National Organic Standards Board Handling Subcommittee Petitioned Material Proposal Magnesium Carbonate and Magnesium Carbonate Hydroxide January 23, 2024

Summary of Petitions [Magnesium carbonate petition; Magnesium carbonate hydroxide]:

This document reviews the petitioned use and inclusion of magnesium carbonate and magnesium carbonate hydroxide as processing aids to the National List at §205.605(b): Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" as the reviews for these materials are essentially the same. As in the TR when referring to magnesium carbonate, "MC" (singular) will be used or when referring to multiple magnesium carbonates (both magnesium carbonate and magnesium carbonate hydroxide) "MCs" will be used.

Introduction:

In December 2022, Leroux petitioned the United States Department of Agriculture (USDA) National Organic Program (NOP) to add both magnesium carbonate and magnesium carbonate hydroxide as processing aids to the National List at §205.605(b).

Relevant Background:

Magnesium carbonate was previously listed on the National List at §205.605(b) with the following annotation: "for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"." (<u>65 FR 80547, page 1708</u>)

In 2005, MC was petitioned for inclusion to the National List as a filtering aid at §205.606. The petition was rejected by the NOP because the petition was incomplete, and this substance was ineligible to be added to §205.606 as it is not agricultural.

During the sunset review process in 2015, the NOSB voted to remove MC from the National List stating, "the material does not appear to be essential to organic handling." MC was removed from the National List effective August 7, 2017. The final rule stated, "AMS received no public comments concerning the proposed removal of...magnesium carbonate from the National List." (<u>82 FR 31241, page 14</u>)

Magnesium carbonate hydroxide has never been petitioned or included on the National List.

Use:

MCs are used as drying agents / anti-caking agents. The petitioned use is focused on organic chicory production, specifically organic instant chicory powder. The petitioner notes that during the final steps of atomization and packing, the instant chicory powder sticks to the walls of the installations, requiring several stops for cleaning which reduces the rate of production.

The petition states, "The use of magnesium carbonate (or magnesium carbonate hydroxide) as a processing aid is intended for the manufacture of the instant extract of chicory obtained by atomization. The incorporation of E504(i) (or E504(ii)) is done in the crown of air at the bottom of the tower feeding the dryer in order to obtain re-aeration and very good homogeneity of the product (figures 1 and 2). The maximum amount used would be 0.05%." The petition includes several diagrams to pictorially represent the use of MCs in the production of organic instant chicory powder.

Summary of Review:

The Handling Subcommittee's (HS) discussion focused on whether the potential presence of nanoparticles in the alternatives -calcium carbonate, tricalcium phosphate, and silicon dioxide - makes the case for the essentiality of MCs. The HS discussed the current prohibition of nanotechnology (NOP PM 15-2) and if this is sufficient in certifiers' material review processes to keep engineered nanomaterials out of organic products and if there is a true concern here that perhaps petitioning removal of those materials in question is the better approach.

The HS also discussed the environmental impact that any substance that is mined or uses a precursor that is mined has on the environment due to the adverse effect the mining industry has on the environment.

Lastly, MCs are generally allowed in all the international schemes included in the TR (Canada, CODEX, EU, JAS, IFOAM). There are some restrictions made by CODEX, EU and JAS allowing MCs only in processed products of plant origin (or alternatively not allowed in food of animal origin). Canada restricts its allowance in meat products with 70-95% organic content. JAS only allows magnesium carbonate but not magnesium carbonate hydroxide. Based on this allowance there could be products imported into the US through an equivalency arrangement that have been produced using MCs as a processing aid.

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 <u>NOP 5033-2</u> as a guide:

MCs are mineral salts. Magnesium carbonate hydroxide is the mixture of magnesium carbonate and magnesium hydroxide rather than a specific chemical compound.

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 <u>NOP 5033-1</u> as a guide:

Evaluation of MCs against Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016) is discussed below. The following is from lines 507-540 in the TR.

1. Is the substance manufactured, produced, or extracted from a natural source?

The substance, MC, is manufactured by chemical reaction of precursors, which themselves may be nonsynthetic, as is the case with some magnesium salts and sodium carbonates, or else synthetic, such as magnesium hydroxide and carbon dioxide. Carbonation of magnesium hydroxide involves the reaction of two synthetic substances. Thus, the answer to whether the substance is manufactured from a natural source in this case would be no, and the end-product is considered synthetic. The determination for MC manufactured by the reaction of a magnesium salt with an alkaline carbonate is more complex.

Assuming a magnesium chloride or magnesium sulfate is from a nonsynthetic source, and the sodium carbonate with which it is reacted is also nonsynthetic, gives the following result when evaluated using the decision tree:

1. Is the substance manufactured, produced, or extracted from a natural source?

One could answer yes because the magnesium and carbonate sources are natural.

2. Has the substance undergone a chemical change so that it is chemically or structurally different than how it naturally occurs in the source material?

The answer to this question would be yes if we consider the source materials to be the reactants, because their ions exchange during the process: in solution magnesium is in ionic form (Mg²⁺), separate from the salt ions (Cl⁻ or SO₄²⁻), but combines with carbonate ions (CO₃²⁻) from a different source in a crystalline structure, yielding the final MC. The next question is:

3. Is the chemical change created by a naturally occurring biological process, such as composting, fermentation, or enzymatic digestion; or by heating or burning biological matter?

The answer to this question is no. The chemical change is the result of a chemical reaction. No biological processes are involved, and while temperature can affect the form of the final MC, the reaction is not driven by heating. Thus, the material is synthetic according to the decision tree.

3. For LIVESTOCK: Reference to appropriate <u>OFPA</u> 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)]

None, as both magnesium and carbonates are naturally occurring.

 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)] MCs are non-toxic. The petition states that magnesium carbonate will dissociate into magnesium and carbonate ions. The petition and the TR discuss the ubiquitous presence of these ions in nature.

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

MANUFACTURE: The main environmental concern regarding MCs pertains to the manufacturing process of magnesium, which is a precursor used in MCs manufacturing. Magnesium itself can be obtained through several different extraction routes and from various magnesium-containing brines and mineral ores. [TR 458-488]

Additionally, the TR, noted that MC is naturally occurring in rock known as magnesite. The TR stated that no commercial sources of food-grade MC produced directly from magnesite were identified. That said, magnesite is one of the mineral ores described above as a precursor to synthetically processed MCs.

USE/MISUSE: Using magnesium carbonate in the manufacturing of chicory extract is unlikely to harm the environment or biodiversity. [TR 649]

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

Magnesium and MCs are not toxic to humans at doses that fall close to the maximum daily intake. High doses of magnesium (from dietary supplements or medications) can result in stomach issues (e.g. diarrhea, nausea, abdominal cramping) as well as magnesium toxicity. Too much magnesium from food does not pose a health risk in healthy individuals because the kidneys eliminate excess amounts in the urine. [TR 753-780]

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 TR doesn't indicate any negative impact by MCs on soil organisms, crops, and livestock. Again, magnesium and carbonates are both found ubiquitously in nature.

However, the magnesium oxide industry impacts soil and groundwater by magnesite dust. Median levels of magnesium content induced toxicity to plants resulting in a gradual necrosis and loss of soil vegetation cover and causing an extremely low vegetation diversity.

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

Using MCs in the manufacturing of chicory extract is unlikely to harm the environment or biodiversity. [TR 649]

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as nonsynthetic and synthetic available materials. [§6518(m)(6)] The TR stated that there was no indication of nonsynthetic MCs being commercially available for applications of food processing.

The TR indicates several alternative practices that help but do not resolve the problems entirely or may not be suitable for all production types. These practices include cooling the chamber wall and scraping the dryer. Sun drying can be used but is limited to locations with favorable climates.

The TR also identified other National List materials including calcium carbonate, tricalcium phosphate, and silicon dioxide. However, the TR did state that as food additives, all three of these substances are under increasing scrutiny in France as sources of nanoparticles.

Lastly, the TR identified corn starch, potato starch, rice hulls, and cane sugar as alternative anticaking agents available as organic agricultural products. However, it was noted that the TR did not find literature that indicated that these have been studied for use in chicory root powder production and therefore may or may not be suitable alternatives to MCs.

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

 The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

MCs are not agricultural products and therefore can't be produced as organic. The TR states that there was no indication that nonsynthetic MCs are commercially available for application in food processing. [TR 545-550]

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

Using MCs in the manufacturing of organic chicory extract is unlikely to harm the environment or biodiversity.

Again, the main environmental concern regarding MCs pertains to the manufacturing process of magnesium, which is a precursor used in MCs manufacturing. Magnesium itself can be obtained through several different extraction routes and from various magnesium-containing brines and mineral ores. The impacts of mining and use of brines are not unique to these substances. There are other substances on the National List whose main environmental concern is due to the adverse effects of mining. [TR 649-709]

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))

Regarding nutritional qualities, the addition of MCs into instant chicory would slightly increase the amount of elemental magnesium in the powder. However, this increment is unlikely to significantly boost the nutritional profile of the product in terms of the elemental magnesium content.

As for the impact on human health, the TR states that magnesium and MCs are not toxic to humans at doses that fall close to the maximum daily intake. High doses of magnesium (from dietary supplements or medications) can result in stomach issues (e.g. diarrhea, nausea, abdominal cramping) as well as magnesium toxicity. Too much magnesium from food does not pose a health risk in healthy individuals because the kidneys eliminate excess amounts in the urine. [TR 753-780]

 The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

According to the TR, the petitioned use of MCs does not fit the FDA's definition of chemical preservative. [TR 564-574]

Additionally, the TR states that MCs can improve the texture of chicory extract by improving the flowability, which reduces fouling in production and packaging. [TR 594-598]

The TR indicates that no studies were found that show that MCs primary use contributes to improving flavors, colors, or nutritive value lost during processing. That said the TR does state that while not a primary function, MCs are an excellent carrier and retainer of perfumes due to their fine texture. Therefore, if added to chicory extract powder it could improve flavor by retaining some of the volatile compounds that characterize the beverage. [TR 607-610]

 The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

As described in *Approved Legal Uses of the Substance*, above, MCs (CAS RN 39409-82-0) are categorized by the FDA as GRAS at 21 CFR 582.1425. The conditions of use are that it be used in accordance with good manufacturing or feeding practice. [TR 556-558]

The TR found no reports of heavy metal or other contaminants in excess of FDA tolerances in MCs [TR 636-637]

 The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

MCs do not appear essential for organic chicory powder production. There are 12 operations currently listed in the Organic Integrity Database (OID).

There are many alternative organic agricultural substances as well as other anti-caking agents that are already listed on the National List.

In 2015, the NOSB recommended that magnesium carbonate be removed from the National List, because it was not essential to organic handling (NOSB, 2015). The NOP removed it from the National List in 2017 (82 FR 31241).

 In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, <u>Compatibility with Organic Production and Handling</u>, <u>April 2004</u>)

Magnesium carbonate and magnesium carbonate hydroxide are not compatible with organic handling due to the existence of several alternatives on the National List.

Questions to stakeholders:

- 1. Essentiality:
 - a. Have we misunderstood the scope of essentiality since organic chicory powders are being produced currently?
 - b. What has changed since 2017 when magnesium carbonate was removed from the National List due to lack of essentiality?
 - c. Why are the other substances (e.g. calcium carbonate, tricalcium phosphate, and silicon dioxide) listed on the National List as drying agents / anti-caking agents not sufficient for organic chicory powder production?
- 2. CERTIFIERS: Given NOP's prohibition (PM 15-2) of engineered nanoparticles, is there truly a risk that nanoparticles are ending up in organic food from calcium carbonate, tricalcium phosphate, and/or silicon dioxide or are current materials review criteria sufficient to review and prohibit materials manufactured using nanotechnology?
- 3. Are there challenges for producers that are importing and/or exporting organic chicory powder? If so, explain the challenges you are facing.

Subcommittee Votes:

Classification Motion:

Motion to classify magnesium carbonate as nonagricultural, synthetic Motion by: Nate Lewis Seconded by: Kyla Smith Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National List Motion:

Motion to add magnesium carbonate – for use only as an anti-caking agent in chicory powder – at § 205.605(b) Motion by: Kyla Smith Seconded by: Nate Lewis Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

Classification Motion:

Motion to classify magnesium carbonate hydroxide as nonagricultural, synthetic Motion by: Nate Lewis Seconded by: Kyla Smith Yes: 8 No: 0 Abstain: Recuse: 0 Absent: 1

National List Motion:

Motion to add magnesium carbonate hydroxide – for use only as an anti-caking agent in chicory powder – at § 205.605(b) Motion by: Kyla Smith Seconded by: Nate Lewis Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1