agency that a pesticide (permethrin) was detected in an agricultural crop, see results in Table 1- "Ag. Crop Tested". However, there were no pesticide labels which would allow for use on that particular crop, which is a food crop. Also the grower was adamant that he did not apply any product containing permethrin to the crop. Independently, the grower had a commercial laboratory analyze the EPA-registered product he had been using, and permethrin was detected.

As part of the investigative process, ODA pesticide investigators collected samples from four locations where unopened containers of the pesticide product (referred to as Pesticide AZ) were available for sale; the ODA regulatory laboratory analyzed the contents of the containers. The results are indicated in Table 1 below (NUF 1-4). The results were shared with other SLAs, and in some instances, they found up to five additional pesticide active ingredients at various levels. Some of the contaminant pesticides found in Pesticide AZ are active ingredients in products that are classified by EPA as restricted use.

The levels of the contaminant active ingredients detected in Pesticide AZ appeared to be related to the lot number of the product. All of the contaminant pesticides detected in Pesticide AZ by the ODA laboratory were manufactured or somehow processed at the same plant as Pesticide AZ. This suggests that contamination took place at the EPA Producer Establishment Facility. EPA did recognize in PR 96-8 that "cross contamination is a reality..."

Table 1. Levels of various pesticides found in unopened containers of Pesticide AZ; contaminant levels found in ag. crop tissue; and examples of EPA established tolerance levels (ppm).

Formulated Product	Pesticides (ppm)					
Sample #	permethrin	bifenthrin	cypermethrin	cyfluthrin	chlorpyrifos	malathion
NUF -1	2.8	1.1	not tested	0.42	0.15	< 0.040
NUF - 2	200	0.37	not tested	0.088	0.51	< 0.040
NUF - 3	25	1.1	12 ppm	< 0.10	2.0	< 0.040
NUF - 4	1.0	0.27	< 0.040	< 0.10	< 0.040	< 0.040
Ag. Crop Tested	0.2 - 0.60	0.21 - 0.48				
Example Tolerances						
Pome Type	0.05 pome	0.5 pear	2.0 pome	0.5 pome	0.01 apple	8 apple
Sweet Cherry	4.0	N/A	1.0	0.3	1.0	8
Radish	N/A	0.10	0.1	1.0	2.0	8
Grape	N/A	0.2	2.0	1.0	0.01 (Regional)	8
Pepper, bell	0.50	0.5	0.2	0.50	1.0	8

Pesticide products from additional registrants containing the same stated active ingredient that is in Pesticide AZ, were also tested by the ODA laboratory. These products also contained various levels of the contaminant pesticides.

Market Barriers

All of the levels of the contaminant pesticides were well below the EPA definition of toxicologically significant levels provided in PR Notice 96-8. However, the contaminant pesticide levels detected in the agricultural crop tested in the ODA investigation suggests that there could be possible exceedance in the established tolerances on certain crops, such as apples or bell peppers.

EPA acknowledged in PR Notice 96-8 that, "theoretically a contaminant could cause residues in food or feed for which no tolerance has been established or that are in excess of an established tolerance", and further added that it would be "a highly unlikely occurrence". However, based on the levels of contaminants found in the agricultural crop tested, this topic should be reexamined to determine whether EPA's original assertion, that it would be "a highly unlikely occurrence", is still valid.

Consumer Confidence and Truth in Labeling

Pesticide AZ is a product bearing the OMRI label, and is a product that can be used under the National Organic Program. Registrants can obtain EPA approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide meet the criteria defined in the United States Department of Agriculture's (USDA) National Organic Program (NOP) Rule.

It is highly likely that consumers, organic growers, and entities that review products to be used in the NOP are unaware that pesticide products being used in organic production, in fact may also contain undeclared conventional pesticides such as, permethrin, bifenthrin, chlorpyrifos, etc.

Herbicide-Resistant Crops

The number of crops bred to be resistant to over-the-top herbicide use have proliferated since 1996. The levels of herbicide contaminants allowable in herbicide products may no longer meet EPA's risk based standard.

ODA is not aware of any verified instances of damage or illegal residues, but many people are aware of allegations that have been made regarding this topic.

Proposed Resolutions or Remedies

Exclusions
EPA currently excludes three contamination scenarios from PR Notice 96-8. These scenarios include: rodenticides; microbial and biochemical pesticides that are manufactured in fermenters; and plant incorporated protectants (PIPS). In these scenarios, any level of contaminant is considered potentially toxicologically significant.

SFIREG requests that products labeled or approved for use in organic production also be added to the exclusions in PR Notice 96-8. See Pesticide Registration (PR) Notice 2003-1 regarding labeling of pesticide products under the National Organic Program (NOP), and EPA's clarification of PR Notice 2003-1.

SFIREG also requests that herbicide products labeled for use on crops which have over-the-top use directions also be added to the exclusions. When PR Notice 96-8 was developed, herbicide-resistant crops were not as widely grown.

- It is SFIREG's opinion that the "resolvability" of this particular issue is very high. It will resolve inconsistencies and conflicts with PR 2003-1, and with the USDA National Organic Program. Ideally this issue could be resolved within one year.

Review

(1) EPA stated in PR Notice 96-8 that they considered unreasonable adverse effects and reviewed the risks for several endpoints, including adulterated food. EPA determined that when addressing cross contamination, phytotoxicity to target plants was the most sensitive endpoint. SFIREG recommends that EPA re-review the endpoints, particularly the potential adverse effects if food should become adulterated.

EPA should consider applying the requirement stated for Category 2 (column 3 in Toxicologically Significant Levels of Contaminants table in PR Notice 96-8) to all categories. This requirement essentially states that the contaminant needs to be accepted for use on all sites for which the product is labeled.

- It is SFIREG's opinion that the "resolvability" of this particular issue is high. It will resolve potential inconsistencies and conflicts with the Federal Food Drug and Cosmetic Act (FFDCA) and FIFRA. Ideally this issue could be resolved within two years.

(2) SFIREG requests that EPA conduct a comprehensive review of its interpretation of the term "toxicologically significant", and incorporate further refinements based on current analytical methods (levels of quantification), current pesticide residue tolerance levels, and agricultural trade practices.

EPA should require additional studies from registrants with products that have short preharvest intervals on any crops. A contaminant with a long half-life may result in a tolerance exceedance.

As part of the review, EPA should evaluate if it has considered each contaminant individually (as indicated in PR Notice 96-8), and also review how registrants are implementing PR Notice 96-8.

- It is SFIREG's opinion that the “resolvability” of this particular issue is moderate and a SFIREG workgroup should be formed. Ideally this issue could be resolved within four to six years.

Respectfully submitted,

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