**OCIA International, Inc.**

1340 N. Cotner Blvd. | Lincoln, NE 68505 | USA

Phone: 402.477.2323 | Fax: 402.477.4325

info@ocia.org | www.ocia.org

**OCIA Natural Flavor Questionnaire**

**USDA National Organic Program (NOP)**

The USDA National Organic Program (NOP) allows the use of certain natural (non-synthetic) substances, including flavors, in products labeled as “Organic” or “Made with Organic…(specified ingredients or food groups)” providing they comply with provisions established in the USDA NOP (*7 CFR Part 205*).

The NOP defines Non-synthetic (natural) in 7 CFR 205.2: a substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (*7 U.S.C. 6502(21)*). Under the terms of the Act, "synthetic" means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Non-synthetic Flavors authorized under the NOP, Section 205.605 (a) must be from non-synthetic sources only and must not be produced using synthetic solvents, carrier systems or any artificial preservative.

"Flavors –nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative."

In addition, non-organic flavors must be produced in compliance with §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling:

“To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in §205.601 or §205.603;

(b) Nonsynthetic substances prohibited in §205.602 or §205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605;

(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606;

(e) Excluded methods, except for vaccines: Provided, That, the vaccines are approved in accordance with §205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.”

Finally, allowed flavors and flavor constituents must:

* Be derived from a non-synthetic source. Flavors that meet the FDA definition of natural flavor are confirmed to be derived from non-synthetic sources.
* Function as a flavor in the “organic” or “made with organic…” product
* Not be produced using synthetic solvents and carrier systems or any artificial preservatives. Allowed extraction solvents include natural ethanol, super-critical carbon dioxide, authentic essential oil, and natural vegetable oils. No hydrocarbon, chlorinated, or halogenated solvents may be used. Propane, hexane, triglycerides, and freon are examples of solvents that are prohibited.
* Contain only allowed other ingredients.

FDA Definition of Natural Flavors *FDA 21 CFR Part 101.22(a)(3)*: “… natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include [*but not exclusively*] the natural essences or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter.”

Certifiers must verify that any flavor used in a processed product labeled as “organic” or “made with organic (specified ingredients or food group(s))” is compliant with the above requirements.

**Canada Organic Regime (COR)**

The COR standards indicate the following restrictions for flavors in CAN/CGSB.311-2020, 6.4: “

Derived from biological sources using approved methods (see Table 11 B (1) & (2)

Origin and mode of production of CAN/CGSB-32.310), and substances (see Table 6.3

Extraction solvents and precipitation aids).

May contain permitted carriers (see Table 6.3 & 6.4 Carriers).”

Extraction solvents and precipitation aids in CAN/CGSB.311-2020, 6.3:

“The following may be used to derive substances listed in Tables 5.2, 6.3, 6.4 and 6.5:

a) water;

b) culinary steam, as described in 8.1.2 b) of CAN/CGSB-32.310;

c) fats, oils and alcohols other than isopropyl alcohol;

d) supercritical CO2; and

e) substances listed in Tables 6.3, 6.4 or 6.5 of this standard.

Precipitation aids derived from biological sources (such as plant proteins, albumin, casein, and gelatin) may also be used. In addition, non-biological precipitation aids, such as bentonite, silicon dioxide, etc., may be used if listed in Tables 6.3, 6.4 or 6.5. If listed in Tables 6.3, 6.4 or 6.5, precipitation aids shall meet any annotation restrictions therein.”

Carriers:

“Carriers of non-agricultural origin may be used if listed on Tables 6.3, 6.4 or 6.5.

Non-organic carriers of agricultural origin (such as wheat starch) may be used if

ingredients or processing aids containing organic carriers are not commercially

available.”

In addition, non-organic flavors must be produced in compliance with 1.4 Prohibited materials or techniques in organic production and preparation and 1.5 Prohibited substances in organic production and preparation:

1.4 Prohibited materials or techniques in organic production and preparation

If producing or preparing organic products, the following materials or techniques are prohibited since they are incompatible with the general principles of organic production:

a) all products of and materials from genetic engineering (GE), as defined in this standard, and as specified in 4.1.3, 5.1.2 and 6.2.1 of CAN/CGSB-32.311;

b) all products, materials or processes intentionally using nanotechnology, as defined in this standard, with the following exceptions:

1) naturally occurring nano-sized particles or those produced incidentally through processes such as grinding flour;

2) contact surfaces, such as equipment, work surfaces or packaging, where transference of nano-sized particles to organic crops, livestock or products is unintended and unlikely to occur;

c) irradiation, as defined in this standard, for the treatment of organic products and inputs used in the production of organic products, except as specified in CAN/CGSB-32.311;

d) cloned livestock and its descendants;

e) equipment, harvest and storage containers, storage facilities and packaging materials treated with fungicides, preservatives, fumigants and pesticides not listed in CAN/CGSB-32.311, except as permitted in 8.2.3 and 8.3.3 of CAN/CGSB-32.310.

1.5 Prohibited substances in organic production and preparation

In addition to Clause 1.4, when producing or preparing organic products, the following substances are prohibited since they are incompatible with the general principles of organic production:

…

b) sewage sludge;

…

f) non-organic ingredients, food additives and processing aids used in organic product preparation,

including sulphates, sulphites, nitrates and nitrites, except as permitted by this standard or specified in CAN/CGSB-32.311;

g) formulants except as specified in CAN/CGSB-32.311;

**Japan Agricultural Standards (JAS)**

The Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606) note that flavorings may be used that are not chemically synthesized.

**Ley de Productos Orgánicos for Mexico (LPO)**

Flavoring agents must be natural and comply with the Codex Alimentarius CAC/GL 29-1987.

**OCIA International Certification Standards (OCIA)**

OCIA standard 5.1.2 (c) allows for the use of flavors that are “wholly derived from botanical or animal sources” and the Processing Materials List defines Natural Flavor as “ All of the flavor constituents used in the natural flavor are from natural sources and have not been chemically modified in a way that makes them different than their natural chemical state. The natural flavor has not been produced using any synthetic solvent and carrier systems or any artificial preservatives. Natural flavors used in products that are labeled “Made with organic ingredients” may not contain propylene glycol or any artificial preservatives, and may not be hexane extracted.”

In order to review the use of a natural flavor used in a certified product, OCIA requests the information below in order to determine compliance under the terms of the applicable organic program. OCIA may request additional information as needed.

|  |
| --- |
| **Natural Flavor Product** |
| Identification of Natural Flavor Product (Name/code on technical data sheet):  |
| Manufacturer Name:  |
| Address:  |
| City:  | State:  | Zip/Postal Code:  |
| Phone:  | Email:  |
| Organic programs flavor is used for:[ ]  NOP [ ]  COR [ ]  JAS [ ]  OCIA [ ]  LPO [ ]  Other:   |
| Type of flavor (select one or more as necessary):[ ]  Protein Hydrolysate [ ]  Extracts [ ]  Essential Oil [ ]  Compounded Flavor [ ]  Oleoresin[ ]  Isolate [ ]  Distillate [ ]  Compounded WONF[ ]  Other (specify):  |
| **A. Flavor Constituents** |
| 1. Do all flavor constituents in the natural flavor product named above meet the FDA/CFIA definition of a natural flavor (see above) as well as any other definitions for the organic program(s) the flavor will be utilized in? [ ]  YES [ ]  NO |
| 2. List all specific sources of the flavor constituents (e.g., spice, plant part, essential oil, etc): |
| 3. Is the flavor product only used for purposes of flavoring and no other purposes (e.g. it’s not for nutritional use, scent, or any other purpose)? [ ]  YES [ ]  NOIf NO, please explain:  |
| 4. Does the flavoring agent(s) in this material only consist of substances that do not impart a specific characteristic flavor, such as flavorings with modifying properties? *For example, if the only flavoring agent in the material is Luo Han Guo (Monk Fruit) derived products, Thaumatin, Glycosylated Steviol Glycosides, or similar the response should be Yes.* [ ]  YES [ ]  NO [ ]  N/AIf YES, attach documentation detailing the maximum usage rate for the overall flavor material to qualify as a natural flavor: [ ]  Attached [ ]  N/A |
| 5. Can the material legally be labeled as a “natural flavor” on the finished product labels per the applicable regulatory body? [ ]  YES [ ]  NOFDA labeling regulations, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.22 sections 101.22(h)(1) states that a natural flavor must be identified in the ingredient statement as a natural flavor, and sections 101.22(i)(1)(i) includes that on the principal display panel the name of the flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored". |
| 6. If the flavor consists of a natural flavoring that must be declared by its common or usual name on the label, list the name here:  [ ]  N/A |
| 7. Do you sell an organic version of this flavor? [ ]  YES [ ]  NO |
| 8. Natural flavors authorized for use in certified products, in addition, must not be produced using synthetic extraction solvents. Extraction may only use natural, non-petroleum based solvents. Is/are the natural flavor constituent(s) made using organic program-suitable extraction solvents?\* [ ]  YES [ ]  NO [ ]  Not Applicable (no solvents used for extraction)If **YES**, please list any solvent(s) used in the production of this Natural Flavor Product. If alcohol (including ethanol) is used, please indicate whether it is produced naturally (via fermentation):\*Allowed natural extraction solvents include water, natural ethanol, super-critical carbon dioxide, authentic essential oil, and natural vegetable oils. No hydrocarbon solvents, or chlorinated, or halogenated solvents may be used. Propane, hexane, and Freon are examples of solvents that are prohibited. |
| **B. Non-flavor Constituents and Other Ingredients** |
| Natural flavors authorized for use in certified products must not contain any synthetic carrier systems or any artificial preservatives. This extends to synthetic processing aids, emulsifiers or antioxidants; i.e. prohibited substances include by are not limited to, e.g., propylene glycol, polyglycerol esters of fatty acids, mono- and di-glycerides, benzoic acid, polysorbate 80, medium chain triglycerides, BHT, BHA, triacetin, etc. |
| 1. List any non-flavor constituents, including solvents, carrier systems, and preservatives, used in this product, as well as the function. Attach any relevant documentation for these ingredients, such as a specification sheet. Additional information may be requested to verify the compliance of these non-flavor ingredients.

|  |  |  |
| --- | --- | --- |
| **Non-Flavor Ingredient/ Adjuvant** | **Function in the Flavor** | **Documentation Attached?** |
|  |  | [ ]  |
|  |  | [ ]  |
|  |  | [ ]  |
|  |  | [ ]  |

 |
|  |
| **C. Additional Information** |
| 1. If glycerin is used, please provide its organic certificate and/or a attach a full manufacturing description. [ ]  Attached [ ]  Not Applicable (no glycerin used) |
| 2. If maltodextrin is used, please attach documentation describing the manufacturing process and GMO status. [ ]  Attached [ ]  Not Applicable (maltodextrin not used) |
| 3. If triglycerides are used as a carrier or solvent, please attach a thorough description of how the triglycerides are made. List processing aids used and their function in the production of the triglycerides. [ ]  Attached [ ]  Not Applicable (triglycerides not used) |
| 4. If citric acid is used, please attach documentation describing the manufacturing process? [ ]  Attached [ ]  Not Applicable (no citric acid used) |
| 5. If alcohol/ethanol is used, please attach documentation describing the manufacturing process. [ ]  Attached [ ]  Not Applicable  |
| **Please note that OCIA may require additional information be provided in order to assess whether or not a preservative, carrier or solvent is synthetically produced.** |
| **D. Excluded and prohibited methods** |
| **Genetically Modified Organism (GMO)** products may not be used at any stage in the process of making natural flavor products for NOP goods. **Excluded methods** (including GMO use) include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Please see the following pages for the definition and examples of excluded methods. |
| 1. This natural flavor product, including any solvents, carriers, preservatives or other processing aids used or contained therein, was produced and handled without the use of excluded methods? [ ]  YES [ ]  NO |
| **Ionizing radiation** is prohibited for the treatment of organic products and inputs used to produce organic products. Other forms of radiation, including those used for food inspection, are permitted providing the uses meet applicable regulations that establish limitations pertaining to all (organic and non-organic) food products. |
| 2. Ionizing radiation as described in 21 CFR 179.26 was not used in the processing of this natural flavor product? [ ]  YES [ ]  NO |
| **Nanotechnology** or technologies intentionally manipulating matter at atomic, molecular, or macromolecular dimensions typically between 1 and 100 nm to create materials, devices and systems with fundamentally new properties and functions, is prohibited for all uses and materials used in organic products. Naturally occurring nano-sized particles or those produced incidentally are permitted. |
| 3. This natural flavor has been handled without the use of nanotechnology as described in NOP Policy Memo 15-2 OR COR as applicable. [ ]  YES [ ]  NO |
| **F. Affirmation** |
| *To be signed by a qualified, technical representative of the manufacturer. Any operation that makes a false statement under The Organic Foods Production Act of 1990 to an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code (205.100(c)(2)).* Pursuant to the applicable regulations for the organic programs the flavor will be used in, I, on behalf of the manufacturer, herby attest that the information provided in this form is accurate and truthful to the best of my knowledge. |
| Company Name:  |
| Printed Name:  | Title: |
| Signature:  | Date:  |

**Other relevant definitions:**

* A **nonsynthetic** (natural) substance is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). (7 CFR 205.2)
* A **synthetic** substance is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. (7 CFR 205.2)
* **Excluded methods** are defined as a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.(7 CFR 205.2) Prohibited excluded methods include, but are not limited to:

|  |  |
| --- | --- |
| ***Method and synonyms*** | ***Method and synonyms*** |
| Targeted genetic modification (TagMo)syn. Synthetic gene technologiessyn. Genome engineeringsyn. Gene editingsyn. Gene targeting | Sequence-specific nucleases (SSNs)Meganucleases Zinc finger nuclease (ZFN)Mutagenesis via OligonucleotidesCRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genesTALENs (Transcription activator-like effector nucleases)Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System |
| Gene Silencing | Gene Silencing |
| Accelerated plant breeding techniques | Reverse BreedingGenome EliminationFasTrackFast flowering |
| Synthetic biology | Creating new DNA sequencesSynthetic chromosomesEngineered biological functions and systems |
| Cloned animals and offspring | Somatic nuclear transfer |
| Plastic transformation |  |
| Cisgenesis | The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation. |
| Intragenesis | The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant. |
| Agro-infiltration |  |
| Transposons – Developed via use of in vitro nucleic acid techniques |  |
| Induced mutagenesis | Developed through in vitro nucleic acid techniques |