

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 21, 2017

Subject: Short DNA Tracers - petitioned

NOSB Chair: Tom Chapman

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: None

Statement of the Recommendation:

The NOSB recommends that the petitioned material, Short DNA Tracers, not be added to the National List at §205.605.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

The NOSB does not believe that the use of short DNA tracers is essential for the handling of organically produced products. The production and sale of organic products has been established and continues to grow without the use of short DNA tracers or similar alternatives.

Additionally, the production method of short DNA tracers falls within the recently updated excluded methods terminology. Where the term “modern biotechnology” is defined in part as “the application of in vitro nucleic acid technologies”. The petitioners use of PCR (polymerase chain reaction) technology to create large numbers of copies of a specific short DNA sequence, would qualify under that definition as an excluded method.

NOSB Vote:

Classification Motion: Move to classify Short DNA Tracers, as petitioned, as non-agricultural, synthetic

Motion by: Lisa de Lima

Seconded by: Scott Rice

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list Short DNA Tracers at §205.605(b)

Motion by: Lisa de Lima

Seconded by: Asa Bradman

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion Failed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Short DNA Tracers**

January 31, 2017

[Summary of Petition, Petition Addendum](#)

Short DNA tracers are being petitioned by manufacturer Safe Tracers for addition to §205.605(b). The petitioner states that inclusion of short DNA tracers in organics would be an improved method for traceability and that current record keeping practices could be simplified and/or supplemented by using short DNA tracers. An advantage pointed out by the petition is that since the short DNA tracers are added to the food, and not to the packaging, it cannot be separated from the food, accidentally or intentionally. Additionally, short DNA tracers do not affect appearance, flavor, aroma, nutritional values or storage requirements of labeled foods and ingredients.

The short DNA tracers could be added by processors to wax or other coatings used in fresh fruits and vegetables. They may also be added to dried products in powder form, encapsulated in various materials that are certified organic or included on §205.605 or §205.606, such as maltodextrin, agar agar, etc. They can also be added directly in liquid form to liquid products such as wine, olive oil, or honey. To obtain maximum sensitivity producers are likely to include short DNA tracers in foods at levels around 1 milligram per ton, which is 1 parts per billion (ppb). The addition of a distinct short DNA tracer would be easily distinguishable through testing at different points in the supply chain, basically tracing the movement and authenticity of the food or ingredient containing the short DNA tracer. Testing currently takes less than an hour and costs less than \$100.

The following is a summary of the manufacturing process of short DNA tracers as explained in the petition. First, full length genomic DNA is purified from a natural source, to serve as the template. Then this template is used to biochemically copy a short targeted region of 50-150 pb in length. This process does not involve genetic modification, and no genes are produced or transferred.

Step one in the manufacturing process is isolation of genomic template DNA from a natural source. Tissue is trimmed, washed and then homogenized through mechanical grinding or via freezing and/or drying. This allows for the release of DNA without breaking into pieces that are too small to be detected later as tracers. Then the homogenate is dissolved in water with the addition of 1-10% lecithin, which breaks up the proteins and lipids. Undissolved solid material is then separated via centrifugation. The clarified liquid is taken from the top and .1-10% sodium chloride is added and stirred to dissolve the solution. Sodium in the salt serves to bind and neutralize the negative charges on the DNA, so the molecules may be forced to clump together in the next step. Next, cold alcohol is added, causing the DNA to be physically forced out of the solution, form a solid, which is separated via centrifugation. The solution, containing the sodium chloride and lecithin, is removed from the top and discarded; the crude DNA pellet is re-suspended in cold alcohol and washed.

Step two is the biochemical copying. After the genomic DNA has been isolated, it is used as a template for biochemical copying. The laboratory biochemical process that reproduces the natural DNA synthesis process requires a pair of single stranded DNA 20-30 bases in length, called primer oligonucleotides. These primer oligonucleotides are manufactured synthetically, as they are too short to reliably procure

from the original natural source (from which the short DNA sequence originates). The primer oligonucleotides represent about 25% of the final product.

The biochemical reaction Polymerase Chain Reaction (PCR) is used for preparation of short DNA tracers from templates. This method does not require insertion, deletion, or modification of any genetic material, and it takes place with no living organism.

Short DNA tracers may also be directly manufactured from genomic DNA using a process involving treatment with restriction endonuclease enzymes but this practice is currently prohibitively expensive.

Summary of Review:

The Handling Subcommittee recommends that the petitioned material, short DNA tracers, not be added to the National List as it fails the “Essentiality & Availability” criteria. Additionally, the use of short DNA tracers would not simplify or change current recordkeeping practices by producers.

Category 1: Classification

1. Substance is for: **Handling**

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

Short DNA tracers are not a product of agriculture. The process to make short DNA tracers mimics the natural synthesis of DNA that occurs in the cells of living things.

- b. If the substance is **Non-agricultural**, 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 step two in the manufacturing process as follows (underlining added by Subcommittee):

“After the genomic DNA has been isolated, it may be used as a template for the second step, which is biochemical copying. The laboratory biochemical process reproduces the natural DNA synthesis process, with a few differences. The main difference is that the lab method requires a pair of single stranded DNA 20-30 bases in length, called primer oligonucleotides. These DNA molecules are designed to bind to either end of the target 50-150 bp region on the template. They serve to delineate the short region of the genomic DNA that is targeted for copying.”

While DNA replication does occur in nature and the technique used is intended to mimic what happens in nature, the use of synthetically derived oligonucleotide primers make this substance synthetic. The synthetic primer oligonucleotides represent about 25% of the final product.

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)]

N/A

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 manufacture of the substance is carried out in controlled environments. Any environmental contamination resulting from production and purification of DNA would be subject to regulations governing waste discharges from the laboratories. Because DNA is not stable in the environment, and extremely small amounts are used as a processing aid or disposed as industrial waste, environmental impact is negligible.

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

The manufacture of the substance is carried out in controlled environments. Because DNA is not stable in the environment, and extremely small amounts are used as a processing aid or disposed as industrial waste, environmental impact is negligible.

The product is considered non-hazardous and does not require a Material Safety Data Sheet.

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

Biochemically produced DNA is GRAS. The petition states that “NIH considers short DNA tracers safe, and this material is not regulated”, and that “...although it is not considered an essential nutrient, DNA is used legally as a dietary supplement, for which FDA registration is not required”.

DNA is a nutrient that is normally abundant in human diets. The amount of short DNA added for tracing purposes is less than one trillionth the amount found in a typical meal. Normal digestive processes completely destroy short DNA tracers, breaking them down into individual nucleotides.

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)]

Short DNA tracers are not intended for use on soil, crops, or livestock. Even if small amounts were occasionally released into the environment, almost all life forms readily use foreign DNA as food source.

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

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)]

The alternative practice to using Short DNA Tracers would be to continue the record keeping processes currently utilized by certified organic operations.

The petition also points out an alternative tracer called Grainfetti, ¼" pieces of paper with printed alphanumeric codes that are mixed into grain. This tracer is not currently approved for organic use.

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)]

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.

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

The use of synthetic primer oligonucleotide is necessary because the naturally occurring enzymes that are used in the DNA production (DNA polymerases), can only attach new DNA nucleotides to an existing strand of nucleotides. The primer oligonucleotide serves to prime and lay a foundation for the DNA production. The primer oligonucleotides are manufactured synthetically because they are too short to reliably procure from the original natural source from which the short DNA sequence originates.

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))

The manufacture of the substance is carried out in controlled environments. Because DNA is not stable in the environment, and extremely small amounts are used as a processing aid or disposed as industrial waste, environmental impact is negligible.

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))

Biochemically produced DNA is GRAS. The petition states that “NIH considers short DNA tracers safe, and this material is not regulated”, and that “...although it is not considered an essential nutrient, DNA is used legally as a dietary supplement, for which DFA registration is not required”.

DNA is nutrient that is normally abundant in human diets. The amount of short DNA added for tracing purposes is less than one trillionth the amount the amount found in a typical meal. Normal digestive processes completely destroy short DNA tracers, breaking them down into individual nucleotides.

4. 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))

The primary use of the substance is as a tracer, not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing.

5. 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))

A GRAS notification for short DNA tracers was submitted to the FDA, and a No Questions Letter was received on August 25, 2014.

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

The Handling Subcommittee does not believe that the use of short DNA tracers is essential for the handling of organically produced products. The production and sale of organic products has been established and continues to grow without the use of short DNA tracers or similar alternatives.

7. 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, [Compatibility with Organic Production and Handling, April 2004](#))

The handling subcommittee does not believe that the use of short DNA tracers is essential for the handling of organically produced products. The production and sale of organic products has been established and continues to grow without the use of short DNA tracers or similar alternatives.

Category 5: Additional criteria for agricultural substances used in handling (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?
N/A
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?
N/A
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?
N/A
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?
N/A
5. Does the industry information about unavailability include (but is not limited to) the following?:
Regions of production (including factors such as climate and number of regions);
 - a. Number of suppliers and amount produced; N/A
 - b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; N/A
 - c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or N/A
 - d. Other issues which may present a challenge to a consistent supply? N/A
6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))
N/A

Classification Motion:

Motion to classify Short DNA Tracers as nonagricultural, synthetic

Motion by: Lisa de Lima

Seconded by: Scott Rice

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

National List Motion:

Motion to add Short DNA Tracers, as petitioned, at 205.605(b)

Motion by: Lisa de Lima

Seconded by: Asa Bradman

Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, January 21, 2017