

January 4, 2021

Anne Overstreet, Deputy Director  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

**Re: Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products**

Dear Deputy Director Overstreet,

On behalf of the Household & Commercial Products Association<sup>1</sup> (HCPA) and its members, we are submitting comments on the *Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products*. 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. Our biggest concern is that all registrants of minimum risk pesticides are on level playing field to provide all an opportunity to be successful. We eagerly await the anticipated Advance Notice on a Proposed Rulemaking for "[Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions Under FIFRA Section 25\(b\)](#)" in which we can expand further upon our thoughts and considerations.

HCPA is not commenting on the merits of listing chitosan but rather, raising a number of concerns that do not appear to have been adequately addressed. The lack of a thorough consideration of these concerns may exacerbate the existing issues with 25(b) products for registrants and state regulatory agencies.

First and foremost, we are concerned that the proposal vastly underestimates costs associated with registering minimum risk pesticides. There is little doubt that cost to the federal government, including EPA, will decrease but the costs incurred by the patchwork of state requirements is non-reflective of the burden for the review of these products. Additionally,

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<sup>1</sup> 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.

numerous states are now requiring generation of additional data as a condition of registration which obviates financial and regulatory relief described in the proposal. It is confusing as to why this was noted in the Cost Analysis document (excerpted below) but was not discussed in the proposal itself.

**Impacts to the Petitioner from State Pesticide Registration Agencies**

*Some states require registration of FIFRA section 25(b) products. If the Petitioner wants to sell their product in these states, the Petitioner may face data generation costs similar to those that would be imposed by EPA for a national registration, eliminating most savings estimated above. The Petitioner could avoid these costs but would forego marketing in those states.*

HCPA recommends expanding the estimated incremental impacts section to better describe the potential cost to registrants at both the federal and state level.

Given that chitosan is currently on the FIFRA inert ingredients list and is approved for non-food use<sup>2</sup>, it is unclear how a registrant or state lead agency would determine whether chitosan is acting as an active ingredient or inert. This is an area that the states lead agencies have expressed as particularly challenging with inert ingredients<sup>3</sup> and the proposal does not address this consideration. Published literature reports a range of possible active ingredient functions, ranging from anti-microbial, plant growth stimulation, and insecticidal functions<sup>4</sup>. It is also reported to enhance the delivery of other active ingredients, making it challenging to ascertain whether it is functioning as an inert, synergist, or active ingredient in a given system. It is not clear from the petition what the applicant is claiming is the particular function of the raw material as an active ingredient or in what usage scenarios. It is not clear how regulatory authorities at the state or federal level would fairly and consistently ascertain its functionality in a formulation, in order to determine if and when it is acting in as an inert ingredient or as an active ingredient. If the material is considered exempt from FIFRA regulation only as an active ingredient and not as an inert ingredient, then this question carries significant importance in determination of whether a product containing it is considered exempt or not from FIFRA regulation. HCPA strongly recommends that EPA address this consideration before finalizing the proposal.

There is one CAS number for Chitosan listed in the petition, however, it is widely reported that this or similar materials are available in a range of varieties (e.g. different molecular weights), are often modified or made into chemical derivatives, or otherwise complexed with other materials (e.g. metal ions) to change the functional properties or to increase or change

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<sup>2</sup> [https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:3:::::P3\\_ID:9212](https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:3:::::P3_ID:9212)

<sup>3</sup> <https://aapco.files.wordpress.com/2020/02/25b-inert-research-guidance-2.10.2020.pdf>

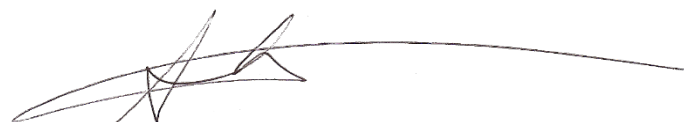
<sup>4</sup> For example, Sang-Hoon Lim & Samuel M. Hudson (2003) Review of Chitosan and Its Derivatives as Antimicrobial Agents and Their Uses as Textile Chemicals, Journal of Macromolecular Science, Part C, 43:2, 223-269, DOI: 10.1081/MC-120020161; Maher Z. Elsabee, Entsar S. Abdou, Chitosan based edible films and coatings: A review, Materials Science and Engineering: C, Volume 33, Issue 4, 2013, Pages 1819-1841, ISSN 0928-4931, <https://doi.org/10.1016/j.msec.2013.01.010>; Chitosan in Horticultural Crops; A Review. Molecules 2018, 23, 872.

functional activity<sup>5</sup>. Given that these modifications can significantly alter the functionality and by extension, the pesticidal activity, it is incumbent upon the EPA to consider and address how the limits or boundaries of the use of such a raw material and the possible derivations of it would be regulated and enforced as being exempt.

There are currently numerous registered FIFRA products containing chitosan<sup>6</sup> and it is unlikely that the registrants of these products will cancel or discontinue their registrations due to the costs already incurred. Additionally, it is unclear whether state lead agencies will register a minimum risk pesticidal product containing the same active ingredient as a FIFRA-registered product, or at least require additional testing to support the state registration. This would again incur additional costs or burden not adequately captured in the proposed rule. HCPA recommends that EPA incorporate additional costing information from the states and update the cost analysis accordingly to better describe the potential costs to registrants.

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 level.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steven Bennett', with a long horizontal line extending to the right.

Steven Bennett, Ph.D.  
Senior Vice President, Scientific & Regulatory Affairs  
Household & Commercial Products Association

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<sup>5</sup> Lei Zhang, Yuexian Zeng, Zhengjun Cheng, Removal of heavy metal ions using chitosan and modified chitosan: A review, *Journal of Molecular Liquids*, Volume 214, 2016, Pages 175-191, ISSN 0167-7322, <https://doi.org/10.1016/j.molliq.2015.12.013>; Assaad Kassem, George M. Ayoub, Lilian Malaeb, Antibacterial activity of chitosan nano-composites and carbon nanotubes: A review, *Science of The Total Environment*, Volume 668, 2019, Pages 566-576, ISSN 0048-9697, <https://doi.org/10.1016/j.scitotenv.2019.02.446>;

<sup>6</sup> A search of the National Pesticide Information Retrieval System (NPRIS) (<http://npirspublic.ceris.purdue.edu/ppis/>) of CAS Reg. No. 9012-76-4 on 12-10-2020 yielded 12 Companies with 1 or more registered product.