Dear AAPCO and SFIREG Colleagues:

Leo Reed (AAPCO President; Office of the Indiana State Chemist)
Rose Kachadoorian (AAPCO Immediate Past President; OR Dept. of Agriculture)
Gary Bahr (SFIREG Chair; WA State Dept. of Agriculture)
Liza Fleeson-Trossbach (AAPCO Director; VA Dept. of Agriculture & Consumer Services)
Jeff Rogers (SFIREG POM Working Committee Chair; VA Dept. of Agriculture & Consumer Services)
Carrie Leach (SFIREG EQI Working Committee Chair; Purdue University, Laboratory)
Amy Sullivan (AAPCO Executive Secretary)

RE: EPA Response to 10/16/2018 SFIREG Issue Paper - Pesticide Impurities in EPA Registered Products

Thank you for submission of the SFIREG Issue Paper “Pesticide Impurities in EPA Registered Products.” This letter presents EPA’s response and planned next steps for addressing related issues associated with organic products, market barriers, and herbicide products.

SFIREG’s issue paper discussed various states’ experiences regarding pesticide products that were contaminated with other pesticidal active ingredients not listed on the Confidential Statement of Formula (CSF) or in the discussion of impurities. The issue paper pointed to the definition of “toxicologically significant levels” as identified in EPA Pesticide Registration Notice (PRN) 96-8 “Toxicologically Significant Levels of Pesticide Active Ingredients” and raised several concerns. The issue paper also proposed certain remedies that EPA could take to improve the status quo or provide resolution, and SFIREG requested that EPA investigate those options.

EPA has explored the concerns raised by the issue paper, and our next steps are described below. In the near term, EPA proposes to support the states and better understand the scope of the issue by providing laboratory support for testing of pesticide products with suspected high levels of impurities through the Office of Pesticide Programs’ (OPP) Biological and Economic Analysis Division’s (BEAD) Analytical Chemistry Branch Laboratory in Fort Meade, MD. Additional work may also be explored over a longer period, as new information comes to light. EPA responses to specific topics raised in the issue paper are provided in the following sections.

Products Labeled with “Organic” Claims

One of the main areas of concern discussed in this issue paper is the topic of pesticide products with label claims accepted by EPA pursuant to EPA’s policy implementing the USDA’s National Organic Program (NOP) set forth in Pesticide Registration Notice 2003-1 “Labeling of Pesticide Products under the National Organic Program,” and subsequently-issued Clarification. Such claims may include “For organic production,” “For organic gardening,” “OMRI listed,” and EPA’s three leaf logo.
The issue paper described challenges to taking enforcement action against pesticides with NOP-related claims that are found to be contaminated with synthetic pesticides not permitted by the NOP for use on commodities labeled “organic.” One of those challenges is confusion about whether the Agency’s position in PRN 96-8, which sets forth the minimum levels of certain impurities that EPA considers “toxicologically significant,” would prevent enforcement where levels of synthetic contaminants are found in “organic”-labeled products in amounts below the thresholds set therein.

EPA’s Office of Enforcement and Compliance Assurance (OECA) and Office of Chemical Safety and Pollution Prevention (OCSPP) have been monitoring this issue and the confusion about the impact of PRN 96-8. It is the opinion of those Offices, with input from the Office of General Counsel (OGC), as was communicated to EPA Regions and their state partners in March 2020, when registered pesticides with EPA-accepted organic labeling claims are found to be contaminated with NOP-prohibited synthetic pesticides in an amount that would not be considered “toxicologically significant” as set forth by PRN 96-8, those products may nevertheless be “misbranded” as defined by FIFRA section 2(q)(1)(A) and “adulterated” as defined by FIFRA section 2(c)(1). When a registered product is labeled with any EPA-accepted “organic” claim and there are any levels of any NOP-prohibited substance in it, then the claims related to the product’s qualifications as acceptable for use in “organic” production are false. Also, whether a product is “adulterated” per 2(c)(1) does not depend on whether the impurity found is “toxicologically significant,” but is instead determined by what level of strength or purity the label promises it to be. EPA-accepted “organic” claims represent that the product is entirely free of NOP-prohibited substances. Sale or distribution of such “organic”-labeled pesticides that are “misbranded” and “adulterated” is prohibited by FIFRA section 12(a)(1)(E).

While this position is based on an analysis of FIFRA and not any particular state law, we believe the states may still find it useful to know that EPA does not believe PRN 96-8 poses vulnerabilities to its own enforcement in this area.

Market Barriers

A second concern relayed in SFIREG’s issue paper was related to “market barriers” for treated agricultural goods and potential for tolerance exceedances in those foods if the labeling information is not truthful. The issue paper suggests that the thresholds of “toxicologically significant levels of contaminants” from PRN 96-8 are too permissive and could lead to foods in the channels of trade that may be adulterated because residues are not covered by an appropriate tolerance or tolerance exemption. Current sources of data such as the USDA’s Pesticide Data Program (PDP)¹, however, suggest that adulterated foods are not a common or system-wide ongoing concern. The standard for whether a food item is considered adulterated under FFDCA, the food safety law, relates to whether any residues of a pesticide chemical for which a tolerance or tolerance exemption has not been established are detected in the food. PRN 96-8 does not weaken this protective standard. At the federal level, EPA, FDA and USDA work together to ensure food safety requirements for pesticides are met.

¹ From https://www.ams.usda.gov/datasets/pdp. “The Pesticide Data Program (PDP) is a national pesticide residue monitoring program and produces the most comprehensive pesticide residue database in the U.S. The Monitoring Programs Division administers PDP activities, including the sampling, testing, and reporting of pesticide residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children.” Accessed 4/13/2020.
Herbicide Products

A third area discussed in the issue paper is related to herbicide products labeled for over-the-top use, and SFIREG included a request that this group of products be exempted from PRN 96-8 and the “toxicologically significant level of contaminants” defined therein. The issue paper stated, “ODA (Oregon Department of Agriculture) 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.” No additional supporting evidence was provided, and at this time, EPA is not aware of herbicide products approved for use on herbicide-tolerant crops that have been proven to be contaminated with other pesticide active ingredients. EPA would need to evaluate additional information on verified occurrences to pursue further action on these herbicide products as related to PRN 96-8. We are willing to continue to engage on this issue moving forward.

Conclusions

As discussed at the beginning of this letter, as a result of receiving this issue paper and subsequent conversations within OPP and with SFIREG, EPA would like to provide laboratory capacity for testing product samples in cases where contamination is suspected. This will require continued collaboration with SFIREG and within EPA to determine the logistics and volume of samples expected and to ensure the requested testing is within EPA’s capacity. This is a concrete way in which EPA can assist states in the short term and inform the concern for products contaminated with other pesticide active ingredients. EPA hopes to gain more insight as to the depth and national scope of this product contamination issue to inform future actions. If SFIREG and the states are interested in pursuing this option, please contact Sandra O’Neill (ONeill.Sandra@epa.gov; 703-347-0141), and we will coordinate a meeting between BEAD laboratory management and the interested parties.

EPA acknowledges that almost 25 years have passed since PRN 96-8 was issued and recognizes that scientific advancement, methods assessment, and product integrity have continued to improve in the intervening years. With the intermediate steps outlined above, EPA and SFIREG can work together to determine the best long-term course of action. EPA would like to continue to work with your departments, our federal partners, and the public on other appropriate methods and collaborations for ensuring food safety and pesticide label accuracy. Therefore, please keep the lines of communication open with us on these topics and relay your enforcement findings and data so that we can continue to work together to ensure pesticide safety.

EPA would like to thank SFIREG for raising these issues to our attention and for the additional EPA and SFIREG brainstorming that occurred at the December 2019 Full SFIREG meeting and during subsequent conference calls with SFIREG members and leadership. We look forward to continuing our work with SFIREG, AAPCO, state, and EPA Regional partners on these and other important pesticide issues.

Sincerely,

Ed Messina, Esq., Acting Director, Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention