National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Low Acyl Gellan Gum
June 2, 2020

Summary of Petition (petition, 8/8/19; petition addendum; 3/6/20):

On August 8, 2019, the NOP received a petition from CP Kelco U.S., Inc. to add low acyl gellan gum (CAS# 71010-52-1) to the National List. The initial petition requested addition to 7 CFR 205.605(a), however the NOP requested the petition be revised to request addition to 7 CFR Part 205.605(b). The petition was provided to the Handling Subcommittee September 17, 2020 reflecting this change.

Upon initial review of the petition, on January 6, 2020 the Subcommittee sent additional clarification questions to the petitioner and a response was received March 5, 2020. On March 17, 2020 the Subcommittee found the petition sufficient.

Regulatory Background
In 2004, CP Kelco U.S. petitioned to add gellan gum to the National List. In 2007, upon completion of its review, the NOSB recommended gellan gum be added to the National List. A proposed rule was published in 2009 and in 2010, gellan gum was added at 7CFR Part 205.605(a) with an annotation that limits its use to the high acyl form. Outside of USDA organic regulations, there is no differentiation between low and high acyl gellan gum made in regulatory approvals, e.g. the CAS numbers are identical and they are treated the same.

In the 2010 final rule publication, the NOP responded to a comment that references the Board's discussion during its review of gellan gum at its November 2007 meeting:

> The comment stated that low-acyl gellan gum is chemically modified by alkali treatment prior to alcohol precipitation and is, therefore, synthetic. The comment indicated that a restriction of the exemption to the high-acyl form aligns with the intent of the NOSB as conveyed during the November 27-30, 2007 meeting discussion.
>
> There are 2 forms of gellan gum: High- and low-acyl. To manufacture the low-acyl form, an alkali is added, and the temperature is raised to remove acetyl groups. A strong acid is then used to lower the pH and the gum is recovered from solution by clarification and precipitation. The high-acyl form is not subject to deacetylation with an alkali salt. After fermentation, the high-acyl form is precipitated out of solution with isopropyl alcohol.
>
> We believe the different manufacturing processes for high- and low-acyl gellan gum merits a revision to the proposed amendment to clarify that only the high-acyl form of gellan gum may be classified as nonsynthetic. Deacetylation, the removal of acetyl group(s) from molecules, results in chemical change. Thus, in accordance with the NOP definition of synthetic, the resulting substance would be synthetic. Based upon this reasoning, we agree with the comment that the recommendation to add gellan gum as a nonsynthetic substance pertains only to the high-acyl form. Therefore, we have amended the listing by adding the annotation "high-acyl form only."

Use
Low acyl gellan gum is used in various food formulations, such as aspics; frostings; brownies and bakery fillings; gelatins and puddings; non-standardized jams and jellies; dairy drinks and soy milks; nutritional products; beverages (dairy alternative milks, dairy drinks, fruit drinks, drinking jellies, novelty drinks); beverage mixers; kefir; yogurt, sour cream and cheese where the standards of identity do not preclude its use; yogurt fruit and fruit sauces; marinades; pourable and spoonable dressings; and dairy desserts.

Gellan gum is approved in animal and pet food and is also used in personal care products such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. The typical amount of gellan gum in food for human consumption doesn't exceed 0.5%.

The mode of action is as a suspending or gelling agent with film-forming and texturizing attributes, forming gels in the presence of ions when heated and cooled.

The petitioner offers a number of unique properties that they feel make gellan gum essential:

- Gellan gum fluid gels are very good at suspending particulate matter since the suspension will remain stable, esp. in products containing pulp or jelly pieces.
- It is heat stable in acid systems unlike carrageenan, which breaks down under acid conditions.
- Gellan gum, unlike carrageenan, can be used in fruit fillings, retorted gels, or low pH beverages.
- Use of low acyl gellan gum in hard and soft capsules gives a functionality that cannot be achieved with most materials currently on the National List. Carrageenan is the only material currently listed which offers producers of hard and soft capsules the necessary technical function/properties.
- Consumers are putting pressure on manufacturers to deliver options that are not animal- or carrageenan- based.
- Gellan gum is used at significantly lower levels (<20%) than other gums on the National List.

Manufacture
The 2018 TR on gums and the 2019 petition note gellan gum is a high-molecular weight polysaccharide, produced by the pure-culture aerobic fermentation of a carbohydrate with Sphingomonas elodea (ATCC 31461), formerly known as Pseudomonas elodea. The carbohydrate fermentation substrate is comprised of glucose syrup derived from maize or wheat, inorganic nitrogen, an organic nitrogen source (protein) and trace elements. Pasteurization kills the bacteria. The structure of high acyl gellan gum consists of a 4-sugar repeating unit with acetate and glycerate side chains. Removing the acetate and glycerate groups results in a linear molecule with unique properties.

The petitioner provides the following detail specific to their manufacturing.

- The first step of producing the gum is by inoculating a carefully formulated fermentation medium with this organism.
- The medium contains a bio-based glucose syrup carbon source, phosphate, organic and inorganic nitrogen sources, and appropriate trace elements.
- The fermentation is carried out under sterile conditions with strict control of aeration, agitation, temperature, and pH.
- Deacylation of the gum develops the required functionality. A strong base is used to deacylate gellan gum. This additional step does not change the polysaccharide backbone of the molecule. After deacylation, acid is used to neutralize the gellan gum solution.
    - High acyl gellan gum is treated with potassium hydroxide and heated. This produces low acyl gellan gum and potassium acetate and potassium glycerate. The potassium acetate

and potassium glycerate are removed from the low acyl gellan gum during the precipitation and recovery of the low acyl gellan gum with isopropyl alcohol.

- The gum is recovered by precipitation with isopropyl alcohol.
- The precipitate is then dried and milled to a fine powder.
- The powdered form of the product is packaged.

In response to a question from the Subcommittee regarding the use of excluded methods in the production of gellan gum, the petitioner stated that the three low-acyl gellan gums they produce (KELCOGEL® [E], KELCOGEL® CG-LA [E], KELCOGEL® F[E]) are Non-GMO Project certified.

International Use:
Canadian General Standards Board Permitted Substances List (Updated in November 2015)
On Table 6.3 (Ingredients Classified as Food Additives) of the Permitted Substances List, gums are listed with the annotation, "The following gums are permitted: Arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum. Shall be derived using substances listed in Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums" (CGSB, 2015).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
CODEX provides Guidelines (CODEX Alimentarius Commission, 2013) for use of food additive gums as follows: Gellan gum (418). CODEX General Standard for Food Additives (GSFA) provides a highly detailed range of uses and specifications for each of these substances (CODEX Alimentarius Commission, 2017).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008
Gellan gum is not listed.

Japan Agricultural Standard (JAS) for Organic Production
Gellan gum is not listed as allowed or prohibited. (Japanese MAFF, 2012).

International Federation of Organic Agriculture Movements (IFOAM)
Gellan gum is neither listed as allowed nor prohibited.

Summary of Review:
Gellan gum, in a high acyl form as a nonsynthetic substance is already included on the National List at 205.605(a) and has been recommended by the Board for relisting through two rounds of sunset review. The low acyl form of gellan gum is technically a synthetic substance as described above but is viewed from a regulatory and food safety perspective as identical to the high acyl form.

The tenets of organic production tend to favor nonsynthetic options when available. However there do not appear to be significant differences between the nonsynthetic high acyl and synthetic low acyl forms of gellan gum. If a distinct functional property is sought from the use of a low acyl form, a difference in impact to human health and the environment through the use of the low acyl form is negligible. If use of low acyl gellan gum contributes to the increased growth and consumption of an organic crop and subsequent processed product, the gains to human health and environment over a conventionally produced crop and product appear to favor its compatibility with organic handling.

Category 1: Classification

1. Substance is for: **__X__ Handling _____ Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or __**X**__ **Non-Agricultural?**
      Describe reasoning for this decision using NOP 5033-2 as a guide:

   The substance is a gum, which is explicitly included in the nonagricultural substance definition at 7 CFR Part 205.2.

   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or __**X**__ **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 NOSB has discussed at length and received much public comment regarding the manufacture of products of fermentation and what processes constitute a synthetic or nonsynthetic determination. Most recently this topic was confronted during the Spring 2020 discussion of the reclassification of L-malic acid. Based on public comment from certifiers, manufacturers and the authors of the TR on L-malic acid, a synthetic or nonsynthetic determination can vary based on where in the manufacturing process one begins the determination. *NOP Guidance 5033 Classification of Materials* and the accompanying *NOP Guidance 5033-1 Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* do not provide clarity or guidance on where this determination is to begin.

   The 2018 TR on Gums further describes this determination as it relates to gellan (and xanthan) gum:

   > Gellan gum and xanthan gum are produced by fermentation of a carbohydrate with bacteria. Fermentation is a naturally occurring biological process. The bacteria strains are not an agricultural source, although agricultural materials may compose the substrate media. After fermentation, further processing is used to separate (recover) the gum from the fermentation media and purify the gum for commercial use. Additional processing steps, as described in *Evaluation Question 1,* may include the following:
   >
   > - Gellan gum and xanthan gum undergo pasteurization.
   > - Gellan gum and xanthan gum undergo alcohol precipitation (with ethanol or isopropanol), similarly to guar gum and locust bean gum. Maximum levels of residual solvents are described in *Approved Legal Uses of the Substances.*
   > - Xanthan gum may be washed with a salt solution.
   >
   > In order for post-fermentation extracted materials to be classified as nonsynthetic, NOP Guidance 5033 on the Classification of Materials requires that at the end of the extraction process, the material: 1) has not been transformed into a different substance via chemical change; 2) has not been altered into a form that does not occur in nature; and 3) that any synthetic materials used to extract the substance have been removed from the final substance such that they have no technical or functional effect on the final product. Reviewing the post-fermentation processing steps described above against NOP Guidance 5033, the following conclusions are made:
   >
   > - Heating of biological materials is not considered a synthetic process.

- Alcohol precipitation, as described above, may be considered a nonsynthetic process provided that any residual solvents are removed such that they do not have a technical or functional effect.

The 2018 TR on Gums appears to determine low-acyl gellan gum as potentially nonsynthetic. However the 2010 NOP response to comments on the proposed rule to list high-acyl gellan gum clarifies the view of the Program on this substance:

> "Deacetylation, the removal of acetyl group(s) from molecules, results in chemical change. Thus, in accordance with the NOP definition of synthetic, the resulting substance would be synthetic. Based upon this reasoning, we agree with the comment that the recommendation to add gellan gum as a nonsynthetic substance pertains only to the high-acyl form."

3. For **LIVESTOCK**: 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?

   N/A

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)]

   It does not appear that gellan gum has detrimental chemical interactions with other materials.

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)]

   The 2018 TR on Gums notes that dues to its low toxicity, the EPA exempted gellan gum from the requirement for a tolerance limit when used as an inactive ingredient in pesticide formulations.

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

   The TR notes the Safety Data Sheets for the solvents used to precipitate gellan gum do not indicate specific impacts on the environment or biodiversity.

   The petitioner notes that any waste from the fermentation media will be discharged to the municipal sewage treatment plant and will be present in only trace amounts. A recovery procedure is used to reclaim isopropyl alcohol.

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

   The 2006 technical report on gellan gum cites one Joint FAO/WHO Expert Committee on Food Additives (JECFA) study indicating no adverse human health impacts. This same study notes that gellan gum acts as a bulking agent and decreases serum cholesterol.

   The 2018 TR states the effect of food additive gums on the nutritional quality of foods varies depending on the type and amount of gum ingested because of their varied properties. The gums' physiological and nutritional effects occur during transit through the stomach, small intestine, and colon, by reducing and mixing actions in the gut and by their effect on the interaction between nutrients, enzymes and mucosal cells, and finally, as a result of their fermentation, by the colonic microflora. Digestion of sugars and fats may change when foods containing gums as food additives are ingested.

   Gellan gum is not affirmed as GRAS. It is listed at 21 CFR Part 172, Food Additives Permitted for Direct Addition to Food for Humans, Subpart G, Gums, Chewing gum bases and related substances: Gellan gum, 21 CFR 172.665

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)]

   The 2018 TR notes no sources were identified that discussed environmental contamination resulting from the commercial manufacturing of any of the six gums. The solvent used to separate the gums at the dissolution phase of the process is typically isopropyl alcohol and residual solvent levels are established.

   The petitioner notes that because gellan gum is a polysaccharide, it is broken down by microorganisms found in the soil and therefore, would have a beneficial effect on soil organisms which in turn would benefit crops.

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

   The 2018 TR on Gums notes the Safety Data Sheets for the solvents used to precipitate gellan gum do not indicate specific impacts on the environment or biodiversity. The gum itself does not appear to impact biodiversity.

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 noted in the 2018 TR on Gums, there are many natural hydrocolloids which can be substituted for any one of the gums currently listed on the National List. The choice of gum for a particular food application is dictated by the functionalities required. Some of these functionalities are unique to a particular gum or combination of gums. The 2018 TR goes into great detail on these various functionalities.

Alternatives do exist but may not provide the same functionality for a particular product. For instance, gelatin could be used as an alternative to gellan, but gellan can withstand higher temperatures. An alternative practice could be to make the product without the additive, resulting in products with different consistencies and textures.

The high acyl form of gellan gum can be produced nonsynthetically. However as noted above, this form may not provide the same functionalities as low acyl gum. The 2018 TR found no information was indicating that organic forms of gellan gum are available commercially.

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   N/A

Classification Motion:

Motion to classify low acyl gellan gum as nonagricultural, synthetic
Motion by: Scott Rice
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 1 Absent: 0 Recuse: 0

National List Motion:

Motion to add low acyl gellan gum to the National List at §205.605(b)
Motion by: Scott Rice
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 1 Absent: 0 Recuse: 0

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOP August 13, 2020