Response to 15-October-2020 letter from Ed Messina to AAPCO & SFIREG on Pesticide Impurities

Introduction: An issue has been raised and discussed by AAPCO and SFIREG concerning impurities in pesticides. This prompted initial discussion at a 2017 AAPCO meeting and preparation of a "white paper" on the issue by SFIREG in November 2017 entitled "Pesticide Impurities in EPA Registered Pesticides". This was followed by presentation of material from the paper at a March 2018 AAPCO meeting by Ms Rose Kachadoorian of the Oregon Dept of Agriculture (ODA). Without further open discussion, EPA responded to this issue through a communication between EPA and its Regions and State Partners in March of 2020, followed by a letter from Mr. Ed Messina to the leadership of AAPCO and SFIREG on October 15, 2020.

Since the issue was brought to light by Ms Kachadoorian due to an investigation of products being distributed and sold in the State of Oregon by PBI-Gordon prior to and in 2017, I feel it necessary to also respond. It is my opinion that Mr. Messina's letter is proposing to change how organic pesticides are to be regulated without proper public comment and discussion.

Background: There is no distinction in FIFRA between the regulation of traditional types of pesticides and pesticides making organic claims or intended for organic food production. USDA eventually set up standards for organic farming around 2000 with the establishment of the National Organic Program (7CFR205) (NOP). Thereafter, USDA authorized several third parties, including OMRI (Organic Materials Research Institute), to certify as "organic" both foods and inputs to the production of foods meeting NOP standards. Similarly, EPA issued PRN 2003-1 to address the labeling of pesticides as "organic." PRN 2003-1 requires that each *ingredient* of the pesticide, including both its "active and inert ingredients," must be on the NOP allowed substances list to qualify as organic. PRN 2003-1 did not address contaminants or impurities contained in "organic" pesticides.

In fact, EPA had addressed permissible levels of contaminants and impurities in pesticides several years earlier, both in its Part 158 Product Chemistry data requirements and in PRN 96-8, which was the product of extensive collaboration among stakeholders. In PRN96-8, EPA recognized that even with safeguards in place, "cross-contamination is a reality." The purpose of PRN 96-8 was to set clear standards that can be followed by EPA, States and industry for acceptable levels of contamination in various types of pesticides using a reasonable risk-based limit. There are only three product-based exceptions to these standards, where any level of contamination is prohibited: (1) rodenticides, (2) microbial and biochemical pesticides, and (3) plant-based pesticides. Nothing in PRN 96-8 prohibits otherwise acceptable contamination below the levels it sets in pesticides that make organic claims or are intended for organic food production. Although PRN 96-8 predates the NOP, there were never any comments received to challenge or suggest changes to this PR Notice. EPA also did not revisit the issue of contaminants or the standards set in PRN 96-8 when it set standards in PRN 2003-1 for active and inert ingredients in products with an organic claim or intended for organic food production.

Concern 1: One of the concerns comes from the fact that there are no specific rules indicating which synthetic pesticide ingredients (as contaminants) are prohibited in products used on a commodity to be sold as organic, but the NOP does define which pesticides can and cannot be found in the treated commodities. Therefore, under the current regulations, an organic-labeled pesticide containing a low level contaminant (which falls below the limits of PRN 96-8) is legal to be sold and used, but if significant residues of the contaminant are found in the treated commodity, the commodity cannot be sold as "organic". If the contaminating pesticide has tolerances on the commodity in question, it can be freely

sold, but not as "organic". One of the statements in the October 15 letter in question was *"EPA-accepted "organic" claims represent that the product is entirely free of NOP-prohibited substances" [paragraph 2, page 2].* This statement does not seem to be based on any laws, rules, or PR Notices established to date. Could more information have been in the communication mentioned in the same paragraph from March 2020 between EPA and their Regions and state partners. Can that communication be shared?

Concern 2: Unfortunately, as mentioned above, the issue raised by ODA was due to inadvertent residues of pesticides being found on an "agricultural crop" which didn't have tolerances for the pesticides found. Of course, this "agricultural crop" was not officially "agricultural" at all, since it was marijuana. A short recent history of pesticide use in marijuana follows:

1) Prior to 2015, the issue of pesticide use on marijuana was a minor one, however, as more states began approving "medical use" and later "recreational use" of the substance, the potential to capitalize on this "new crop" moving up in production caused many growers to look for help in being able to produce better crops of marijuana (cannabis). Unfortunately, it became apparent that since the Federal Government still considered marijuana and THC illegal substances, EPA would not consider approving use of pesticides on marijuana.

2) This situation got a bit confusing when in May 2015, Jack Hausinger of the EPA wrote a letter to Colorado Dept of Ag, suggesting they pursue 24(c)s to address their needs. A change in politics by 2016 altered EPA's willingness to grant any 24(c)s for this and states were left fending again for themselves with an increasing number of growers asking for some relief.

3) Several states such as OR, CO, WA, and CA struck out on their own, coming up with their own ways to deal with the situation, creating lists of possible products that could be used on crops such as marijuana. Products were placed on these lists because of the fact that they were either organic or were of a nature to not need a tolerance for use on food commodities. These states also set up analytical laboratories to determine if pesticide residues were being found on marijuana commodities. Any commodity found with residues of pesticides above what the state lists allowed, were determined to be illegal and had to be destroyed. In most cases, the allowed limits were set at the Limit of Detection, so if it was detected in the crop, the crop was adulterated.

4) Many companies, PBI included, got caught up in the confusing situation, as the products being used by growers had to be ultra pure and if there were any pesticide impurities in the products (even if below that allowed by PRN 96-8) and they were detected in the harvested marijuana, crops had to be destroyed and suddenly lawsuits were popping up regularly between growers and states, growers and pesticide companies, and between States and companies. And of course, federally, there were still no EPA-approved pesticide labels with valid instructions for use on marijuana.

5) State representatives took the issue to SFIREG and APPCO resulting in the "white paper" discussed above, asking for it to be resolved by adding pesticide products labeled or approved for use in organic products as a fourth exclusion from PRN 96-8. Not too surprisingly, SFIREG threw in the new dicamba OTT use as a possible additional source of need for PRN 96-8 to be reconsidered.

6) The 2018 Farm Bill opened the door for pesticides to be used on hemp (a cousin of marijuana), but not on crops containing more than 0.3% THC.

The recent election increased the number of states where marijuana is legal either for medical or recreational use to 35. It is definitely best that the federal government work with states and the industry to define solutions to pesticide use so there is not the continued move for states to create laws which are different across the country and impossible to enforce federally.

Conclusions: There have definitely been some issues raised in the interpretation of the regulation of pesticides which are not covered by FIFRA. The issues appear to be similar for organic pesticides and those pesticides used on marijuana, but more information and discussion is needed to see if a common remedy can be used for both. The recent issues and concerns have come from the questions about how to deal with impurities which may be found in products used in organic farming and/or the production of marijuana, but more than likely, the bigger issues deal with creating a risk-based evaluation of pesticides residues in these crops in general.

FIFRA does not even mention "organic" or "marijuana" and PRN 96-8 was researched and authored before organic and marijuana production became larger issues. The NOP and PRN 2003-1 do not cover or redefine terms such as "adulteration" or "misbranding" and were more defined for characterizing organic opportunities and the ability to label products for use as such. To my knowledge, there have been no Federal enforcement actions taken on products that fall into this gap (organic vs traditional) relative to being "adulterated" and "misbranded" outside of the PRN 96-8 guidance. It's only been States bringing lawsuits against companies due to their problems with regulating pesticide use on marijuana.

In marijuana production, it appears that farmers are using products recommended by states that have not gone thru any research and testing for proper ways to apply those products. No research has been done on residues in the raw agricultural commodity nor in any of the processed commodities which are produced from this crop. It is not known how various pesticides may concentrate in oils that might be extracted from marijuana and more research needs to be done on the crop and oils themselves.

Conducting the appropriate research to resolve these issues and concerns is always best done when the topics are openly discussed between the appropriate parties. When rules are openly established, industry is more open to producing products which can be used by the appropriate parties and better input is gained when all parties are involved. The definitions set up in FIFRA and risk-based contaminant standards put forward in PRN 96-8 are what has been used by the regulated community up to now. While it appears that some changes might be appropriate, more open discussion and possible research are needed to be sure those changes are based in accurate knowledge of the problems and solutions.

As previously mentioned, Mr. Messina's letter did much in defining what some of the issues were, but some of the statements related to the regulation of organic products are definitely not what has been in practice to date. The letter was not published for comment, nor even made generally available. As far as I can tell, it was only published on AAPCO's website (https://aapco.org/documents/). I was alerted to it by a lawyer colleague, when it was produced in a legal case he is assisting with. Toward the end of the letter, the comment was made to AAPCO & SFIREG that *"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."* Since the pesticide industry is a key partner in producing the products being used, I would hope that this cooperation would also extend to it as well.

Please let me know if you would like to discuss this further.

Jim Kunstman, PhD.

FIFRA References:

Section 2 (§136. Definitions)

(c) Adulterated The term "adulterated" applies to any pesticide if—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

Section 12 (§136j. Unlawful acts)

(a) In general

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.