July 7, 2021
Charles Smith, Acting Director
Biopesticides and Pollution Prevention Division (7509P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW, Washington, DC 20460–0001

Re: Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions Under FIFRA Section 25(b) (EPA–HQ–OPP–2020–0537)

Dear Acting Director Smith,

On behalf of the Household & Commercial Products Association[1] (HCPA) and its members, we are submitting comments on the ANPRM Minimum Risk Pesticide Products (EPA–HQ–OPP–2020–0537). The members of HCPA recognize that minimum risk pesticides are an important analogue to conventional pesticides, and we have undertaken numerous efforts to improve and expand the 25(b) program. We support the intent of minimum risk products as originally intended of protecting the end user from non-public and public health threats and driving innovation while affording appropriate regulatory oversight without over-burdening the EPA, states and registrants. Further, this letter proposes a refinement to this valued program by implementing changes at the Federal level that are inclusive of the needs of all stakeholders and do not place an unfair burden on any one agency or stakeholder group.

Since 1996, when EPA finalized a rule under section 25(b) of FIFRA that exempted minimum risk pesticide products (MRP) from federal registration requirements if products met specific conditions, HCPA has worked to constructively improve the program.[2] The number of 25(b) products in the marketplace has grown significantly since inception and many HCPA companies have embraced these products to meet consumer demand. Consumers are increasingly seeking

[1] HCPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than $180 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. HCPA member companies employ hundreds of thousands of people globally. HCPA represents products including disinfectants that kill germs in homes, hospitals and restaurants; air fresheners, room deodorizers, and candles that eliminate odors; pest management products for pets, home, lawn, and garden; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day.

[2] Consumer Specialty Products Association Letter and EPA Response re: Minimum Risk Pesticide Exemption Petition https://www.epa.gov/minimum-risk-pesticides/consumer-specialty-products-association-letter-and-epa-response-re-minimum

alternatives to traditional pesticide products and the Minimum Risk Pesticide Listing Program enables companies to meet these demands in a safe, compliant, and timely manner. Importantly, minimum risk and conventional pesticides are available in retail locations side-by-side, therefore it is essential that all pesticidal products be held to consistent labeling and efficacy requirements in order to protect the public health.

While 25(b) MRP products are exempt from federal registration under FIFRA, the majority of states (currently about 40) require registration and requirements vary from state-to-state. The requirements include submission of labels, safety data sheets (SDS), confidential statements of formulation (CSF), efficacy data and multiple combinations thereof. Ironically, the two states most adept at reviewing pesticide products and associated data are California and New York[3] whom rely on the 25(b) product exemption and, therefore, do not currently review MRPs before market entry.

In an effort to address these varied requirements, in 2017 the American Association of Pest Control Officers (AAPCO) formed the FIFRA 25(b) Work Group with the mission "to facilitate the collaboration of states and industry in order to share information, provide guidance, foster label consistency, and reduce the duplication of efforts in the review and registration of minimum risk pesticide products," and to further this goal, AAPCO developed Data Efficacy Guidelines,[4] Label Guidance[5] and Inert Ingredient Research Guidance[6]. Additionally, most states lack sufficient resources or expertise to review technical efficacy data and generally cannot legally share registrant data or the outcome of the review to leverage collective resources. This in turn forces registrants to submit data to multiple states with concern that each state will interpret it differently. Unfortunately, the resource and technical skills required for state review of registration for MRPs has created a higher registration burden on states to ensure public health protections than for Section 3 registration products, which significantly rely upon the Federal review.

This situation has paved the way for an industry-state partnership seeking alignment on increased Federal oversight to address the public health concerns and resource burden associated with MRPs. Change is necessary to the MRP regulation to ensure consistent protection of consumers from public health threats, reduce the burden upon state regulatory agencies, create a level playing field for registrants and drive innovation of minimum risk pesticide products. We share a common concern that all consumers using MRPs remain

[3] New York has indicated that they will pursuing state registration in the future. https://www.dec.ny.gov/docs/materials_minerals_pdf/320slides.pdf

[4] https://aapco.files.wordpress.com/2019/03/efficacy-data-guidelines-1-22-19.pdf

[5] https://aapco.files.wordpress.com/2021/02/25b-label-guidance-with-labels-revised-2021.pdf

[6] https://aapco.files.wordpress.com/2020/02/25b-inert-research-guidance-2.10.2020.pdf

protected from public health pests and with that in mind, we offer the following comments for consideration:

HCPA recommends that EPA develop a streamlined registration process for Minimum Risk Pesticides focusing on those products that make public health claims (or claims to control public health pests). Our proposal is for a modified registration limited to a review of a document listing only the proposed public health pests and associated efficacy claims for a market label along with the supporting efficacy data. The document would be similar to a master label but would not include typical Section 3 requirements. The data would continue to be exempt from GLP requirements. HCPA understands this modified registration will require Agency resources and are willing to work with stakeholders to address this concern. This proposed program could be accomplished by the addition of a Condition 7 that mandates registrants generate efficacy data in support of public health claims and claims to control public health pests. EPA review and acceptance of this data with subsequent sharing of these reviews with state agencies would obviate the need for individual state requirements and inconsistent reviews.

HCPA recommends the development of guidelines, either as part of the 810 guidelines or as a separate PR Notice, to provide registrants the details and the success criteria of the efficacy studies required for MRP products. These guidelines would give the states the necessary tools to review products against the same success criteria, reduce inconsistencies between multiple individual state reviews and create a consistent level playing field for registrants.

HCPA also recommends greater enforcement from Federal EPA on 25(b) products currently in the market that do not meet the 6 conditions required to qualify for the Minimum Risk Pesticide exemption.

HCPA recommends EPA develop a formal process for the evaluation of substances for inclusion as active and inert ingredients for MRPs. The current Administrative Procedure Act petition process is ineffective and makes it challenging to adding substances in a timely manner. As the three plus year petition for inclusion of chitosan demonstrates,[7] the process can take many years and is dealt with on a case-by-case basis. This significantly increases the costs and burden, by both EPA and petitioners, associated with adding a substance, which further discourages addition of minimum risk substances. The lack of a thorough consideration of these concerns may exacerbate the existing issues with MRP products for registrants and state regulatory agencies, especially when there are existing Section 3 products making similar public health claims. Additionally, numerous states are now requiring generation of additional

[7] https://www.govinfo.gov/content/pkg/FR-2020-11-02/pdf/2020-22646.pdf

data as a condition of registration and suggesting that a consistent, science-based approach would be beneficial.

HCPA recommends formalizing a petition process that will also identify and hopefully address concerns earlier in the petition process.[8] HCPA further recommends EPA develop a process to enable greater degrees of flexibility within the existing lists of permissible active and inert ingredients. For example, EPA has established precedence for permitting the inclusion of mixtures such as cat food and nutria meat in the inert list and HCPA would like to request that similar allowances are permitted for MRP actives, too. As manufacturers have become more accurate with their CAS number assignments, it is increasingly difficult to find materials that match the CAS numbers on the inert or active list. For example, sodium lauryl sulfate (SLS) has the CAS number 151-21-3 listed in the active ingredients list, but there are other CAS numbers associated with SLS depending upon source, purity and range of carbon atoms present[9] that share similar favorable toxicological character and pose little to no risks to human health or the environment. HCPA recommends a similar re-evaluation for other materials with multiple CAS numbers such as Vitamin E and oleic acid, to name a few.

HCPA believes that expansion of the MRP program is an important tool to encourage the use of lower risk pesticide products, and by extension lessen impacts to all communities, especially low-income and minority populations.

HCPA recommends reviewing the current list of inert ingredients for identification of potential ingredient additions to the MRP Listing Program. Additionally, HCPA encourages EPA to utilize other EPA programs to assist in identifying additional lower risk ingredients, e.g., low priority chemicals under the TSCA program or the Safer Choice Ingredients List. These ingredients should still be evaluated as described previously but they would be an excellent starting point to populate a list of additional ingredients.

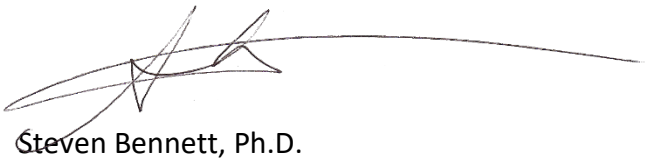
A change is necessary to the MRP regulation and registration process to ensure consistent protection of consumers from public health threats, reduce the burden upon state regulatory agencies, create a level playing field for registrants and drive innovation in the minimum risk pesticide category. Streamlining the MRP registration process along with increased Federal oversight and enforcement would assist state agencies in removing non-conforming products from the market and ensuring that only compliant products are registered and sold. In

[8] For example, comments contained within chitosan docket https://www.regulations.gov/docket/EPA-HQ-OPP-2019-0701

[9] https://www.productingredients.com/ingredient/info/sodium-lauryl-sulfate

addition, it would leverage the expertise of EPA scientists to benefit the Federal-State partnership. We thank you for this opportunity to share our concerns and look forward to improvements in minimum risk pesticides program at both the state and federal levels.

Sincerely,



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