



25(b) Workgroup

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Via Electronic Submission

RE: Docket ID Number EPA-HQ-OPP-2020-0537

Pesticides: Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions Under FIFRA Section 25(b)

The Association of American Pesticide Control Officials (AAPCO) FIFRA Section 25(b) Workgroup (member list in Appendix A) appreciates the opportunity to comment on EPA's advance notice of proposed rulemaking regarding minimum risk pesticides and other exemptions under FIFRA Section 25(b). The opinions in this document are those of the workgroup members and do not necessarily represent the opinions of the individual state's Secretary of Agriculture. It is the opinion of the workgroup that the current process for initiating a review of a substance or for implementing a decision of a substance for use in a minimum risk pesticide is efficient. However, the current lists of active and inert ingredients need further clarification and/or standardization. Even though these lists are relatively limited, states have seen an explosion in the quantity of minimum risk products entering the marketplace in just a few short years. This reflects industry's response to the increasing public demand for minimum risk products. Accepting additional ingredients under FIFRA Section 25(b) will increase the number of potentially exempt products, thereby increasing the burden on states, which are already expected to review such products in their entirety, because EPA does not.

As EPA is likely aware, the shifting of the review for minimum risk products to states has resulted in an inconsistent patchwork of requirements for product labels, advertising, and efficacy data among states that registrants must navigate to achieve state approval for their products. This process proves frustrating both for industry and state regulators and potentially dangerous to consumers and the environment. In the current system, states put in duplicative labor reviewing minimum risk products, often with widely varied interpretations of acceptability—much to the frustration of industry, who must then allocate additional time and resources to meet each state's needs. This in turn generates different versions of market labels, creating "compliance" that cannot be verified through market enforcement and often goes unnoticed. Relaxing or streamlining the process by which substances are approved for addition to the ingredient lists increases the risk for substances to be accepted without the proper time, data, and other information necessary to allow for thorough vetting by EPA. Such a change would place even greater pressure onto state agencies, agencies that, in many cases, already struggle to complete a thorough review of every minimum risk product and to identify those that have entered the marketplace without proper submission.

In response to these pressures, the AAPCO FIFRA 25(b) Workgroup has worked diligently over the past several years to combat inconsistencies between states, putting together various guidance documents for minimum risk manufacturers regarding both product labeling and efficacy data standards (see Appendix B & Appendix C respectively). These documents are an effort to bring consistency in terms of what states will consider acceptable submissions for minimum risk products and are those which most states will approve if the criteria are met. Due to the challenges and time involved with



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rulemaking, some states have only been able to partially adopt the AAPCO FIFRA 25(b) Workgroup's guidance, or have not been able to officially adopt it at all, leaving these states behind in terms of consistency with the rest of the group. As the majority of state participants in the workgroup have adopted at least a portion of the guidance, and nearly all participants are in support of it, the workgroup suggests that EPA consider the addition of the AAPCO workgroup's label guidance and potentially the efficacy data guidance to the existing Conditions for Minimum Risk Pesticides. Addition of the label guidance to the existing conditions would bring consistency in minimum risk product labeling requirements to a national level that would be sufficiently acceptable in nearly all states. This would also provide support based on an official EPA action for states that have thus far been unable to adopt the guidance as official policy or rules. Failing that, the workgroup proposes that EPA draft additional guidance on minimum risk products, their qualifying ingredients, and efficacy data required to support claims.

The current criteria for determining whether a substance should be exempt from FIFRA is adequate; however, states and industry are in dire need of guidance on the mode and minimum threshold of efficacy data for minimum risk products. This is particularly important in the case of products that claim to control pests EPA has designated as Pests of Significant Public Health Importance. States are simply not equipped to evaluate efficacy data at the same standard as EPA and, whether the claim is made outright or implicitly, consumers do not understand the distinction between minimum risk pesticide products and Section 3 products. Consequently, products that do not sufficiently protect against public health pests find their way to market and, in time, will literally be a matter of life or death. A CDC survey from May 2020 showed that about one third of participants engaged in misuse of disinfectants; if current use directions are already ignored, it is likely the distinction between a Section 3 registered disinfectant and a minimum risk antimicrobial product that kills odor causing bacteria will be ignored or misunderstood by the general public.

Even when they do not directly endanger human life, 25(b) "minimum risk pesticides" pose other hazards to health and the environment. The "Minimum Risk Pesticides" classification carries the unfortunate implication that these products are harmless at any concentration, but that is simply not the case. For example, many products contain high percentages of active and "inert" ingredients which may pose an eye or skin danger or other health concerns, an issue further complicated by the fact that minimum risk pesticides are not required by the EPA to bear a signal word, precautionary statement, or adequate First Aid directions. The EPA should consider placing limits on the percentage of certain active ingredients that are available in the formulated product. If the product would require a "Danger" signal word due to concerns for eye damage, the product is not a "minimum risk." If the formulated product would require anything other than a "Caution" signal word along with the basic precautions, then it should not be considered a "minimum risk" pesticide product.

There are also environmental concerns with the use of products in water bodies for the control of mosquitoes and mosquito larvae. The application of any product to water bodies must be done with great care and only in conjunction with sufficient data to ensure the protection of all aquatic organisms and the quality of the water. Further, when considering products that are a "minimum risk" to public health and the environment, the products should be scrutinized more for possible impacts to low-



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income and minority populations. Due to the higher probability of consumer fraud and the prevalence of low quality, ineffective products in low-income and minority communities, additional protection is warranted.

One suggested improvement of the existing system is a review of the current list of ingredients to establish additional guidance for potential dual use active/inert ingredients. A table that identifies the percentage by weight in which a dual-purpose ingredient would require acknowledgment as an active ingredient would be particularly helpful. For example, corn gluten meal is listed as an acceptable active ingredient. However, corn gluten meal is also listed as a commonly consumed food commodity and therefore could also be an acceptable inert ingredient. Another example of a dual-purpose ingredient is vinegar. Vinegar is currently listed as an acceptable inert ingredient for a minimum risk pesticide. However, this same ingredient is also a registered Section 3 active ingredient. States have seen products that claim to be minimum risk pesticides for controlling weeds that contain greater than 40% vinegar as an “inert” ingredient. At such a concentration, there is little doubt that the vinegar is an active ingredient and therefore does not qualify as a minimum risk pesticide per established guidance. States have encountered similar problems with diatomaceous earth. Like vinegar, this ingredient is acceptable as an inert in minimum risk pesticides but is a registered active for Section 3 products. Flea and tick powders with high percentages of diatomaceous earth have been submitted to states as 25(b) exempt products under the guise of listing the ingredient as inert. Federal guidance on inert ingredient thresholds would be exceptionally helpful in such instances.

Minor improvements to changes already instated by EPA would also be of great assistance to states. The standardization of the label display name for ingredients in the 2015 rule change has made it slightly easier for states to ensure a company is using the correct ingredient. However, there are some states that statutorily cannot request a statement of formula for minimum risk pesticides. In these cases, the state does not see the Chemical Abstract Service (CAS) number for the listed ingredients. This could lead to companies listing an acceptable label display name while using an ingredient with an unacceptable CAS number. The workgroup suggests requiring the CAS number to be listed on the label for every ingredient. This would alleviate some of the burden on states and aid in ingredient transparency for consumers.

Another new suggestion the workgroup proposes is for EPA to require additional label elements on all minimum risk pesticide labels. Regular meetings between participating SLAs and the AAPCO workgroup has provided a more organized outline for review of ‘questionable’ labels, but these are again state-by-state requirements. States would find it helpful if EPA requirements could include the “Keep Out of Reach of Children” statement on all labels and requiring labels to include at minimum the signal word “Caution.” EPA could also require the addition of the disclaimer “Registration by a state is not an endorsement of safety or efficacy of this product” on all minimum risk pesticide labels, as well as a standardization of the First Aid section to include a minimum of the following precautionary language: “Avoid contact with eyes. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. If swallowed, immediately call a poison control center or doctor.”



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The workgroup also proposes implementing a procedure for minimum risk pesticide manufacturers to report all adverse effect information they receive to EPA and/or states. While EPA's added requirement for the inclusion of the company name, address, and phone number on the label as part of the 2015 rule change has increased the ability for states and/or consumers to reach out to individual companies regarding their products, companies are under no obligation to report to anyone when there is an adverse effect from one of their minimum risk pesticides. This information would be very beneficial in assisting with determining if the ingredient and/or product should remain classified as a minimum risk pesticide. If a product/ingredient causes a large number of adverse effects, then the product would not be minimum risk and could require registration as a Section 3 product.

Should EPA decide to consider adopting new acceptable ingredients into 25(b) products, it is imperative that all of the risk factors EPA currently uses be considered when making a determination. For example, allergen concerns are especially relevant as the open-ended nature of the inert list's "edible fats and oils" and "commonly consumed food/feed items" has led to friction between states and industry. Fish oil is one such ingredient—states have stated that fish oil is excluded as a commonly consumed food commodity due to its allergen potential, but a recent prospective minimum risk product registrant claims that fish oil is an acceptable inert ingredient since it is an edible fat and oil. Guidance from a federal level would eliminate this discrepancy.

One of the areas of concern for states regarding 40 CFR 152.25 is the lack of or inconsistent oversight and enforcement of EPA for non-compliant products. Individual states struggle to stop sales of pesticide products which meet some but not all of the minimum risk exemption criteria (non-compliant 25(b) products). These non-compliant 25(b) products are especially difficult when the company manufacturing and distributing the product is based in another state. At this time, there are only nine states that do not review and/or register 25(b) products. Even if one state successfully prevents a non-compliant 25(b) product from selling into its own state, the patchwork of different enforcement across states leaves a wide gap for a company to continue manufacturing and distributing a non-compliant 25(b) product nationwide. The growth of e-commerce has compounded this issue significantly. By definition these non-compliant 25(b) products are unregistered pesticides and violate Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A). However, EPA's Office of Enforcement and Compliance Assurance (OECA) has only very rarely taken enforcement actions against companies who manufacture and sell pesticides that meet some but not all of the 25(b) minimum risk pesticide criteria. OECA has repeatedly failed to take action against distributions of unregistered pesticides if they are non-compliant 25(b) products. Pennsylvania has reported numerous minimum risk pesticide products claiming to prevent malaria or even control SARS-CoV-2 to EPA and has not seen any action taken by EPA. In those 9 states that do not review or register minimum risk products, there is almost no oversight or enforcement of non-compliant 25(b) products at either the state or federal level. Wisconsin's suggestions would be to set up a referral system whereby states can refer non-compliant 25(b) products to OECA and/or Regional EPA enforcement officers. Referrals could be limited to non-compliant 25(b) products that are being actively sold in multiple states which fail to meet all of the 25(b) minimum risk exemption criteria and which have not been able to be brought into compliance after working with state registration officials. Additionally, we would like to see an increase in enforcement efforts by OECA for



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non-compliant 25(b) products, specifically, having EPA Regions and OECA issue Stop Sale, Use, or Removal Orders (SSURO) for non-compliant 25(b) products which would prohibit the distribution or sale of unregistered pesticide products under Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136k(a). These products are in fact unregistered pesticides but are not treated as such by EPA.

When considering the addition of a new class of exempt pesticides like peat, EPA should write the exemption to be clear and concise. The workgroup has no issue with the addition of peat as described and ask that EPA write the exemption for peat similar to the current exemption for cedar. The exemption would be only for the raw commodity for the specific uses presented. If the peat were processed in any way the product would not be exempt. A clear exemption reduces the burden on the states and industry for those products.

In closing, the workgroup would reiterate that all aspects of compliance and enforcement, and the ramifications of those upon state workloads, should be considered before any new ingredients or classes of product are incorporated into the FIFRA 25(b) exempt category. Already, many state agencies are stretched thin and unregistered products move into the market, undocumented and unregulated. That said, industry and consumer interest has shown that there is merit to minimum risk pesticides, and with proper federal attention and guidance, these products can be brought up to the correct standards to adequately protect both people and the environment.

On behalf of the AAPCO FIFRA 25(b) Workgroup, thank you for this opportunity to comment on this advanced notice of proposed rulemaking and to express our concerns. Please contact emillette@nmda.nmsu.edu if you have any questions.

Sincerely,

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