

Tidal Vision

From the Ocean, for the Ocean.

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Via Certified Mail & Electronic Mail (Email)

Zach Wilkinson, COO
Tidal Vision Products, LLC (submitters)
5506 Nielsen Ave., Ste A
Ferndale, WA 98248

October 10, 2018

**Re: PETITION TO LIST THE MATERIAL CHITOSAN CAS # 9012-76-4 ON THE US EPA
FIFRA MINIMUM RISK PESTICIDE LIST 40 CFR 152.25(f)**

Dear Administrator Wheeler:

This petition is in reference to Environmental Protection 40 CFR Part 152.25(f), Exemption of Certain Pesticide Substances from Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Requirements. This rule became effective May 6, 1996, under the authority of FIFRA Section 25(b). The US Environmental Protection (US EPA) identified a list of pesticidal active ingredients that it believed were not of a character necessary to be regulated under FIFRA because they pose little to no risk to human health or the environment. This list is referred to as the Minimum Risk Pesticide list (MRP List).

This petition proposes that the substance commonly called chitosan, with a CAS # of 9012-76-4, be added to the list of pesticide active ingredients on the EPA Minimum Risk Pesticide List, 40 CFR Part 152.25(f).

Chitosan meets all seven of the criteria the EPA considers when placing a substance on the MRP List. Just like the other substances on the MRP List, chitosan is a safe, natural substance, abundant in nature, with many beneficial applications. There are no environmental, health, or economic risks to making this change. In fact, there are strong environmental, and economic benefits to making this change. This petition describes all of these points in great detail.

The primary purpose of this rule change will be to eliminate the burden on the US EPA and on the businesses that manufacture, sell, distribute, transport, and use chitosan in the USA. Additionally, this action responds to society's increasing demand for more natural and benign methods of pest control. This change will result in a significant reduction in cost and time for the US EPA and the industry; and will not materially increase or change the overall risk to the environment or the public. It may, in fact, reduce the overall risk to the environment and the public by increasing availability of chitosan and increasing safer chemistry use and innovation in the USA.

Commercially produced chitosan typically utilizes a three-step process which extracts chitin from crustacean shells (a waste stream from the seafood industry), and then produces chitosan from the chitin by deacetylation.ⁱ While this process has been the industry standard for many years, it creates waste streams that can create environmental hazards, limiting production of chitosan in countries with good environmental laws like the USA. However, in recent years, several companies have developed cleaner processes for producing chitosan that do not produce waste streams. One such company, Tidal Vision (the submitters of this petition), was awarded the 2015 Safer Chemistry Champion Award from the Washington State Department of Ecology and the US EPA.

Chitosan is a naturally-occurring substance that is produced in nature and found in the cell walls of nearly all fungi. Chitosan can also be derived from chitin, which is also naturally-occurring and contained in the exoskeletons of arthropods, such as crustaceans (i.e. crab, shrimp, lobster, etc.), insects, and in the cell walls of algae and fungi. Chitin is the second most abundant polysaccharide after cellulose.ⁱⁱ Microbes in nature produce enzymes that break down chitin and chitosan, resulting in sugars that are metabolized as a carbon and nitrogen source.ⁱⁱⁱ Chitosan does not persist in the environment and there are no reports of a naturally-occurring accumulation of chitin, indicating the abundant biopolymer has a high turnover rate due to natural degradation.^{iv}

This petition outlines in detail how chitosan meets the seven criteria that were considered for placing the original materials on the 40 CFR part 152.25(f) (MRP List). In addition, this petition explains some of the ways in which chitosan will continue to be regulated once listed on 40 CFR part 152(f) as well as the expected benefits to the US EPA, industry, and the environment in making this change.

Thank you for your time and consideration of this petition that is critically important to our business and to that of our associates. Please do not hesitate to contact me if you have any questions.

Sincerely,

Zachary R. Wilkinson

Zach Wilkinson

COO, Tidal Vision USA

With letters of support provided from:

- 1. United States Senator Dan Sullivan (AK)**
- 2. United States Senator Lisa Murkowski (AK)**
- 3. United States Congressman Seth Moulton (MA)**
- 4. Alaska State Governor Bill Walker (AK)**
- 5. Washington State Senator Doug Ericksen (WA)**
- 6. Trident Seafoods (WA Seafood Company)**
- 7. Leigh Fibers (SC Textiles)**
- 8. Method Home (CA Home Cleaning)**
- 9. Bornstein Seafoods (WA Seafood)**
- 10. Pacific Grow (WA Fertilizer)**
- 11. Apollo Nantotech Inc. (CA, Biotech)**
- 12. Karamedica, Inc. (NC Biotech)**
- 13. Tramfloc, Inc. (TX Water treatment)**
- 14. Trees of Corrales (NM Tree Farm)**
- 15. Northwest Green Chemistry (WA Environmental Non-Profit)**
- 16. West Coast Seafood Processors Association**
- 17. National Council of Textile Organizations**
- 18. Alaska Bering Sea Crabbers**
- 19. Aleutian Pribolof Island Community Development Association (APICDA)**
- 20. Alaska Seafood Marketing Institute (ASMI)**
- 21. Alaska Fisheries Development Foundation (AFDF)**
- 22. Juneau Economic Development Council**
- 23. The Port of Bellingham**
- 24. Washington State University, Dr. Jeremy Jewell Ph.D.**
- 25. Washington State University, Dr. Kiwamu Tanaka, Ph. D.**
- 26. Washington State University, Dr. Natalie Moroz, Ph. D.**
- 27. Washington State University, Dr. Lee Hadwiger Ph. D.**

1.0 INTRODUCTION

Below is a summary of the contents of each section in this petition. The submitters of this petition have put considerable effort into providing robust documentation for each of the points brought forward by this petition based on publicly available information. As often as possible, US EPA published documents have been cited. It is recognized that the US EPA has access to a wealth of internal scientific data and expertise, as well as economic data regarding the costs associated with this regulation and this substance and therefore may be able to bring even greater light to some of these topics.

2.0 Costs Associated with the Current Regulation.

This section outlines the costs and time burdens of the current regulation on both the Agency and the registrants from three perspectives:

1. A third party report on the topic,

2. Data gathered from the US EPA, Information Collection Request (ICR) which was submitted to the US Office Management and Budget (OMB), and
3. The recent experience of the submitters of this petition.

In addition, this section describes some of the impacts the current regulation has on consumers, society, and the economy.

3.0 Costs and Oversight Associated with the Proposed Rule Change.

This section describes how the costs and burdens will be improved for the Agency and the registrants after this change has been completed, as well as the oversight and regulation that will remain on chitosan after the change.

4.0 Applying the Considerations to Listing Substances on the US EPA's Minimum Risk Pesticide List to Chitosan

This section identifies the seven considerations and criteria applied to the substances currently on the MRP List and how each of them relates to chitosan.

5.0 Environmental Advantages of the Proposed Rule Change

This section describes environmental advantages of domestic chitosan production and to increasing chitosan's availability to consumers and industry. These are positive, indirect effects of making the rule change proposed by this petition. While these are somewhat speculative, they are relevant given the overall mission of the Agency.

6.0 US Economic Competitiveness Advantages of the Proposed Rule Change

This section describes some of the ways in which making this rule change will increase the US economic competitiveness, specifically by increasing economic incentives for businesses and researchers to pursue innovation, and manufacture of chitosan and chitosan products domestically. This section also explores some of the ways in which the current regulation obstructs these advantages.

7.0 Conclusion

This section is a summation of the request this petition puts forth.

2.0 COSTS ASSOCIATED WITH CURRENT REGULATION

The term "registrants" is used to describe companies who are required to apply for pesticidal product registration to the US EPA under the current regulation.

In proposing the addition of chitosan to the MRP List, the goal is to reduce the monetary burden to the US EPA and registrants, and to respond to societies increasing demand for more natural and benign methods of pest control. This section discusses the costs associated with the current regulation to the Agency, to the registrants, and to society. The following section (Section 2) addresses what those costs or differences will be after the proposed change.

The submitters of this petition recognize that the EPA understands its internal costs better than can be easily understood from an outside perspective. The submitters do not attempt to dictate what those exact costs are, but intend to provide readers of this document from outside the Agency with a frame of reference regarding the expenses associated with the registration process.

Due to the complexities of the process and the large number of variables, determining an average cost per registration is not prudent. This section offers three perspectives on the costs associated. While none of these perspectives arrive at the same numbers exactly, they all indicate significant costs to the Agency and the registrants for pesticidal product registration. For the substance in question, costs range from the hundreds of thousands into the millions and the process takes anywhere from 1.5 to 4 years.

2.1 Costs /Burdens associated with current regulations (registration)

Monetary costs incurred by the EPA for a single registration have been estimated to be \$940,600 according to *"Analysis of Cost Estimates and Additional Resources Required for Timely FIFRA/ESA Pesticide Registration Review"* documented by Summit in 2013.^v These costs assume:

1. Labor costs for US EPA estimated to be \$142,000 per Full Time Employee (FTE)
2. An assumed 2.3 FTE and \$30,000 in non-labor costs
3. A fixed cost of 2 FTE and \$300,000 for maintaining Bulletins Live

This does not include the costs incurred by the company for registering their product, the costs to the general public, or the time required to move through the registration process.

2.2 Costs/burdens according to EPA Document No.: 0277.17, OMB No.: 2070-0060 "Supporting Statement for an ICR"

The US EPA is required to submit Information Collection Requests (ICRs) to the US Office Management and Budget (OMB) with estimates of the cost to the Agency as well as the cost or financial burden for applicants according to the Paperwork Reduction Act.^{vi} The documents cited in this section were developed by the US EPA and submitted to OMB as estimates of the Burden of costs, both in terms of time and money to the Agency and to the registrants in order to register pesticides according to the current regulation.

"The paperwork burden from pesticide registration comes from two sources: the burden that results from preparing and filing the registration application, and the PRA burden associated with scientific study data generation."

The total annual costs to the Agency associated with the paperwork burden from data generation is \$96.25 million per year^{vii}. The total cost for data generation for new products is \$33.66 million per year.

Since chitosan is a known active ingredient which has already been registered, new products containing chitosan are considered "new products" or "Type B". Type B new chitosan products can either fall under the BPPD (Biopesticides, and Pollution Prevention Department) or the AD (Antimicrobials Division) depending on the intended use of the product being registered. In the case of a company that manufacturers chitosan as a raw material and manufactures products containing chitosan, there are countless uses and products for such a ubiquitous material. Each product or use could require its own registration. For the submitters of this petition, the costs to the Agency and the registrant will be many times the costs for one new product registration. Registrations will be required for multiple forms of the substance, for multiple products, and for both BPPD and AD independently.

"Registrants spend a total of 31,551 burden hours, at a cost of \$2.888 million to prepare and submit "Type B" to the Antimicrobial Division, and 8055 Burden hours at a cost of \$737 thousand to prepare and submit "Type B" applications to the Biopesticides and pollution Prevention Division."^{viii}

For a single new product, the US EPA estimates the cost to applicant for data generation and paperwork to be \$140,100 for a product under the Antimicrobials Division, and \$155,800 for products under the Biopesticides and Pollution Prevention Division.^{ix}

The complexities of the registration process mean there are a multitude of ways to calculate the burden or costs associated with registration for the Agency and the registrants. For any registrant whose business model requires one or more registrations, the costs to the Agency and the registrant will most certainly be in the hundreds of thousands, and quite possibly into the millions.

2.3 Costs/burdens of registration according to the petition submitters' recent experience

Concurrent to submitting this petition, the submitters of this petition when faced with the overwhelming complexity and burden of registering pesticidal products, sought the help of several consultants who specialize in assisting businesses with navigating this process, and preparing and submitting pesticide registration applications. Formal quotations for services as well as outlines of the registrations required based on the business model were received from two consulting firms. Both of these quotations were presented under the burden of non-disclosure, so the submitters of this petition cannot legally share the documents, or the names of the firms. Rather, a generalization of the information has been presented below. This information is real and recent. Concurrent to the submission of this petition, the submitters of this petition is pursuing at least six chitosan pesticide product registrations currently, with more to follow.

2.4 Company registration costs

- At the time this petition was submitted, the submitters had already spent greater than \$35,000 in consultation fees. This is in addition to greater than 200 hours of company time. This does not include testing and data collection which will be required, and it does not include time spent working on this petition.
- The submitters of this application were originally unaware that the material they manufacture, chitosan (their one and only product), was listed as a pesticide by the US EPA. Upon this discovery in the first quarter of 2017, the submitters began the process of pesticide registration. At the time of this petition submission, the submitters have not yet been able to compile an adequate application for registration. Given the timeline estimated for review, the most optimistic timeframe for bringing these products to market is early 2020, three years behind schedule and acutely above budget.
- Based on actual quotes, consulting services can range in cost depending upon the nature of the registration requirements. A conservative estimate based on experience is \$50,000- \$150,000 per registration.
- Data collection, either through independent lab testing or citing available compensable literature, can easily exceed \$30,000 - \$100,000 per registration.
- Animal testing can be required to provide toxicity data for registration. In this case animal testing may prove redundant since chitosan's toxicity profile has been studied extensively and is well documented.
- Time commitments for testing, assembling a complete application for registration, meetings with the US EPA, and waiting for the application to be reviewed can take at least 18 to 36 months. During that time, each company pursuing registration is unable to take full advantage of economic potential in the marketplace. The delay to bringing a product to market could cost millions alone. In many cases, due to the critical role timing plays in a successful product launch, these losses might never be recovered.
- In today's economic environment, successful product launch is fast paced, and often necessitates trying a wide range of product variations in order to learn the precise product details that the market and consumers demand. Under the current regulation, even slight formula adjustments are virtually impossible due to the rigid specificity required for FIFRA product registrations. This results in mismatched products/applications because companies are forced to predict very specific consumer demand multiple years into the future. This further dissuades businesses from launching new products with substances regulated in this way. While the submitters agree that regulatory rigidity makes sense for hazardous or dangerous substances, chitosan is a safe and non-hazardous material, and the regulatory process is acting counter to its intent.

2.5 Effect on consumers and society

In the original ruling for the MRP List, the US EPA states, "The Agency, in promulgating this rule, is responding to society's increasing demand for more natural and benign

methods of pest control, and to the desire to reduce governmental regulations and ease the burden on the public.”^x

- Under the current regulation, the expenses above ultimately fall on the consumer in the form of federal taxes and increased prices of products containing chitosan. Companies are forced to recover regulatory costs by increasing prices of end products, and the expense to the US EPA for product registrations is significant.
- Under the current regulation, the satisfaction of society's demand for more natural and benign methods of pest control is reduced because when faced with this regulatory burden, most companies simply choose not to launch or even research/develop products containing chitosan.
- Under the current regulation, product developers, investors, and start-up businesses choose not to pursue new innovations which include chitosan due to the regulatory burden involved with bringing a product to market. Product launches are delayed one to three years
- Under this regulation there are many examples in supermarkets today (beyond chitosan alone) where companies simply remove pesticidal claims from labels rather than registering products. As a result, consumers have less information available to them about the products they buy. The MRP List presents a very practical compromise —while still maintaining adequate labeling requirements— without overburdening companies for demonstrably safe products. In other words, it encourages companies to play by the rules, which is ultimately better for the consumers

3.0 COSTS AND OVERSIGHT ASSOCIATED WITH THE PROPOSED RULE CHANGE

3.1 Costs / Burdens after chitosan has been moved to the MRP List

According to “Labeling Change for Certain Minimum Risk Pesticides under FIFRA Section 25(b)”, EPA No. 2475.01, OMB No. 2070-0187,^{xi}

“Since minimum risk pesticide products are not registered by EPA, the product information associated with the pesticide registration process under Section 3 of FIFRA are never submitted to EPA. However, approximately 37 states and the District of Columbia require products that are exempt from FIFRA requirements under 152.25(f) to obtain a state registration.” “In some states, manufacturers of minimum risk products are only required to pay a registration fee; in others, there may be label review, which can include a review of ingredients used in the products and a few require safety data sheets and data on product efficacy.”

And

“Minimum risk pesticide products are exempt from federal registration requirements, and manufacturers of these products do not submit any data, forms, or labels to EPA.”

So, the result of this proposed change will be that the US EPA will no longer incur any future costs related to regulation of chitosan products, and businesses will not have any direct costs associated with US EPA regulation of chitosan. Additionally, the path to the market for products will be 1-4 years faster. This will make chitosan a viable product for innovative startups in America to pursue.

However, once chitosan is added to the MRP List, it will still be subject to federal protective oversight. This proposed change would relieve the burdens listed above, however, extensive regulation of products using this material will still exist.

3.2 Federal Oversight that will still apply

Below is the federal list of conditions that would still be required to be met by any chitosan product making pesticidal claims after adding chitosan to the minimum risk pesticide list.

Ingredients listed on the minimum risk list are still required to meet the following conditions:^{xii}

- **Condition 1:** The product's active ingredients must only be those that are listed in 40 CFR 152.25(f)(1).
- **Condition 2:** The product's inert ingredients may only be those that have been classified by EPA as:
 - Listed in 40 CFR 152.25(f)(2)
 - commonly consumed food commodities, animal feed items, and edible fats and oils as described in 40 CFR 180.950(a), (b), and (c); and
 - certain chemical substances listed under 40 CFR 180.950(e).
- **Condition 3:** All of the ingredients (both active and inert) must be listed on the label. The active ingredient(s) must be listed by label display name and percentage by weight. Each inert ingredient must be listed by label display name.
- **Condition 4:** The product must not bear claims either to control or mitigate organisms that pose a threat to human health, or insects or rodents carrying specific diseases.

- **Condition 5:** The name of the producer or the company for whom the product was produced and the company's contact information must be displayed prominently on the product label.
- **Condition 6:** The label cannot include any false or misleading statements.

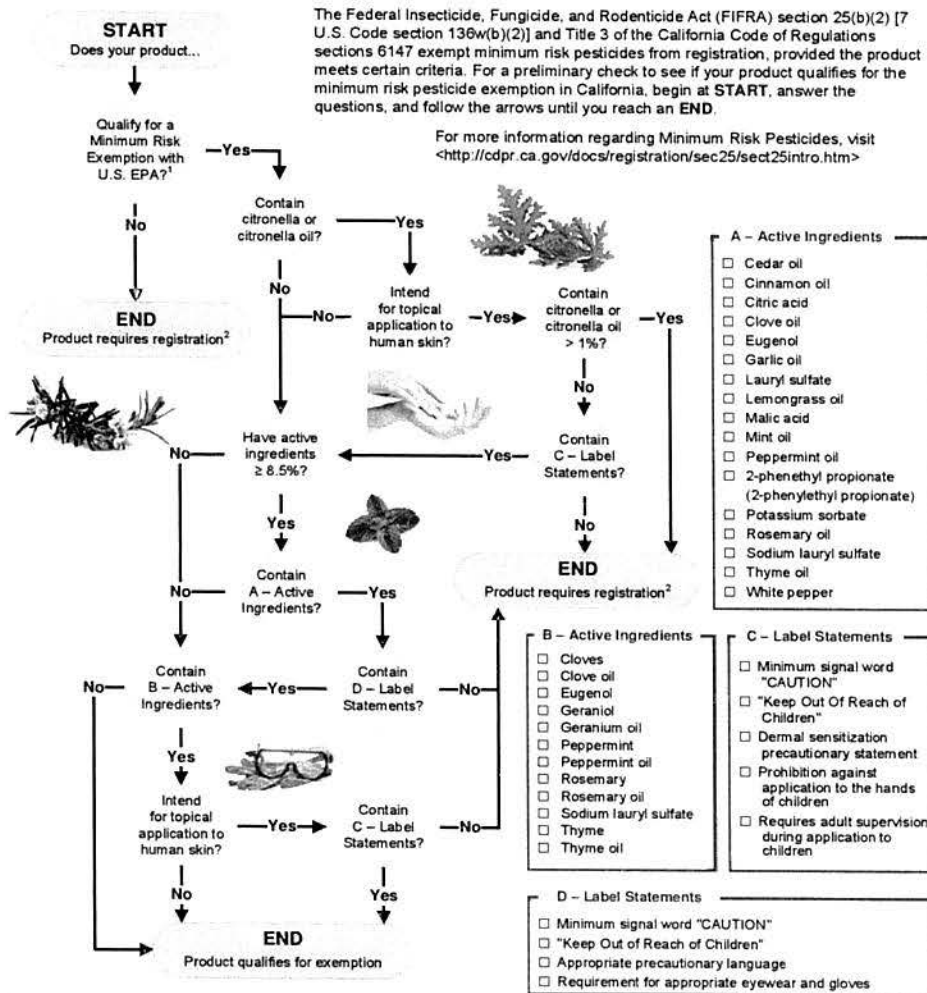
3.3 State Level Regulation that will still apply:

According to FIFRA Section 24 (a), "A State may regulate the sale or use of any Federally-registered pesticide or device in the state, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act."

In addition to the federal labeling requirements listed above, at least 37 states (probably all 50), and District of Columbia, have product label registration requirements for any product making pesticidal claims. Any company that chooses to launch a product using chitosan, even after it is listed on the MRP List, will still be required to register each product individually, in every state where that product is sold. These registration requirements are independent of, and in addition to the federal requirements. The states still have the authority to regulate these substances regardless of whether or not the substance is on the EPA's MRP List (FIFRA Section 25b). As evidence of this, a flowchart for MRP pesticide registration in the State of California can be found in Figure 1 on the next page.



Does your product qualify for a Minimum Risk Pesticide Exemption in California?



¹If you are unsure if your product qualifies for a Minimum Risk Exemption, visit <http://www.epa.gov/minimum-risk-pesticides>

²Product requires registration with DPR, unless the label can be appropriately modified. For more information regarding registering a product with DPR, visit <http://cdpr.ca.gov/docs/registration/instructions.htm>

Rev. 07/16/18

Figure 1. Flowchart to determine if your product qualifies for MRP Exemption in California

4.0 APPLYING THE CONSIDERATIONS FOR LISTING SUBSTANCES ON THE US EPA'S MINIMUM RISK PESTICIDE LIST TO CHITOSAN

In developing its MRP List of exempted substances, US EPA gave consideration to seven factors. In this section, each of those seven factors is listed, along with a detailed description of how chitosan fits within those factors:

4.1 Criterion 1. Whether the pesticidal substance is widely available to the general public for other uses

Chitosan is widely available to the general public via online sales or common retailers for a variety of applications that do not involve pesticidal claims. Some of the most common uses of chitosan are Storm Water Treatment, Pool and Spa treatment (clarifying), Beverage processing (fining agent), as a Dietary weight loss supplement, and in common household cosmetics and cleaning supplies. Other specific uses are as a hemostatic aid (powder/sponges) and in a modified form called glucosamine for joint health in humans and animals. Chitosan can be easily procured by any consumer worldwide via online stores, large retailers such as Walmart and Costco, specialty retailers such a brewing supply stores, first aid stores, pool and spa stores, and more. A simple internet search revealed the following wide variety of purchase options for the general public, without any regulation or restriction.

- Chitosan Products: GSA Advantage Search ([Link](#))
- Chitosan Products: Generic google search results. ([Link](#))
- Natural Balance Chitosan, Fat-Burning Fiber - 120 capsules \$9.25. ([Link](#))
- Now Chitosan (500 mg) 120 caps \$9.29 – ([Link](#))
- Chitosan Plant Biostimulant, Fertilizer Additive \$249.95 – ([Link](#))
- Chitosan Shower Gel Body Wash \$15.50 – ([Link](#))
- Zep Clear Shell - Home Depot – ([Link](#))
- SeaKlear Natural Chitosan Clarifier for Spas- ([Link](#))
- Chitosan Fining 1% 1 Liter - ([Link](#))
- LD Carlson 6388a Chitosan Fining Agent – ([Link](#))
- Pantene Powerful Body Booster Spray 5.7 oz. – ([Link](#))
- Chitosan Page at Alibaba – ([Link](#))

4.2 Criterion 2. If it is a common food or constituent of a common food

1. Chitosan is contained in crustaceans such as crab, shrimp, and lobster, mushrooms, and algae - making it a common food constituent. The vast majority of chitosan on the market today is extracted from crustacean shells that are a byproduct and waste stream of the seafood industry, but other sources are derived from fungal sources. ^{xiii}
2. One common derivative of chitosan commonly called glucosamine, is available in virtually every supermarket and health food store in America as a dietary supplement for joint health in humans and animals. .
3. Chitosan is sold as a weight loss dietary supplement which binds to fat in the intestine.
4. Chitosan is commonly sold and used as a beverage fining agent in the process of making beer, wine, and other beverages.

4.3 Criterion 3. If it has a nontoxic mode of action

Chitosan provides two primary functions that make it marketable and which could fit under the current regulation in question. It is used to enhance plant growth and to provide antimicrobial properties. According to information in the publicly accessible scientific literature, neither of these functions uses a toxic mode of action. Chitosan's ability to be functional without a toxic mode of action is part of what makes it attractive to businesses and consumers.

1. A plant immune elicitor that enhances plant growth:
 - a. According to the EPA's fact sheet on chitosan, poly-D-glucosamine 128930^{xiv} - chitosan is used to increase plant defenses against fungal infections and is therefore primarily used as a plant growth enhancer.
 - b. When introduced to certain plants, chitosan can induce resistance against pathogens.^{xv, xvi, xvii}
 - c. While chitosan's modes of action are still being investigated by researchers, it has been found that Chitosan elicits an immune response in plants that provides protection from a variety of pathogens, fungi, microorganisms, and pests. This immune response also has the added benefit of increasing crop yield in certain plants by triggering growth enhancing properties throughout the plant system.^{xviii, xix, xx, xxi, xxii, xxiii, xxiv}
2. Antimicrobial and bacteriostatic:
 - a. "There are many hypotheses about how chitosan could exhibit its bactericidal activity, but almost all studies underline the determinant contribution of the polycationic nature of chitosan. Therefore, the electrostatic interaction emerges as a fundamental feature of the killing potential, since the interaction with the negatively charged microbial surface would dramatically affect the bacterial vitality."^{xxv}
 - b. In simplified language, it is believed that since chitosan has a positively charged surface and many microbes and bacteria have negatively charged surfaces, chitosan attaches to these surfaces via electrostatic forces. Once attached, the effects of chitosan vary depending upon a number of factors and are different for differing microbes and bacteria.

4.4 Criterion 4. If it is recognized by the Food and Drug Administration (FDA) as safe

Of the 44 substances listed on EPA MRP List, only seven of them have successfully achieved Generally Regarded as Safe (GRAS) standing with the US FDA.^{xxvi, xxvii} One chitosan product from a company called KitoZyme has been granted GRAS status.^{xxviii} In the FDA's Agency Response Letter approving the GRAS exemption claim, it is stated that while KitoZyme produces their product from *Aspergillus Niger*, the same fundamental substance is derived from

crustacean shells which is chemically equivalent to shell waste chitosan.^{xxxix} If chitosan is added to the US EPA's MRP List, it would be the eighth substance of 45 to be exempted on both lists.

4.5 Criterion 5. if there is no information showing significant adverse effects

1. According to the EPA's Chitosan fact sheet, "Risks to the environment are not expected because chitosan has not shown toxicity in mammals, it is abundant in nature, and is used in tiny amounts."^{xxx}
2. Chitosan is currently under review by the US EPA to be listed on the Safer Chemical Ingredient List (SCIL). The EPA's SCIL workgroup is currently reviewing chitosan and a decision is expected very soon.^{xxxi}
3. Extensive toxicity testing has been done on chitosan, in part for the purpose of providing data to the EPA for pesticide registrations. This data is available to the EPA and the public. Consistently, the only toxicity shown is that there is aquatic toxicity at a rate of .37 - 2.2 mg/L, and only once chitosan has been dissolved in organic acids such as vinegar. Chitosan is not water soluble. All known use patterns of chitosan are well below the level which could cause aquatic toxicity.
4. There has been unfounded concern at times about the presumed allergenicity of chitosan because it may be derived from crustacean shells, and some people possess allergies to crustacean proteins. Chitosan itself is in fact hypoallergenic^{xxxii} and is reported as biocompatible through scientific research in dental applications.^{xxxiii} The process of producing chitosan removes the proteins which cause an allergic response. Chitosan is currently used frequently in swimming pools and spas, food, beverages, medical devices, cosmetics, pharmaceuticals and more with no reports of allergic reactions. There are other substances on the current MRP List—such as garlic oil and sesame oil—that have known allergic potential.
5. According to a US EPA Office of Pesticides and Toxic Substances memorandum (2008), "Based on the existing data, adverse effects on non-target organisms are highly unlikely and there will be NO EFFECTS (NE) on threatened or endangered species resulting from application of products containing Chitin and Chitosan (including Chitosan Hydrolysate) when products are used in accordance with approved labeling."^{xxxiv}

4.6 Criterion 6. If its use pattern will result in significant exposure

4.6.1 Environmental Exposure

Chitosan is already present in the environment virtually everywhere. Making the proposed rule change is not expected to affect the way in which it is used commercially or by consumers. The most significant environmental exposure likely comes from agricultural applications, or storm water treatment, both of which are already common, acceptable uses.

4.6.2 Human Exposure

Some of the most common applications of chitosan today are in pool/spa treatment, beverage processing, cosmetics, textiles, medical and surgical applications, and in dietary supplements. On a massive scale, humans ingest chitosan and its derivatives, immerse their bodies in water treated with it, wear clothing treated with it, floor their homes with carpet treated with it, and apply it to their skin, hair, mouths, and other parts of the body. Some of these applications are directly affected by FIFRA, and some are not, but none have any known health or safety issues. Making the proposed change will not result in human exposure beyond that which is already common and acceptable.

4.6.3 Potential new product developments

The majority of new technical developments for uses of chitosan are in medical or food applications, both of which could result in some potential change in exposure, but both of which are subject to their own state and federal regulation (FDA), so they are not affected by FIFRA anyway.

4.7 Criterion 7. If it is likely to be persistent in the environment

Chitosan does not persist in the environment and there are no reports of a naturally-occurring accumulation of chitin, indicating the biopolymer has a high turnover rate due to natural degradation.^{xxxv}

Since chitosan is the second most common material on the planet next to cellulose; it exists in virtually every place in the environment.^{xxxvi} Chitosan's similarity with cellulose goes beyond its ubiquity in that chitosan is made with modified forms of glucose, a similar material (substance) with which cellulose is made. Therefore, risks associated with the environment and organisms are expected to be low to non-existent since it has not shown toxicity in mammals, its natural abundance, and that it is used in tiny amounts.^{xxxvii}

5.0 ENVIRONMENTAL ADVANTAGES OF THE PROPOSED RULE CHANGE

It is estimated that 8 million metric tonnes of crustacean shell waste is produced globally annually.^{xxxviii} In the US, 802 million pounds of crustaceans are harvested on average each year.^{xxxix} Of this amount, approximately 25% - 35% (200-280 million lbs) of that catch becomes shell waste. This waste stream has very little or no commercial value, and becomes a liability for seafood producers. In some cases, this material is dumped back in the ocean or sent to landfills. These shells can become an environmental and or biological hazard. Development of the domestic chitosan market is a potential solution to this byproduct problem, and while FIFRA has no direct application to the manufacture of chitosan, as an obstacle to marketing the end

product, it is a significant deterrent for new companies to enter this market and for existing companies to produce new products containing chitosan.

While chitosan is widely available for purchase without regulation, commercial use of chitosan for any pesticidal applications (including plant growth regulation and antimicrobial applications), the current FIFRA regulation heavily restricts its use. In markets like commercial agriculture, household cleaning, textile treatment, home gardening and more, there are more toxic and less benign products being used today that could be displaced in the marketplace if chitosan were more widely available for these applications.

Chitosan has application in storm water treatment, industrial water treatment, and heavy metals remediation as a flocculent/coagulant. Currently chitosan's application in these markets is limited primarily to storm water treatment, and mostly in areas where local regulations dictate that chitosan be used due to its low toxicity compared to alternative chemicals. This limitation is primarily due to price. Pricing for chitosan in these markets tends to be high enough that it is not competitive against more toxic, synthetic chemical alternatives. It is possible for chitosan to be produced and sold at rates which would be competitive with these other chemicals, and could therefore significantly displace other chemicals. However, large volume chitosan production is required in order to reach economies of scale, so expansion of other markets—such as those regulated by FIFRA—will be necessary. With this proposed change, reaching economies of scale will indirectly help companies compete against more toxic, synthetic materials in the water treatment and environmental remediation markets.

6.0 US ECONOMIC COMPETITIVENESS ADVANTAGES OF THE PROPOSED RULE CHANGE

Currently, there are only three small startup companies claiming to produce chitosan in North America. According to the 2018 Chitosan Market Report by Global Industry Analysis, there were 7,750 metric tons (~17 million lbs) of chitosan sold in the USA in 2016.^{xi} Of that, almost none of it was produced by domestic companies. At a conservative average price of \$20/lb, that is a \$340 million/year market opportunity that US companies are missing.

Historically, the primary obstacles to domestic chitosan production in the US have been FIFRA regulation of end use products, and waste streams associated with the traditional methods of extracting chitosan from crustacean shells. In recent years, several companies have developed methods to extract chitosan that do not produce problematic waste streams, so that obstacle has been removed. Hence, domestic startup companies have begun to enter the chitosan market despite the regulatory hurdles

Now, the single largest obstacle to US chitosan production is the regulation that this petition addresses. The regulation inhibits companies from becoming major chitosan producers in North America despite the abundance of raw material, improved production technology, market

demand, environmental benefits, and favorable pricing. By adding chitosan to the MRP List, new economic opportunities for innovation and competitiveness will be realized.

7.0 CONCLUSIONS

In 1996 the US EPA created the 40 CFR part 152.25 (f), Exemption of Certain Pesticide Substances From FIFRA for certain pesticides that are of a character not necessary to be regulated under FIFRA and that will not pose unreasonable risks to public health or the environment and will, at the same time, relieve producers and the US EPA of the burden associated with regulation. The Agency acknowledged that the regulatory steps required to register any pesticide substance are formidable, not only for the Agency but for the applicants, which are often small businesses. The novice registrant often requires extra attention and instruction. The US EPA believes that both the applicant and the Agency are consuming valuable time, energy, and money to register chemicals that pose such low risk. In addition, the Agency, in promulgating this rule, responded to society's increasing demand for more natural and benign methods of pest control and to the desire to reduce governmental regulations, which ultimately eases the burden placed on the public.

The submitters of this petition are a domestic manufacturer of the substance chitosan. In the process of preparing to submit six chitosan pesticide registration applications, the submitters became aware of this superior alternate solution that appears to be tailor made for this substance. This petition clearly and thoroughly highlights the reasons for which moving chitosan to the minimum risk pesticide list fits within the criteria and intent of the rule.

This action will pose no risk to the environment or humans, it will save the EPA approximately \$1.8 million dollars immediately (this is what it will cost the Agency to process the submitters' six pending registration applications) and much more in the near future as additional applications are filed. It will reduce the burden on the applicants and consumers, and stimulate the US economy and innovation while positively affecting the environment. This action will be a big win for America, and serves as an example of great rulemaking that the US EPA can be very proud of.

The submitters of this petition have the utmost respect for the US EPA and appreciate the challenging work it performs. This petition is a formal request that the Acting Administrator of the US EPA exercise the 40 CFR part 152.25(f) and take swift action to move chitosan to the Minimum Risk Pesticide List without further delay.

The submitters understand and appreciate the US EPA's need to perform due diligence and make informed decisions, and therefore has gone to great expense to provide a clear, well documented petition, with public and private support. The submitters welcome any requests for discussion, dialogue, documentation, or information. The submitters would also like to highlight that this is not a special interest request, but rather a request for change that would affect any companies who wish to sell chitosan in America, foreign and domestic, including direct competitors of the submitters. The submitters believe this is the right course of action for the environment, the US EPA, consumers, and the economy.

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United States Senate

WASHINGTON, DC 20510

October 2, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington D.C. 20460

Acting Administrator Wheeler,

This letter is to convey our support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the Environmental Protection Agency's (EPA) Minimum Risk Pesticide List in order to minimize regulatory burdens on the EPA as well as businesses and consumers who produce and use chitosan in America.

The state level regulation of chitosan which already exists and will remain intact is adequate without additional federal regulation. Chitosan is used in industries ranging from agriculture, water treatment, cosmetics, textiles, and medical applications—just to name a few. Chitosan is also used widely by the U.S. Government, including multiple products commonly found in military First Aid Kits. Currently, almost all chitosan used in America is imported, and this change will greatly increase opportunity for domestic chitosan production. Domestic chitosan production also offers a great opportunity to American seafood producers to increase full utilization of their catch, and reduce waste.

This change will reduce economic and regulatory burdens on industries nationwide, reduce government spending, increase societies' access to safer chemistry, stimulate innovation, and advance development of the U.S. economy.

We appreciate your swift action in this matter, and ask that you consider it consistent with the policies and procedures of your agency

Sincerely,



Dan Sullivan
United States Senator



Lisa Murkowski
United States Senator

SETH MOULTON
SIXTH DISTRICT, MASSACHUSETTS

COMMITTEE ON ARMED SERVICES
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
RANKING MEMBER
COMMITTEE ON THE BUDGET



UNITED STATES
HOUSE OF REPRESENTATIVES

1408 LONGWORTH BUILDING
WASHINGTON, D.C. 20515
202.225.8020

21 FRONT STREET
SALEM, MA 01970
978.531.1669

moulton.house.gov
@TeamMoulton

August 28, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington D.C. 20460

Dear Acting Administrator Wheeler,

I am writing in support of Tidal Vision's petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the United States (US) EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as seafood and agriculture businesses and consumers who produce and use chitosan in America.

Chitosan production and sales represent an opportunity for seafood companies to fully utilize crustacean shells and produce a high value, sustainable material that is safe for the environment. Production of chitosan from waste crustacean shells increases domestic profitability for companies and converts waste from seafood production into a beneficial and sustainable raw material feedstock that can be sold to consumers. In regions with struggling fishing industries such as New England, chitosan extraction and production is an innovative solution that will maximize the value of the seafood being caught and put money back in the pockets of fishermen and their communities. In addition to the seafood industry, chitosan from shellfish can be used commercially and biomedically in industries ranging from agriculture, water treatment cosmetics, textiles, and medical applications.

I have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). I understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which according to Tidal Vision, is not of a character necessary to be regulated under Federal Insecticide, Fungicide and Rodenticide Act and will not pose unreasonable risks to public health or the environment. Adding chitosan to the Minimum Risk Pesticide List will relieve American producers of the burden associated with regulation allowing small

producers to reasonably enter domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

I trust that Tidal Vision's petition will receive the consideration that it deserves, and I appreciate your attention to this matter. If you have any questions, please do not hesitate to contact Morgan Bell, Regional Director in my office, at morgan.bell@mail.house.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Seth Moulton", with a stylized flourish at the end consisting of two horizontal lines.

SETH MOULTON
Member of Congress

STATE CAPITOL
P.O. Box 110001
Juneau, AK 99811-0001
907-465-3500
fax: 907-465-3532



550 West Seventh Avenue, Suite 1700
Anchorage, AK 99501
907-269-7450
fax 907-269-7463
<https://gov.alaska.gov/>

Governor Bill Walker
STATE OF ALASKA

September 21, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, DC 20460

Dear Acting Administrator Wheeler,

I write today in support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the EPA's Minimum Risk Pesticide List. This action will minimize regulatory burdens on the EPA as well as businesses and consumers who produce and use chitosan in America.

Here in Alaska, chitosan production and sales represent an opportunity to fully utilize our crustacean shells and produce a high value, sustainable material that is safe for the environment. Production of chitosan from waste crustacean shells increases domestic profitability of seafood, reducing our seafood trade deficit by converting waste from seafood production into a beneficial and sustainable raw material feedstock, thus decreasing imports of such products. We should all support this type of innovative value-added endeavor, as we seek to bolster our domestic economic production and remove regulatory red tape. Currently, much of the chitosan in our domestic market is imported – this action could help to change that.

I understand the Minimum Risk Pesticide List was, and remains, intended for materials like chitosan which, according to the Minimum Risk Pesticide List ruling 40 "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment*". Adding chitosan to the list will relieve significant regulatory burden, allowing small producers to enter the domestic market to compete with the foreign chitosan imports that currently dominate the U.S. chitosan market.

I appreciate your swift action in this matter.

Sincerely,

A handwritten signature in black ink that reads "Bill Walker".

Bill Walker
Governor



Washington State Senate

Olympia Address:
PO Box 40442
Olympia, WA 98504-0442

Senator Doug Ericksen
42nd Legislative District

(360) 786-7682
FAX: (360) 786-1323
E-mail: Doug.Ericksen@leg.wa.gov

August 23, 2018

Andrew Wheeler, Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, D.C. 20460

Dear Acting Administrator Wheeler,

I'm writing to express my support for the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the U.S. EPA's Minimum Risk Pesticide List. This will minimize regulatory burdens on the U.S. EPA, as well as businesses and consumers who produce and use chitosan in America.

I have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). I conclude that the Minimum Risk Pesticide List was, and is, intended for materials like chitosan, which "is not of a character necessary to be regulated under FIFRA" and "will not pose unreasonable risks to public health or the environment." Adding chitosan to the Minimum Risk Pesticide List will "relieve producers of the burden associated with regulation" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the U.S. chitosan market.

I believe that the state level regulation of chitosan, which already exists and will remain intact, is adequate without additional federal regulation. This change will reduce economic and regulatory burdens on industries nationwide, reduce government spending, increase societies' access to safer chemistry, stimulate innovation, and advance development of the U.S. economy.

I appreciate your consideration.

Sincerely,

A handwritten signature in black ink that reads "Doug Ericksen".

Senator Doug Ericksen
42nd Legislative District



TRIDENT SEAFOODS CORPORATION

5303 Shilshole Ave NW, Seattle, WA 98107-4000 USA • (206) 783-3818 • Fax: (206) 782-7195
Domestic Sales: (206) 783-3474 • Fax: (206) 782-7246
Canned Sales: (206) 781-7606 • Fax: (206) 781-7604
Export Sales: (206) 783-3818 • Fax: (206) 782-7195

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

August 17, 2018

Dear Acting Administrator Wheeler,

Trident Seafoods requests your agency favorably act on Tidal Vision's recently submitted petition to move chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List. This action would reduce regulatory burden on the US EPA and businesses who produce and consume chitosan in the US without increasing risk to the public or environment.

Trident Seafoods is the largest vertically integrated seafood company in North America, employing during our peak fishing seasons 8,000 men and women in the US. Trident is family owned, and takes its stewardship responsibility seriously. We are working to reduce our environmental footprint of both vessel and shore-based operations through minimizing pollution and waste. Making chitosan more accessible to US businesses and consumers who seek safe and environmentally responsible alternatives to less natural pesticides would substantially expand Trident Seafoods' opportunity to increase full utilization of shell waste from its Bering Sea crab processing operations.

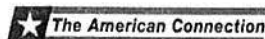
We have reviewed Tidal Vision's petition and are confident the Minimum Risk Pesticide List is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Please expedite review of Tidal Vision's well researched petition and take action to add chitosan to the Minimum Risk Pesticide List to "*relieve producers of the burden associated with regulation*" allowing small, innovative, companies like Tidal Vision to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market while supporting US seafood producers' efforts to minimize waste.

We appreciate your swift action in this matter.

Sincerely,

Joe Bundrant
CEO
Trident Seafoods

Alaska



Washington

Akutan • Anchorage • Chignik • Cordova • Dillingham • Dutch Harbor • Ketchikan
Kodiak • Naknek • Petersburg • Sand Point • South Naknek • St. Paul • Wrangell



Anacortes • Bellingham • Everett
Tacoma • Seattle

LEIGH FIBERS INC

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Leigh Fibers
1101 Syphrit Road
Wellford, SC 29385

July 2, 2018

Dear Acting Administrator Wheeler,

This letter is to convey Leigh Fibers support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

As a Textile producer and recycler, chitosan production and sales represent an opportunity to add value to our business and our customers, using a sustainable material that is safe for the environment.

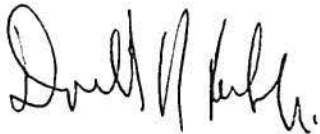
We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which *"is not of a character necessary to be regulated under FIFRA"* and *"will not pose unreasonable risks to public health or the environment."* Adding chitosan to the Minimum Risk Pesticide List will *"relieve producers of the burden associated with regulation"*

LEIGH FIBERS INC

allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald N Bockoven Jr". The signature is fluid and cursive, with the first name being the most prominent.

Donald N Bockoven Jr
President and CEO
Leigh Fibers

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

August 23, 2018

Dear Acting Administrator Wheeler,

This letter is to convey support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

As a cleaning and personal care products producer, chitosan for use in the production and sales of products represent an opportunity to add value to our industry, using a sustainable material that is safe for the environment.

I have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). I understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is of minimal risk*". Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,



Kaj Johnson
Sr. Director, R&D
Method Products
637 Commercial Street
San Francisco, CA 94111



BORNSTEIN
SEAFOODS INC.

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Andrew Bornstein
Bornstein Seafoods Inc
PO Box 187
Bellingham, WA 98225

July 2, 2018

Dear Acting Administrator Wheeler,

This letter is to convey Bornstein Seafoods support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

As a seafood processor, chitosan production and sales represent an opportunity to fully utilize our crustacean shells and produce a high value, sustainable material that is safe for the environment. Production of chitosan from waste crustacean shells increases our domestic profitability and diverts materials that we otherwise must send to landfills.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,

Andrew Bornstein



Seafood for the Sea!

Production Plant: 1905 Ocean Avenue, Raymond, WA 98577

September 5, 2018

To Whom It May Concern:

This letter is in support of the initiative undertaken by our colleagues at Total Vision LLC to change the regulatory status of chitosan, to align its categorization and end uses with that of the European Union. The

Regulation (EC) No 1107/2009 introduced the new category of "basic substances", which are described among others as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited.

Basic substances may be used in organic agriculture. Chitosan is a basic substance allowed in organic agriculture under these regulations. Chitosan hydrochloride is fulfilling the criteria of Annex II to Regulation 889/2008. As such it can be used in organic agriculture. The substance chitosan hydrochloride, as specified in Annex I of Regulation (EU) No 561/2014, Article 23(1) of Regulation No. 1107/2009 of the European Parliament and is approved as a basic substance and subject to the conditions laid down in that Annex. These are:

Specific provisions: Chitosan hydrochloride may be used in accordance with specific conditions included in the conclusions of the review report on Chitosan hydrochloride (SANCO/12388/2013):

- Only uses as basic substance being elicitor of the crop's self defence mechanisms are approved.
- The Maximum application rate of chitosan hydrochloride for a single treatment is 800 g/ha.
- Maximum content of heavy metals: 40 ppm.

By legal recognition as a non-toxic basic substance chitosan chloride (this useful material) falls into the least dangerous category of allowed substances. In many industries this widely available and utilized substance has an important range of uses, including biomedical and water treatment. We have a small amount of debris to chitosan in our marine-derived, OMRI certified organic fertilizer hydrolysate products, since we use crab and shrimp shell as key ingredients in our production. While we neither list this as a specific ingredient nor make any claims, we feel that it is important that chitosan be recognized for what it is: a valuable, non-toxic, natural material that should be de-regulated for the benefit of organic agriculture.

Thank you for your consideration, Michael Maki,

Product and Project Specialist, Pacific Gro, division of Creative AG Inc, Bellevue, WA USA 98009

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Apollo NanoTech Inc.
Mayuki Yanagawa, President
3555 Lomita Blvd., Ste, Torrance, CA 90505

July 2, 2018

Dear Acting Administrator Wheeler,

This letter is to convey my support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.


The state level regulation of chitosan which already exists and will remain intact is adequate without additional federal regulation. Chitosan is used in industries ranging from agriculture, water treatment, cosmetics, textiles, and medical applications—just to name a few. Chitosan is also used widely by the US Government, including multiple products commonly found in US military First Aid Kits. Currently, almost all chitosan used in America is imported, and this change will greatly increase opportunity for domestic chitosan production. Domestic chitosan production also offers a great opportunity to US Seafood producers to increase full utilization of their catch, and reduce waste.

This change will reduce economic and regulatory burdens on industries nationwide, reduce government spending, increase societies' access to safer chemistry, stimulate innovation, and advance development of the US economy.

I have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). I conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

I appreciate your swift action in this matter.

Sincerely,



Mayuki Yanagawa, President



Karamedica, Inc.
310 S Harrington St.
Raleigh, NC 27606

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

August 20, 2018

Dear Acting Administrator Wheeler,

This letter is to convey Karamedica's support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

Increased domestic chitosan production and sales represent an opportunity to add value to our business and our customers, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which *"is not of a character necessary to be regulated under FIFRA"* and *"will not pose unreasonable risks to public health or the environment."* Adding chitosan to the Minimum Risk Pesticide List will *"relieve producers of the burden associated with regulation"* allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,

Wolff Kirsch, MD

Chief Executive Officer

Karamedica, Inc.

wkirsch@llu.edu

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Richard Binkowski
Tramfloc, Inc.
6046 FM 2920 Road, Suite 615
Spring, TX 77379

August 22, 2018

Dear Acting Administrator Wheeler,

This letter is to convey Tramfloc, Inc.'s support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

As a water treatment chemical producer, chitosan production and sales represent an opportunity to add value to our business and our customers, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,

Richard Binkowski

Richard Binkowski
Secretary
Tramfloc, Inc.

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Courtenay W Koontz
Trees of Corrales Wholesale, Inc.
PO Box 1326
Corrales, NM 87048

August 27, 2018

Dear Acting Administrator Wheeler,

This letter is to convey Trees of Corrales Wholesale's support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

As a horticultural producer, chitosan production and sales represent an opportunity to add value to our business and our customers, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,



Courtenay W Koontz
President / Owner
Trees of Corrales Wholesale, Inc.



Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Lauren Heine, Ph.D.
Northwest Green Chemistry
89108 S Krell Ridge
Spokane, WA 99223

August 14, 2018

Dear Acting Administrator Wheeler,

This letter is to convey Northwest Green Chemistry's support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America; and to drive opportunities for sustainable innovation.

As a non profit organization committed to advancing green chemistry and engineering as a driver for economic innovation, chitosan production and sales represent an opportunity to create products and jobs using a sustainably produced material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which *"is not of a character necessary to be regulated under FIFRA"* and *"will not pose unreasonable risks to public health or the environment."* Adding chitosan to the Minimum Risk Pesticide List will allow innovative start-ups and small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market. We believe that chitosan is a material platform that can be used to generate important products that benefit human health and the environment with little to no risk.

We appreciate your swift action in this matter.

Sincerely,

Lauren Heine, Ph.D.
Executive Director
Northwest Green Chemistry
Mobile: 360.220.2069
lheine@northwestgreenchemistry.org



West Coast Seafood Processors Association
650 NE Holladay Street, Suite 1600
Portland, OR 97232
(503) 227-5076

September 5, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

RE: Petition to Move Chitosan to EPA Minimum Risk Pesticide List

Dear Acting Administrator Wheeler,

This letter is to convey the **West Coast Seafood Processors Association's support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the U.S. EPA's Minimum Risk Pesticide List** to minimize regulatory burdens on the U.S. EPA as well as businesses and consumers who produce and use chitosan in America.

The West Coast Seafood Processors Association (WCSPA) represents shore-based seafood processors in California, Oregon, and Washington. Our member companies process much of the Dungeness crab harvested on the West Coast as well as most of the cold-water pink shrimp harvested in all three West Coast states. These companies, from the smallest mom-and-pop operations that process crab, to the largest processors that employ hundreds of workers who process crab and shrimp, are key employers in our coastal communities. Each of these environmentally conscious companies look for innovative ways to use processing byproducts. chitosan is one such byproduct; opportunities related to utilizing chitosan could enhance employment in seafood communities while providing a natural pesticide product that is environmentally safe.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25(f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the U.S. chitosan market.

We appreciate your attention to this matter. Please contact me if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Lori L. Steele". The signature is written in a cursive, flowing style.

Lori Steele
Executive Director, WCSPA



September 20, 2018

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Dear Acting Administrator Wheeler:

This letter is to convey the National Council of Textile Organizations (NCTO) support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

NCTO, headquartered in Washington, DC, is the national trade association representing the entire spectrum of the textile sector. The U.S. textile industry is one of the most innovative and scientifically advanced industries in the world providing products to the automotive, aerospace, military, medical, technical, home furnishings, and apparel industries. For more information about the U.S. textile industry, view NCTO's website at www.ncto.org.

The state level regulation of chitosan which already exists and will remain intact is adequate without additional federal regulation. Chitosan is used in industries ranging from agriculture, water treatment, cosmetics, textiles, and medical applications—just to name a few. Chitosan is also used widely by the US Government, including multiple products commonly found in US military First Aid Kits. Currently, almost all chitosan used in America is imported, and this change will greatly increase the opportunity for domestic chitosan production. Domestic chitosan production also offers a great opportunity to US Seafood producers to increase full utilization of their catch and reduce waste.

This change will reduce economic and regulatory burdens on industries nationwide, reduce government spending, increase societies' access to safer chemistry, stimulate innovation, and advance development of the US economy.

We are familiar with the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f) and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

Sincerely,

Augustine Tantillo
President & CEO



Aleutian Pribilof Island Community Development Association

302 Gold Street, Suite 202 | Juneau, Alaska 99801 | Phone: (907) 586-0161 | Fax: (907) 586-0165

717 K Street | Anchorage, Alaska 99501 | (907) 929-5273 | Fax: (907) 929-5275 | www.apicda.com

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

August 30, 2018

Aleutian Pribilof Island Community Development Association
302 Gold Street
Juneau, AK 99801

Dear Acting Administrator Wheeler:

The Aleutian Pribilof Island Community Development Association (APICDA) supports the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List to minimize regulatory burdens on the U.S. EPA as well as businesses and consumers who produce and use chitosan in America.

APICDA is one of six community development quota (CDQ) organizations in Alaska whose mission is to promote fisheries related economic development and alleviate poverty in coastal communities in the Bering Sea and Aleutian Islands (BSAI). Our organization has significant investments in the harvesting and processing sectors in all commercial species in the BSAI, including crab. As such, we are strong advocates for the continued sustainability of our fisheries, maintaining healthy oceans and promoting production efficiencies for domestic companies.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,

Luke Fanning
Chief Executive Officer
APICDA

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Alexa Tonkovich
Alaska Seafood Marketing Institute
311 North Franklin Street
Juneau, Alaska 999801

September 4, 2018

Dear Acting Administrator Wheeler,

This letter is to convey the Alaska Seafood Marketing Institute's support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

As the official marketing arm for Alaska seafood products, chitosan production and sales represent an opportunity to add value to Alaska seafood businesses and local communities, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which *"is not of a character necessary to be regulated under FIFRA"* and *"will not pose unreasonable risks to public health or the environment."* Adding chitosan to the Minimum Risk Pesticide List will *"relieve producers of the burden associated with regulation"* allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,



Alexa Tonkovich
Executive Director
Alaska Seafood Marketing Institute

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

August 29, 2018

RE: Support for petition to move chitosan to minimum risk pesticide list

Dear Acting Administrator Wheeler,

I am writing to express support of the Alaska Fisheries Development Foundation (AFDF) for the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the U.S. EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as on businesses and consumers who produce and use chitosan in the U.S.

AFDF is a non-profit organization which broadly represents the seafood industry (harvesters, processors, and support sector businesses). Since AFDF's inception in 1978, the organization has focused on challenges which broadly affect the industry and finding solutions based on research and development built on partnerships with industry and researchers. Full utilization, waste reduction and product development have been one of the primary areas of focus for AFDF.

As a representative of the seafood industry, chitosan production and sales represent an opportunity to fully utilize crustacean shells and produce a high value, sustainable material that is safe for the environment. Production of chitosan increases profitability, converts waste from seafood production into a beneficial and sustainable raw material feedstock, and reduces environmental impact.

AFDF supports moving chitosan to the Minimum Risk Pesticide List; chitosan *"is not of a character necessary to be regulated under FIFRA"* and *"will not pose unreasonable risks to public health or the environment,"*. Adding chitosan to the Minimum Risk Pesticide List will *"relieve producers of the burden associated with regulation"* allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market, and further reduce the seafood trade deficit, which is of particular concern to U.S. Secretary of Commerce Wilbur Ross.

Thank you for your attention this matter.

Sincerely,



Julie Decker, Executive Director

Cc: Chris Hladick, Region 10 Administrator, EPA



Board of Directors

Jan Jacobs – President

Harvester, Region IV
American Seafoods Company

Ken Simpson – Vice President

Harvester, Region II
F/V Lady Simpson

Trevor Sande - Treasurer

Harvester, Region I
Marble Seafoods

Mark Scheer - Secretary

Service Sector
Williams Kastner

Al Burch

Harvester, Region III
Alaska Whitefish Trawlers Association

Jim Denning

Service Sector
AquaStar

Tom Enlow

Processor, At-large
UniSea

Buck Laukitis

Harvester, At-Large
Magic Fish Company

Chris Mierzejek

Service Sector
Aleutian Pribilof Island Community
Development Assoc.

Stefanie Moreland

Processor, At-large
Trident Seafoods

Glenn Reed

Processor, At-large
Pacific Seafood Processors Assoc.

Tommy Sheridan

Processor, At-large
Silver Bay Seafoods

John Sund

Service Sector
Stellar North LLC



JEDC.org

612 West Willoughby Ave. Suite A

Juneau, AK 99801

Phone 907-523-2300

Fax 907-463-3929

August 24, 2018

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Dear Acting Administrator Wheeler:

The Juneau Economic Development Council (JEDC) fosters a healthy and sustainable economic climate in Juneau and throughout Southeast Alaska. In collaboration with other organizations, JEDC implements initiatives to maintain, expand, and create jobs and economic opportunities. The focus of our work includes promoting entrepreneurship and supporting small business initiatives.

It is our understanding that Tidal Vision of Bellingham, Washington is submitting a petition to the US EPA to move chitosan to the Minimum Risk Pesticide List. We urge you to review the petition as soon as possible, as a favorable determination will allow this small company and other small producers to reasonably enter the market with domestic production in order to compete with the foreign chitosan imports that currently dominate the US chitosan market. This change will reduce economic and regulatory burdens on our industries, reduce government spending, increase societies' access to safer chemistry, stimulate innovation, and advance development of the US economy.

We appreciate your swift action in this matter.

Sincerely,



Brian Holst
Executive Director

Juneau Economic Development Council



PORT OF BELLINGHAM
Washington State

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

John Michener
Port of Bellingham
1801 Roeder Ave
Bellingham, WA 98225

August 15, 2018

Dear Acting Administrator Wheeler,

This letter is to convey the Port of Bellingham's support for Tidal Vision's ability to bring new products to market and in doing so increase employment in our region.

Tidal Vision came to the Port of Bellingham a year ago and applied for a loan through our Economic Development Agency Port of Bellingham Revolving Loan Fund. The credit application they submitted was professionally done and required no additional questions on part of the Loan Committee. The loan was easily approved and Tidal Vision has adhered to the terms of the loan since closing in October of 2017 including the hiring of additional staff.

Tidal Vision is exactly the type of company we desire for our community. They are professional, innovative and developing new products that have the potential to grow their business, employ additional people and bring increased economic vitality to our region.

Sincerely,



John Michener
Economic Development Specialist
Port of Bellingham

August 14, 2018

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Dear Acting Administrator Wheeler,

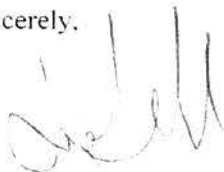
This letter is to convey my support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in USA.

As an academic researcher, I anticipate that chitosan production and sales represent an opportunity to add value to our national business and customers, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,



Jeremy B. Jewell, Ph.D.
Postdoctoral Research Associate
Department of Plant Pathology
Washington State University
P.O. BOX 646430, Pullman, WA 99164-6430
Tel (509) 335-6418 | Fax (509) 335-9581
jbjewell@wsu.edu
<https://labs.wsu.edu/tanaka-lab/>

August 14, 2018

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Dear Acting Administrator Wheeler,

This letter is to convey my support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in USA.

As an academic researcher, I anticipate that chitosan production and sales represent an opportunity to add value to our national business and customers, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,



Kiwamu Tanaka, Ph.D.
Assistant Professor

Department of Plant Pathology
Washington State University
P.O. BOX 646430, Pullman, WA 99164-6430
Tel (509) 335-6418 | Fax (509) 335-9581
kiwamu.tanaka@wsu.edu
<https://labs.wsu.edu/tanaka-lab/>

August 14, 2018

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

Dear Acting Administrator Wheeler,

This letter is to convey my support of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in USA.

As an academic researcher, I anticipate that chitosan production and sales represent an opportunity to add value to our national business and customers, using a sustainable material that is safe for the environment.

We have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). We understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,



Natalia Moroz, Ph.D.
Postdoctoral Research Associate
Department of Plant Pathology
Washington State University
P.O. BOX 646430, Pullman, WA 99164-6430
Tel (509) 335-6418 | Fax (509) 335-9581
natalia.moroz@wsu.edu
<https://labs.wsu.edu/tanaka-lab/>

Acting Administrator, Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington D.C. 20460

August 13, 2018

Dear Acting Administrator Wheeler,

This letter is to convey a science based of support from the laboratory of Professor Lee A. Hadwiger, Dept. of Plant Pathology, Washington State University, Pullman, WA of the petition to move the material commonly referred to as chitosan (CAS # 9012-76-4) to the US EPA's Minimum Risk Pesticide List in order to minimize regulatory burdens on the US EPA as well as businesses and consumers who produce and use chitosan in America.

Since my laboratory first discovered in 1979 that chitosan had fungicidal activity (Mycology vol.3 :285.) It could have been more widely utilized over the decades. We also discovered that it had the potential to activate defense responses in plants. (reviewed in Plant Science (2013) Vol. 208:42.) It is scientifically embarrassing to have allowed other countries to out innovate US scientists in many applications of chitosan. As indicated in the petition, "it will not pose unreasonable risks to public health" in fact it has beneficial aspects for improving health in many areas. A recent article in Science (18 May 2018- vol. 360 739.) indicates that there is the realization of an emergence of resistance to antifungal drugs that challenges both human health and food security --which doesn't include resistance to chitosan. This petition is a channel to take positive steps to get more extensive clearance for the use of chitosan.

I have read the petition and the original Minimum Risk Pesticide List ruling 40 CFR Part 152.25 (f). I understand the information presented in both and conclude that the Minimum Risk Pesticide List was, and is intended for materials like chitosan, which "*is not of a character necessary to be regulated under FIFRA*" and "*will not pose unreasonable risks to public health or the environment.*" Adding chitosan to the Minimum Risk Pesticide List will "*relieve producers of the burden associated with regulation*" allowing small producers to reasonably enter the market domestically in order to compete with the foreign chitosan imports that currently dominate the US chitosan market.

We appreciate your swift action in this matter.

Sincerely,


Lee A. Hadwiger, Professor of Plant Pathology,
Dept. of Plant Pathology
Washington State University.
Pullman, WA 99164 6430
Chitosan@wsu.edu

