FIFRA Section 25(b) Workgroup

December 21, 2020

VIA ELECTRONIC SUBMISSION

United States Environmental Protection Agency
Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Sir/Madam:

Re: Docket ID Number EPA-HQ-OPP-2019-0701
Proposal to Add Chitosan (Chemical Name: Poly-D-Glucosamine) to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products

The Association of American Pesticide Control Officials (AAPCO) FIFRA 25(b) Workgroup appreciates the opportunity to comment on the EPA's proposal which is in response to the 2018 petition brought forth by Tidal Vision Products LLC. This petition seeks to add the substance commonly referred to as chitosan to the list of active ingredients allowed in minimum risk pesticide products exempt from registration and other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* Chitosan is also known by its chemical name poly-D-glucosamine (CAS Reg. No. 9012-76-4).

It is the opinion of the workgroup that the proposal to add chitosan to the permitted active ingredients in Minimum Risk Pesticide products should not be granted. There are numerous concerns with the potential composition and purity of chitosan produced for Minimum Risk Pesticide products as well as potential adverse effects due to significant increase in exposure. Any adverse effects from the use of chitosan in Minimum Risk Pesticide products would not be required to be reported. This would include adverse human health and/or environmental effects. There are also concerns regarding inappropriate use and claims for the control of bacteria and mold.

The following seven factors described at 61 FR 8876 (March 6, 1996) are considered when substances are added to the list of substances exempted from FIFRA requirements as pesticides:

1. Whether the pesticidal substance is widely available to the general public.
2. If it is a common food or a constituent of a common food.
3. If it has a nontoxic mode of action.
4. If it is recognized by the Food and Drug Administration as safe.
5. If there is no information showing significant adverse effects.
6. If its use pattern will result in significant exposure.
7. If it is likely to be persistent in the environment.

Points 1, 2, 3 and 7 have been adequately addressed. However, points 4, 5 and 6 require additional scrutiny and discussion.

Point 4 - Recognized by the Food and Drug Administration as safe

According to the supporting documents, a search of the FDA inventory of Generally Recognized As Safe (GRAS) Notices indicates that chitosan does not have FDA GRAS status under 21 CFR 170.36. This point should be highlighted.

Point 5 - No information showing significant adverse effects

The following is taken directly from the EPA Science Review dated August 23, 2019 (EPA-HQ-OPP-2019-0701-0003):

> Although the source material for chitosan (chitin) is obtained from shellfish, industrially-manufactured chitosan is not likely to have allergenicity concerns, provided that all animal proteins are removed during the extraction and purification process from chitin. The harsh manufacturing process that involves demineralization with hydrochloric acid, protein removal with sodium hydroxide and a final extraction with organic solvents (review by Hamed et. al., 2016) is likely sufficient to remove and/or denature any proteins, fats and other contaminants of allergenic or other toxic concern (review by Muzzarelli, 2010). There are few credible reports of allergic responses to Chitosan exposure. One study in Japan noted that a “47-year-old female developed systemic urticaria and difficulty breathing” following oral ingestion of a chitosan-containing dietary supplement, but the purity of the Chitosan used in the study was unclear, and it appeared to be derived from a non-shellfish source (Kato et. al., 2005).

There may be allergenicity concerns for exempted chitosan products. Chitosan products which are currently registered by the EPA have undergone the EPA registration process and are produced by credible companies and entities. There is a real concern that if chitosan is added to the list of exempted active ingredients, products will be produced using inadequate extraction and purification processes and will contain chitosan of substandard purity and composition. Such products may be quite harmful to individuals with allergies. There may be little concern for allergenic response following exposure to highly purified chitosan, however, there is no control over the production and resulting level of purity for EPA exempted products.

Point 6 – If use pattern will result in significant exposure

The proposal declared “no increased risk to human health or the environment is expected from chitosan.” However, this is based on current use patterns and use rates of chitosan. Once an active ingredient is exempted from EPA registration, there is very little control on what new uses or use rates may be employed. It is impossible to know what future uses may be developed. In addition, currently registered chitosan products

bear labeling which warns of moderate eye irritation and this coincides with a relatively low percentage of active ingredient (0.25%). All EPA registered chitosan products have extensive First Aid Statements regarding eye and skin protection. Agricultural products bear extensive Personal Protective Equipment (PPE) requirements for applicators, mixers and loaders which include long sleeved shirt, long pants, waterproof gloves and protective eyewear. Minimum Risk Pesticide products are exempt from the Worker Protection Standard and in accordance with the six label conditions outlined by the EPA for exemption, they are not required to have any precautionary and first aid statements. Therefore, it is highly likely that there will be significant exposure if chitosan is added to the list of permitted active ingredients for Minimum Risk Pesticide products. Increase in use with additional use patterns and potentially higher concentrations with unknown purity without the current precautionary and first aid label statements will result in significant exposure.

The main reason given to add chitosan, and other active ingredients, to the list of active ingredients allowed in Minimum Risk Pesticide products is to save money associated with EPA PRIA fees and registration maintenance fees, as well as saving EPA resources that would be used reviewing and registering pesticide products of minimum concern.

The deregulation of pesticide active ingredients has far reaching impacts that are difficult to completely list or fully anticipate. In addition to the exemption from registration is the exemption from other FIFRA requirements and provisions. Those provisions include the requirement to report adverse effects in accordance with FIFRA Section 6(a)(2). This includes adverse effects to humans, domestic animals and the environment – especially bees and beekills. Also, Minimum Risk Pesticide products are not covered under the EPA provisions which protect Confidential Business Information.

The burden of review and registration is shifted to the states. Currently, **only nine states do not require registration** of Minimum Risk Pesticide products. The AAPCO 25(b) Workgroup was formed in the Spring of 2017 in order to help states deal with the many issues involved with Minimum Risk Pesticide products. The following is the mission statement: *The workgroup's mission is 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.* States have various requirements for data including efficacy data and limits. The workgroup has produced guidance documents regarding labels and labeling requirements as well as efficacy data requirements.

The lack of EPA regulation of Minimum Risk Pesticide products has caused confusion in the regulated community and pesticide users. Some agricultural and commercial pesticide users are hesitant to use products that are not EPA registered because there is a question as to whether the products are actually compliant with all exemption criteria. The lack of an easily identifiable EPA Registration Number and associated product label is very problematic. It is difficult to ascertain whether a product is legal and compliant.

The proposal stated the following regarding impacts to state pesticide registration agencies:

> The impact to each state will depend on how each state regulates conventional pesticides versus how they regulate FIFRA section 25(b) products. States which register conventional pesticides but not FIFRA section 25(b) products would see a reduced burden from the addition of chitosan to the FIFRA section 25(b) list. However, since most states defray that burden through registration fees, the overall impact is expected to be negligible.
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> Because the EPA does not review labels of FIFRA section 25(b) products, states may see an increased regulation burden of enforcing the conditions for labeling these products.

The amount of time, effort and resources expended by the states for the review and registration of Minimum Risk Pesticide products is exponentially compounded due to the lack of central EPA oversight. It certainly cannot be characterized as "negligible." Enforcement of Minimum Risk Pesticide products in the channels of trade is extremely burdensome due to the confusion surrounding these products and the lack of support for the pursuit of enforcement actions.

The exemption of certain active ingredients from EPA regulation has also blurred the line between pesticides and non-pesticides. Pesticides are no longer viewed as black and white; Minimum Risk Pesticides are in the unsure gray area. Some people are under the impression that exempted pesticides are actually not pesticides, not chemicals, are all natural and organic, and are "safe and non-toxic." This causes concern that the products will not be handled or used properly.

Chitosan is formed naturally by chitin deacetylases that have been identified in marine bacteria, fungi, and insects. Chitosan used in pesticide products is not a naturally occurring substance and must be chemically derived. Therefore, industrially-manufactured chitosan would not be considered "organic" or "natural" and such claims would be false and misleading.

Many unscrupulous companies take advantage of the lack of central EPA oversight. Chitosan is currently registered as an antimicrobial to inhibit growth of bacteria, mold, mildew and fungi. There is a real concern that products will be produced with false and misleading statements regarding efficacy against bacteria or for mold remediation. Many Minimum Risk Pesticide products present consumer protection concerns. Legitimate companies would prefer EPA registration instead of seeking registration in numerous states with numerous registration requirements.

Instead of switching the burden to the states, the maintenance of EPA's registration and central oversight would be the best option. The creation of separate lower fee PRIA categories to review and register chitosan and other minimum risk pesticide products would be the best option.

In conclusion, there are numerous concerns with the potential composition and purity of chitosan produced for Minimum Risk Pesticide products as well as potential adverse effects due to significant increase in exposure. There are also concerns regarding inappropriate use and claims for the control of bacteria and mold.

It is the opinion of the workgroup that the proposal to add chitosan to the permitted active ingredients in Minimum Risk Pesticide products should not be granted.

On behalf of the AAPCO 25(b) Workgroup, thank you for this opportunity to comment on this proposal and to express our concerns.

Please contact me if you have any questions.

Sincerely,

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