Summary of Petition:

Chitosan has been petitioned for use in organic crop production for addition to the National List at §205.601(j)(4) for plant disease control. The NOSB requested a technical review (TR) of chitosan since the last one was from 2004 when there was a petition for its use as an adhesive adjuvant. Much of the material in the current analysis comes from the TR received by the NOP in July 2020. Chitosan is a copolymer composed of two different chemical subunits that repeat in particular order: glucoseamine and N-acetylegluosamine. It is derived from chitin which is structurally similar to cellulose. The petitioner stated that chitosan is an alternative to sulfur-based pesticides, which can be phytotoxic to plants. The petitioner bases the request on chitosan's antimicrobial properties as well as its role in plant defense signaling pathways.

Most commercial chitin, from which chitosan is derived, is produced from shrimp, prawn, and crab waste. Chitin forms structures that strengthen cell walls, insect skeletons, crustacean shells, and internal mollusk body parts. The manufacture of chitosan uses relatively large amounts of corrosive chemicals, notably sodium hydroxide and hydrochloric acid. That said, relatively little chitosan is produced. Only 2000 metric tons of chitosan are produced each year while 70 million tons of sodium hydroxide are produced for use in all types of industrial processes. In contrast to the chemicals used to isolate and synthesize the material, chitosan is produced from chitin, a food related marine biowaste and is thus, part of a recycling process. However, as part of an industry that requires the use of sodium hydroxide and hydrochloric acid, considerable energy is consumed producing these products with concomitant production of chlorine gas, carbon dioxide, carbon monoxide, freon and mercury.

Chitosan has a variety of potential uses. It is a registered pesticide (OPP No. 128930) that is used in crop production as a plant growth enhancer and plant defense booster (EPA 2003). Chitosan is applied to treat field crops, ornamentals, turf, home gardens, and nurseries. It is also listed as an animal feed component in the Official Publication of the Association of Animal Feed Control Officials. The State of Oregon has approved the use of chitosan in unrestricted amounts as a soil amendment (fertilizer). Chitosan was recommended to be added to the National List in 2005 as an adjuvant although it was already present on EPA List 4, and therefore would have been redundant. Chitosan also has a variety of other uses that include as a flocculant allowed for precipitating proteins during animal food production, a plant growth regulator in or on wheat, and as a seed treatment for specific crops. The FDA also allows chitosan produced from the fungus Aspergillus niger as a secondary direct food ingredient in alcoholic beverages.

Chitosan is not toxic as demonstrated in acute toxicity studies in mice, rats and rabbits and is naturally occurring in the environment in large concentrations. EPA exempted chitosan from the requirement for a tolerance limit due to its low toxicity and abundance in the environment. As mentioned in the summary above, EPA states that chitosan is not expected to harm people, pets, wildlife, or the environment when used according to label direction.
Summary of Review:
A survey of regulations for organic production from a number of countries and international organizations indicates that chitosan is not included within the Canadian Organic standards as an allowed material. CODEX Alimentarius does not include chitosan within the Codes guidelines. European Economic Community (EEC) Council Regulation shows that chitosan hydrochloride is allowed for pest and disease management under European Union organic regulations but may not be used as an herbicide.

Category 1: Classification

1. For CROP use: Is the substance Non-synthetic or Synthetic?
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.
   The petition describes the process of producing chitosan from chitin as proprietary so the exact process they use is unknown. Generally, however, chitosan is produced from chitin by using dilute sodium hydroxide to separate and extract chitin from shells or acids for demineralization, but a more concentrated solution is required to effectively deacetylate chitin to form chitosan at a range of 40 to 60% concentration. Chitin can also be converted into chitosan using a high-heat process or a lower temperature process using enzymatic conversion.

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?
   The petitioner is requesting that chitosan be added to 7 CFR 205.601(j)(4) as a synthetic substance allowed for use in organic crop production as a plant disease control.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]
   Based on information in the 2020 Technical Report, the application of chitosan as an active ingredient in pesticidal products is unlikely to be harmful to the environment. It occurs naturally in quantities exceeding what would be used in organic crop production and it degrades into substances that are non-toxic and readily used as nutrients.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]
Due to the variety of results found in different studies it is likely that chitosan has multiple antibacterial modes of action. One hypothesis is that positively charged chitosan binds to negatively charged cell surface molecules. Another hypothesis is that smaller chitosan molecules move through cell walls and inhibit gene transcription. There is also another thought that chitosan chelates essential nutrients making them unavailable to bacteria. Chitosan can also initiate systemic resistance in plants and may act directly between host and pathogen to block the growth of the pathogen itself. Since chitosan is used at low levels and is degraded by soil microorganisms the is expected to be no increase in the environment.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Because of the low toxicity of chitosan, the misuse of the product or its disposal are expected to have minimal effects on the environment. Both chlorine and sodium hydroxide are used in production of chitosan, and are toxic in the environment if not contained in transport.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

According to numerous sources as reported in the Technical Report chitosan is nearly non-toxic to humans and most other animals and its degradation products do not cause side effects in the body (US EPA).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

Pesticide studies about the use of chitosan as an active ingredient have shown that there might be temporary changes to soil microbial communities. Being a large polymer with numerous reactive sites, it is difficult to characterize all possible chemical interactions involving chitosan. the Technical Report found studies that chitosan can limit the ability of some microorganisms to absorb nutrients, but it can also act as a chelator. It has been suggested because of this, it might be used as a material to improve the anionic exchange capacity of soils to limit the leaching of anionic nutrients and improve nutrient delivery to plants.

6. Are there any adverse impacts on biodiversity? (§205.200)

At the rates this substance is applied, no adverse impacts on biodiversity are expected.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

As the Technical Report emphasizes, good farming practices, including suppressive soils, creating unfavorable conditions for pathogens, managing disease vectors such as aphids,
sterilizing soils with heat and planting resistant cultivars reduce the need to use disease control substances. Also, there are more than 200 products listed by OMRI for use as plant disease control. Some do contain synthetic active ingredients, but many contain nonsynthetic active ingredients such as bacteria, microorganism extracts, botanical substances, oils, and natural acids.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Chitosan is a relatively benign product and also has the advantage of taking a waste stream of seafood shells and converting them to a useful recycled product. Both chlorine and sodium hydroxide are energy-intensive, toxic chemicals used in the production of chitosan, and must be considered. Additionally, chitosan is classified as synthetic, and the Subcommittee questions whether there is a need for an additional synthetic plant disease control product on the National List. The Crops Subcommittee is divided on whether chitosan should be added to the National List.

Classification Motion:
Motion to classify chitosan as synthetic
Motion by: Rick Greenwood
Seconded by: Brian Caldwell
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:
Motion to add chitosan to the National List at 205.601(j)(4) for plant disease control
Motion by: Rick Greenwood
Seconded by: Steve Ela
Yes: 4 No: 4 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP June 1, 2021.