

# GUIDANCE ON FORMULATION AND MARKETING OF DIETARY SUPPLEMENTS UNDER THE NATIONAL ORGANIC PROGRAM

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Prepared by the American Herbal Products Association, Quality Assurance International, and the Organic Trade Association



CERTIFIED ORGANIC



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## Introduction

The Organic Foods Production Act (OFPA), adopted by the U.S. Congress in 1990, established the legal criteria for labeling and selling a raw or processed agricultural product as organic in the United States. The National Organic Program (NOP<sup>1</sup>) is the regulation<sup>2</sup> under which the U.S. Department of Agriculture (USDA) implements the OFPA, and the Agricultural Marketing Service (AMS) is the USDA department responsible for this regulation and its enforcement.

Food, dietary supplement, and other products that contain agricultural products grown and processed in accordance with the NOP may be identified as organic. If certain conditions are met, these organic products may bear the USDA Organic seal and a statement that the product is “100 percent organic” or “organic” on the product label’s principal display panel (PDP). Furthermore, all such products may truthfully identify any certified organic ingredients on a label’s ingredient panel.

This document provides guidance to companies that wish to market organically labeled dietary supplements in the United States. It includes information about the types of supplements that are eligible for organic certification under the NOP, and the various NOP labeling categories that are available for several types of supplement products. It also provides an overview of the regulatory obligations that must be met from the farm to the packaged products, as finished product marketers have regulatory obligations not only for their own manufactured products but also for the organic ingredients they use.

This document does not, however, serve as a substitute for a thorough understanding of the NOP rule as codified in Title 7 of the Code of Federal Regulations, Part 205 (7 CFR 205), or any other federal or state law or regulation. It is essential that any company that markets organic dietary supplements be familiar with the relevant sections of these regulations, either directly or through the services of a qualified consultant or knowledgeable legal counsel.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry, consisting of growers, processors, manufacturers and marketers of herbs and herbal products. AHPA’s mission is to promote the responsible commerce of herbs and herbal products. AHPA member companies sell consumer products in the form of herbal teas and flavor extracts, and provide herbal ingredients for other conventional food products. The majority of the products sold by AHPA’s members, however, are marketed as herbal dietary supplements<sup>3</sup>, usually in the form of teas, tablets, capsules, or tinctures.

QAI (Quality Assurance International) is a USDA-accredited organic product certifying agency. Founded in San Diego, California in 1989, QAI has been an active leader in the organic industry, advocating for stringent organic regulations since its beginning. QAI is committed to ensuring organic integrity at every link in the organic production chain and providing excellent customer service, domestically and internationally. Operating throughout the United States, Canada, Mexico, Central America, Japan and

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<sup>1</sup> The abbreviation NOP is used to indicate both the regulation and the program. Where it is not obvious which is intended, clarification is provided, for example by stating “the NOP rule” or “the NOP program.”

<sup>2</sup> Codified as Title 7, Code of Federal Regulations, Part 205 (7 CFR 205).

<sup>3</sup> As defined in 21 USC 321(ff).



the European Union, QAI is dedicated to fostering organic food production to benefit both people and the planet while providing educational outreach to the organic community and consumers.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products. OTA includes the full value chain for the organic industry, ensuring that all segments, from farm to marketplace, have a strong voice. OTA brings farmers and growers, ingredient suppliers, processors, manufacturers, distributors, retailers and others—brokers, certifiers, health practitioners—together to promote and protect the growing sector. The Organic Trade Association is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. The Organic Trade Association Board of Directors is democratically elected by its members. OTA represents organic foods, ingredients and beverages, as well as organic fibers, personal care products, pet foods, household cleaners, flowers and nutritional supplements. The Organic Trade Association’s Dietary Supplements Council provides interested members a forum for discussing issues, challenges and opportunities related to the sector.



## Background on the National Organic Program (NOP)

Most products marketed in the U.S. as organic under the NOP are fresh or processed conventional foods.<sup>4</sup> Organic foods include raw agricultural commodities, such as fresh fruits and vegetables, meat and poultry products, dairy products and manufactured foods like pasta, soups, breakfast cereals, etc.

### Dietary Supplements and the NOP

When the final NOP rule was published in December 2000, the labeling of dietary supplements (as well as other non-food products, such as cosmetics and body care products) was stated as “outside the scope of these regulations.”<sup>5</sup> However, in August 2005, NOP announced that any raw or processed agricultural product that meets NOP standards can be labeled and marketed as organic “irrespective of the end use of the product.”<sup>6</sup>

This means that dietary supplements may be marketed with organic labeling, so long as they: 1) contain agricultural products such as herbs or vitamins and minerals derived from organically produced plants or animals; and 2) comply with the NOP regulation.

With increasing interest and demand from consumers for products that are natural and free from harmful chemicals and pesticides, the market has grown steadily for consumer products cultivated, processed and labeled as organic in accordance with the NOP. U.S. sales in 2016 of organic dietary supplements were reported at \$1.2 billion, an increase of 10.7% over the prior year and up from \$410 million in 2007.<sup>7</sup> The 10.7% growth is much stronger than the 6.0% reported for all dietary supplements.

Despite the growth in sales of dietary supplements that are labeled as organic under the NOP, organic dietary supplements are still a relatively new and relatively small sector of the overall organic industry. While makers of organic foods have developed considerable experience in conforming to the NOP, far fewer dietary supplement companies are familiar with complexities of this regulation.

### Organic Supply Chain

To bring any processed organic agricultural product to market – whether food or dietary supplement – the ingredients themselves and every stage of processing must meet the applicable NOP requirements. More specifically, a dietary supplement must meet all of the requirements below in order to be labeled as organic in the U.S., whether the described farm or facility is located in or outside the U.S.

- A farm growing organic crops certified as organic by a certifying agent must be in compliance with the NOP. If the dietary supplement manufacturer is receiving organic agricultural goods direct from farms, it must obtain and be in possession of a copy of the organic certificates from each of its organic agricultural sources. This obligation applies whether crops are grown in the United States or in another country.

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<sup>4</sup> The term “conventional foods” is used here to differentiate foods that are an ordinary part of the diet from dietary supplements, which are also classified as food under U.S. law. Use of the word “food” throughout the rest of this document means conventional food exclusive of dietary supplements.

<sup>5</sup> Federal Register, Vol. 65, No. 246, p. 80557. December 21, 2000.

<sup>6</sup> Robinson BC. Memorandum to all USDA accredited certifying agents. August 23, 2005.

<sup>7</sup> Organic Trade Association, *2017 Organic Industry Survey*.



- All post-harvest and processing facilities that prepare, process or transform organic crops into ingredients must be operations certified to the NOP standard. If the dietary supplement manufacturer is sourcing organic ingredients from processing facilities, it must obtain and be in possession of a copy of the organic certificates showing that each of the processors from whom it sources organic ingredients is third-party certified as organic.
- Manufacturers of finished products using organic ingredients must have their facilities certified in order to make “100 percent organic,” “organic,” or “made with organic [specified ingredients or food groups]” claims on their products. No such requirement is applicable to companies that make products that do not make an organic claim on the Principal Display Panel (PDP) and are labeled only to identify individual organic ingredients in the ingredients statement. In such cases the operation is exempt from certification. However, while exempt operators do not need to be certified, they are required to comply with the labeling provisions of the NOP regulation and they must maintain documentation to prove that the ingredients identified as organic were organically produced and handled and verify the quantities produced from such ingredients. Exempt operators must maintain records for no less than 3 years beyond their creation and make records available for review during normal business hours.
- Dietary supplement products can contain only those nonorganic nonagricultural ingredients that are on the National List, except for products that simply label individual ingredients as “organic” on the ingredient panel. In order to include nonorganic ingredients in dietary supplements labeled as organic, any nonorganic ingredients must be allowed on the National List and are limited to no more than 5% of the finished product.

## The National List

The National List of Allowed and Prohibited Substances (the National List - actually maintained as six separate lists, from 7 CFR 205.601 to 205.606, inclusively) identifies synthetic substances that may be used, and nonsynthetic substances that cannot be used, in organic production and handling operations. Two of these lists are specifically relevant to processed organic products, including 7 CFR 205.605: Allowed nonagricultural (nonorganic) substances and 7 CFR 205.606: Allowed nonorganically produced agricultural products. Substances listed on 7 CFR 205.606 may only be used after the manufacturer has demonstrated to their certifier that the substance was not commercially available in organic form.

The food industry has been quite active in continued development of the NOP regulations, and has expended considerable effort in having many of the nonagricultural ingredients essential in food manufacturing added to the National List.

Some of the nonagricultural and nonorganic agricultural products used exclusively as ingredients in supplements, however, have not been considered for inclusion in the list. For example, microcrystalline cellulose, hypromellose capsules, and methyl cellulose are prohibited ingredients under the NOP. Since the NOP uses the same rules that apply to food to regulate dietary supplements, such exclusions limit the range of supplement products that may be marketed as organic.

Any individual or organization may submit a petition to add, remove or amend the listing of a substance on the National List. The National Organic Standards Board (NOSB) is the Federal Advisory Committee charged with making recommendations to the NOP regarding the addition, removal or amendment of



the listing of a substance on the National List. The process<sup>8</sup> for requesting consideration of an amendment to the National List can be viewed as a 7-step process that includes opportunities for stakeholder participation. The complete process is available on the NOP website.



## Global Supply Chain

Manufacturers of dietary supplements need to be aware of North American trade developments in the organic industry which have affected both market opportunities and the availability of a broader range of certified organic ingredients for supplements. In June 2009, the U.S. and Canada signed an equivalency agreement, which allows trade of organic products with few restrictions. In June 2012, the U.S. and the European Union engaged in a similar equivalency agreement for organic agricultural products. Additional equivalency arrangements with the U.S. that were established between 2013 and 2017 include the U.S.-Swiss Equivalency Agreement, the U.S.-Korea Equivalency Agreement and the U.S.-Japan Equivalency Agreement. While these agreements have little impact on the international markets for finished dietary supplements, they expand the availability of certified organic ingredients for use in these products. More information about the NOP’s international partnerships can be found on the NOP website as well as on OTA’s Global Market Opportunities webpage (<https://www.ota.com/resources/global-market-opportunities>).

## Labeling of Products as Organic Under NOP

The NOP allows four distinct organic labeling claims for finished products, dependent on the proportion of organic ingredients in the products. These categories are described in the following table; see 7 CFR 205.300-305 for additional labeling details.

<sup>8</sup> Information on the process for filing a petition to amend the National List can be found here <https://www.ams.usda.gov/rules-regulations/organic/national-list/filing-petition>. Accessed October 28, 2017.



Claim	Product	Label
<b>“100 percent organic”</b>	<p>Must contain only ingredients that are certified 100 percent organic, and, if applicable, organic processing aids<sup>9</sup></p> <p>Most relevant for single-ingredient raw commodities and simply processed foods, and difficult to achieve for most processed foods</p>	<p>Can display “100 percent organic” and the USDA organic seal anywhere on the label including the principal display panel (PDP)</p> <p>Must identify the name or logo of the USDA-accredited agent that certified the final certified handler on the information panel</p>
<b>“organic”</b>	<p>Must contain at least 95 percent organic ingredients</p> <p>Can only contain nonorganic ingredients and processing aids that:</p> <ul style="list-style-type: none"> <li>• Are included in the National List (205.605 and/or 205.606)</li> <li>• Were produced without genetically modified organisms, irradiation or sewage sludge (as a fertilizer)</li> </ul>	<p>Can display an “organic” statement and the USDA organic seal anywhere on the label including the PDP</p> <p>Must identify the name or logo of the USDA-accredited agent that certified the final certified handler on the information panel</p> <p>Must identify each organic ingredient as organic in the ingredient statement</p>
<b>“made with organic [specific ingredients]”</b>	<p>Must contain at least 70 percent organic ingredients</p> <p>Can only contain nonorganic ingredients and processing aids that:</p> <ul style="list-style-type: none"> <li>• Are included in the National List (205.605) or are verified to be “agricultural” ingredients</li> <li>• Were produced without genetically modified organisms, irradiation or sewage sludge (as a fertilizer)</li> </ul>	<p>Can display “made with organic [specific ingredients]” anywhere on the label including the PDP</p> <p><b>Cannot</b> display the USDA organic seal</p> <p>Must identify the name (logo is optional) of the USDA-accredited agent that certified the final certified handler on the information panel</p> <p>Must identify each organic ingredient as organic in the ingredient statement</p>
<b>Some organic ingredients</b>	<p>Applies only to processed products</p> <p>Contains less than 70 percent organic ingredients; or</p> <p>Organic ingredient statement claim only</p>	<p>Can identify organic ingredients as organic in ingredients statement only</p> <p>If the organic ingredients are identified in the ingredient statement, display the product’s percentage of organic contents on the information panel</p> <p><b>Cannot</b> display:</p> <ul style="list-style-type: none"> <li>• Any other reference to organic or organic content on the PDP</li> <li>• The USDA organic seal</li> <li>• The certifier name or seal</li> </ul>

<sup>9</sup> For example, organic apple juice that is processed with organic rice hulls would comply with this organic labeling category.





## Calculating the organic percentage of a product

The NOP regulations at 7 CFR 205.302 specify the method that should be used to determine the organic percentage of a product. The organic percentage of a product must be calculated by dividing either the total net weight or volume (excluding water and salt) of combined organic ingredients *at formulation* by the total weight or volume (excluding water and salt) of the product (organic and non-organic ingredients combined). If the product and ingredients are liquid, the same calculation method applies but fluid volume should be used instead of weight. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product (See NOP Policy Memo PM 11-9 – Calculating the Percentage of Organically Produced Ingredients (Appendix C)).

For products containing organically produced ingredients in both solid and liquid form, the calculation is made by dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the combined organic and non-organic ingredients.

In all cases, the percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number. Furthermore, the percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

There are some challenging nuances involved in calculating the organic percentage of NOP certified products, therefore NOP has issued guidance to assist certified operators and certifying agents. See the section on NOP Guidance, Policy and Instruction below.

## How Dietary Supplements Can Meet NOP Labeling Rules

The previous section discussed the four categories of organic labeling claims available under the NOP. Some supplement products consist only of ingredients that are agricultural products and others contain one or more agricultural substances with other nonagricultural ingredients. Understanding which organic label can be applied to a specific dietary supplement depends on the product's formulation.

The following is a compilation of the types of dietary supplements that may be able to comply with each of the NOP organic labeling claims. For both the "organic" and the "made with organic" labeling claims, any nonorganic ingredients or processing aids used to produce the final product must be produced without the use of genetically modified organisms, irradiation and sewage sludge (used as a fertilizer).

### Dietary supplement products that may be labeled as "100 percent organic"

- Certified organic raw agricultural herbs; that is, bulk lots of such herbs including bulk lots packaged in consumer packaging
- Herbal teas in which the sole ingredients are certified organic herbs or organic herbs with 100 percent organic flavors (e.g. essential oils)



- Powdered extracts of certified organic raw agricultural herbs in which the only solvent is water and which are processed to powdered form without the use of any nonorganic substances<sup>10</sup>

Note: For any of the above described products, the use of “100 percent organic” labeling is not allowed if the product is packaged with a nitrogen flushing step.

### Dietary supplement products that may be labeled as “organic”

- Herbal teas in which at least 95% of the ingredients are certified organic herbs and certified organic flavors or sweeteners, so long as the remaining 5% ingredients are included on the National Lists 7 CFR 205.605 or 7 CFR 205.606. In the case of ingredients on 7 CFR 205.606, organic forms must be used if they are commercially available (i.e. available in the necessary quality, quantity or form).
- Extracts, in either liquid or dry form, of certified organic raw agricultural products in which all solvents (other than water) are certified organic, and in which any substances used as ingredients or processing aids do not make up more than 5% of the finished product and are included on the National Lists 7 CFR 205.605 or 7 CFR 205.606. Volatile synthetic solvents and solvents that are not on the National List may not be used in the manufacture of the extract. In the case of ingredients on 7 CFR 205.606, organic forms must be used if they are commercially available.
- Non-herbal dietary ingredients, such as vitamin C from organic rose hips, that are derived from certified organic plants without the use of any nonorganic, nonagricultural products other than those on the National List 7 CFR 205.605.
- Tablets that are manufactured with a minimum of 95% certified organic raw agricultural herbs, or certified organic extracts, and not more than 5% of the weight of the ingredients at formulation of the tablet (including the tablet coating) consists of nonorganic ingredients that are on the National Lists 7 CFR 205.605 and 7 CFR 205.606. Note: many of the excipients used in the manufacture of dietary supplement tablets are not currently on the National List, which may be a limiting factor for tablet manufacturers.
- Encapsulated products (in either hard-shell or soft capsules) in which at least 95% of the ingredients are composed of organically produced raw agricultural herbs or extracts of organically produced herbs, and the capsule is organically produced (example, organically produced and certified gelatin or pullulan capsules). Note: The percentage weight of capsules is counted when determining the organic ingredient content of the finished product. The weight of the capsules will often exceed the maximum 5% by weight of nonorganic content allowed for the “organic” claim, and the capsule component cannot be overlooked when a manufacturer determines the appropriate organic labeling claim for its product. Therefore, in order to make an organic claim on an encapsulated product, the capsule must also be certified organic. Not more than 5% of the total weight of all ingredients at formulation of the encapsulated product

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<sup>10</sup> Liquid extracts of certified organic raw materials in which the solvents are limited to water and 100% organic ethyl alcohol (i.e. ethyl alcohol produced by fermentation and distillation from organic grain, fruit, etc.) would conceivably be able to meet requirements to be labeled as “100 percent organic,” but only if the organic alcohol is produced with organic processing aids and ingredients that are certified 100 percent organic themselves.



(including the capsule itself) consists of nonorganic ingredients that are on the National Lists 7 CFR 205.605 and 7 CFR 205.606. Many of the excipients used in the manufacture of capsules are not currently on the National List, which may be a limiting factor for producing a capsule that could be labeled as “organic.”

### **Dietary supplement products that may be labeled as “made with organic [specified ingredients]”**

- Herbal teas in which at least 70% of the ingredients are certified organic raw agricultural herbs and certified organic flavors or sweeteners, so long as all of the other ingredients consist of nonorganic agricultural ingredients or substances included on the National List 7 CFR 205.605.
- Extracts of certified organic raw agricultural products, as long as a minimum of 70% of the ingredients, including solvents, are certified organic. The remaining substances used as ingredients and processing aids can either be nonorganic agricultural ingredients or substances included on the National List 7 CFR 205.605. Volatile synthetic solvents and solvents not listed on the National List may not be used in the manufacture of the extract. However, synthetic solvents may be used to produce nonorganic agricultural ingredients which can be used in a “made with organic” extract.
- Tablets in which at least 70% of the ingredients are organically produced raw agricultural herbs or extracts of organically produced herbs. The remaining ingredients must either be nonorganic agricultural ingredients or substances included on the National List 7 CFR 205.605. Note: Many of the excipients used in the manufacture of tablets are not currently on the National List, which may be a limiting factor for producing a tablet that could be labeled “made with organic [specific ingredients].”<sup>11</sup>
- Encapsulated products (in either hard-shell or soft gelatin capsules) in which at least 70% of the ingredients are organically produced raw agricultural herbs or extracts of organically produced herbs. Note: The percentage weight of capsules is counted when determining the organic ingredient content of the finished product. The weight of the capsules will often exceed the maximum 5% by weight of nonorganic content allowed for the “organic” claim, and the capsule component cannot be overlooked when a manufacturer determines the appropriate organic labeling claim for its product. Therefore, most capsule products will only be able to make “made with organic...” or ingredient display panel claims. In addition, the capsule must be composed of materials on the National List 7 CFR 205.605, or agricultural materials such as gelatin or pullulan. Many of the excipients used in the manufacture of capsules are not currently on the National List, which may be a limiting factor for producing a capsule that could be labeled as “made with organic [specific ingredients].”

### **Dietary supplement products in which certified organic agricultural ingredients may be labeled as “organic” in the ingredient statement**

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<sup>11</sup> There is no NOP list of approved excipients, but companies can search the National List for specific excipients. Approved excipients include silicon dioxide, colors, flavors and tricalcium phosphate.



- Any herbal product that contains less than 70% certified organic herbal ingredients, including teas, extracts, tablets, capsules, etc., is not allowed to use the term “organic” on the principal Display Panel. It is allowed under the NOP to label each certified organic ingredient with the word “organic” on the ingredient statement, so long as the product is in conformity with 7 CFR 205.305 of the NOP. In addition, a percentage of organic ingredients statement can be made on the information panel only.

## NOP Guidance, Policy and Instruction

The National Organic Program maintains a compilation of guidance documents, policy memos and instruction titled *“The Program Handbook: Guidance and Instruction for Accredited Certifying Agents and Certified Operations.”* The goal of the Program Handbook is to provide those who own, manage, or certify organic operations with guidance, instructions, and policy memos that can assist them in complying with NOP regulations.

There are several documents in The Program Handbook that help to clarify the composition and labeling requirements for dietary supplements. Notable documents include, but are not limited to:

- NOP 5032 – Products in the “Made With Organic \*\*\*” Labeling Category (Appendix A)

This guidance describes the requirements for products in the “made with organic (specified ingredients or food group(s))” labeling category. Specifically, it clarifies 1) composition; 2) compliant organic labeling claims; 3) organic and non-organic forms of the same ingredient; 4) percentage of organic ingredient statements; and 5) ingredients or food groups in the “made with organic \*\*\*” claim.
- NOP 4012 – Use of Brand or Company Names Containing the Word “Organic” (Appendix B)

This instruction document clarifies the requirements for use of brand or company names containing the word “organic” on the labeling of agricultural products. Specifically, it clarifies that brand or company names containing the term “organic” should not be used on the principal display panel (PDP) of agricultural products certified in the “made with organic \*\*\*” labeling category.
- PM 11-9 - Calculating the Percentage of Organically Produced Ingredients (Appendix C)

This Policy Memo provides answers to several questions NOP has received regarding the protocol to be used by handlers in determining compliance with the composition requirements found at 205.302(a) of the organic regulations.

Guidance, Instruction, and Policy Memo documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or the program. Rather, the documents explain how the organic regulations apply to certain regulated activities. The documents do however represent NOP’s current thinking on regulatory topics and provide a uniform method for operations to comply that can reduce the burden of developing their own methods and simplify audits and inspections.

The entire Program Handbook may be viewed electronically through NOP’s website at:

<https://www.ams.usda.gov/rules-regulations/organic/handbook>.



## Organic Dietary Supplement Certification Process

The NOP does not itself perform inspection or certification activities. Instead, the NOP accredits certifiers around the globe to perform these functions. Domestically and abroad, all NOP-accredited certifying agents, including QAI, ensure integrity in each link of the product handling chain, helping to ensure compliance with organic standards for agricultural producers, processing facilities, manufacturing operations, contract manufacturing operations, traders, distributors, retailers and, ultimately, for consumers. For an operation to become certified to the National Organic Program, it must be certified by a NOP- accredited certifying agent.

Organic certification is a five-step process, which includes application, inspection, technical review, resolution/notification and certification as described in the following figure:



Each of the steps in the organic certification process is further detailed as follows:

- **Application:** The operation seeking certification submits an application and organic compliance plan to an accredited certifying agent for review. This review ensures that the organic compliance plan adequately describes how the applicant will comply with the NOP. Once the



certifying agent determines that the applicant has the ability to comply with the NOP, an inspection is scheduled.

- **Inspection:** Each farm or department within a manufacturing facility that has any responsibility for organic compliance is methodically assessed by an organic inspector during the on-site inspection to confirm that it is in compliance with the NOP and the farm's or manufacturer's organic compliance plan.
- **Technical Review:** Once the inspection is carried out, an inspection report and supporting documentation are sent to the certifying agent for the technical review. The technical review assesses all information from the on-site inspection against the NOP regulations to determine compliance.
- **Resolution/Notification:** After technical review, either the applicant is granted certification with minor corrective actions to be made to the organic system, or a letter of noncompliance is issued. Certification may be denied if the inspection found that the farm or manufacturing operation was not able to comply with the NOP regulation.
- **Certification:** Once all corrective actions are submitted, assessed by the certifying agent and approved, an organic certificate is issued, listing the products that have been determined to be in compliance with the NOP.

Once the applicant has been certified, the NOP requires that the certified operation submit, on an annual basis, an updated organic compliance plan, a summary of any revisions to or deviations from the plan since the last update, an update on minor corrective actions from prior inspections, and any other information required by the certifying agent. An annual inspection will also be conducted by the certifying agent. New products can be added to an existing certification when they are produced under the certified operation's existing organic compliance plan.

There are some issues that dietary supplement manufacturers may encounter during the certification process. Some of the most common are highlighted in the next section.

## Common Organic Certification Issues for Dietary Supplements

The primary focus of the NOP since it was established by the OFPA has been on addressing organic agricultural food and fiber production, but it is also relevant to substantiate organic production claims by manufacturers of other types of products such as dietary supplements and personal care products. As stated previously, the NOP is neutral as to the type of product being certified, as long as it is an agricultural product. This section provides guidance to manufacturers of dietary supplements regarding some of the commonly encountered challenges to achieving organic certification for these products.

### Determination of Organic Certification Claims

Many dietary supplement products are manufactured in processed forms such as extracts, tablets and capsules that utilize inputs and production methods different from those used in food production. To determine the appropriate category of organic claim that can be made for a specific product under the



NOP, dietary supplement manufacturers must fully evaluate the composition of their products against NOP requirements, particularly any ingredients that are not certified organic agricultural commodities.

For products making “organic” claims, it is important to remember that any nonorganic agricultural substances listed on 7 CFR 205.606 may only be used after the manufacturer has demonstrated that the substance was not commercially available in organic form. Commercial availability is defined as the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan. Therefore, nonorganic herbal ingredients cannot be used unless they are listed on 7 CFR 205.606 and the manufacturer has successfully demonstrated to their certifying agent that the ingredient is commercially unavailable in organic form.

Products making a “made with organic [specific ingredients]” claim must contain by weight (excluding water and salt) at least 70% certified organic ingredients. The remaining ingredients must be composed of substances that are on the National List 7 CFR 205.605 (nonagricultural ingredients) or are conventional agricultural ingredients produced without the use of genetically modified organisms, irradiation and sewage sludge used as a fertilizer in the production of the ingredient.

## Production Methods for Allowed Ingredients

After determining that all ingredients used in the dietary supplement product are allowed according to the National List for the category of organic claim being made, the manufacturer should determine that the production methods used to generate those ingredients are in compliance with NOP requirements, such as:

- All organic and nonorganic ingredients and additives/processing aids must not be produced with genetically modified organisms. Inputs derived from crops, such as corn and soybeans, are very commonly derived from genetically modified plants in the U.S. This may include enzymes, starches, and some vitamins.
- All organic and nonorganic ingredients and additives/processing aids must not be processed with irradiation. Particular attention may be needed for supplement ingredients that may also be used as culinary herbs and spices, because federal regulations specifically allow treatment with ionizing irradiation of these ingredients when used to impart flavor in conventional foods, and also allow this treatment of turmeric and paprika when used as color additives.<sup>12</sup>
- All organic and nonorganic raw agricultural ingredients and additives/processing aids must not be produced with the use of sewage sludge.
- Vitamins and minerals listed in 21 CFR 104.20(d)(3)<sup>13</sup> may be added. This section permits the use of the following nutrients for fortification in accordance with its policy: protein, calcium, iron, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, magnesium, zinc, iodine, copper, potassium, and vitamins A, C, C, E, B6, and B12. Vitamins and minerals must be nonagricultural for their use to be covered under the National List 7 CFR 205.605.

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<sup>12</sup> 21 CFR 179.26 (b)(5)

<sup>13</sup> 21 CFR 104.20 Nutritional Quality Guidelines for Food, Subpart B – Fortification Policy



- Agricultural nutrients must be organically produced, if used in a product making an “organic” claim, unless they are listed on 7 CFR 205.606 and are found to be commercially unavailable in organic form.
- Non-organic agricultural nutrients may be used in the 30% allowed non-organic portion of a “made with organic...” product.
- Only those nutrients listed by FDA in 21 CFR 101.9 as essential are approved as nonagricultural, nonorganic ingredients.

## Technical Additives and Processing Aids

Approved technical additives and processing aids must meet at least one of these criteria:

- Appear on the National List 7 CFR 205.605 for non-agricultural materials such as flavors, stabilizers, preservatives;
- Appear on the National List 7 CFR 205.606 for non-organic agricultural materials such as colors, gelatin and starches and be commercially unavailable in organic form; or
- Are other agricultural ingredients for products making a “made with organic...” claim.

Note: The use of lubricants to keep capsule contact surfaces non-sticky would need to be NOP compliant. Further, materials used that are listed on the National List must also meet the specific restriction associated with the material. For example, flavors are allowed in organics but the specific restriction, as stated on the National List 7 CFR 205.605, is that any flavor use must be “nonsynthetic and must not be produced using synthetic solvents, carriers or preservative systems.”

In addition, while cellulose is permitted on the National List with the specific restriction “non-chlorine bleach only and only for use as an anti-caking agent or filtration aid,” other forms of cellulose that are typically used in dietary supplements, e.g. microcrystalline cellulose and methylcellulose, are not permitted.

## Labeling Issues

In addition to being labeled in accordance with the FDA’s requirements for dietary supplements, manufacturers should be aware of the NOP labeling requirements for organic claims. The NOP places restrictions on the relative type size and the placement of organic labeling on product packaging. All organic ingredients must be identified as such on the ingredient panel. A “certified organic by...” statement must appear next to the information identifying the accredited certifying agent on the label. Due to the small size of the labels and containers for many dietary supplements, manufacturers may have to redesign packaging to ensure that all information is displayed in a compliant manner.

Manufacturers should also review labels to determine appropriate use of the term “organic” in relation to other information on the label. For example, the term “organic” cannot modify a nonorganic ingredient, so a label cannot read “organic vitamin C” if the ingredients that supply the vitamin C in the product are not organic. All labels need to be reviewed and approved by the certifying agency (this includes all version updates).





The labeling permitted for certified products should enable consumers to easily distinguish “100 percent organic” or “organic” products and products certified as “made with organic (specified ingredients or food groups).” When a company or brand name containing the term “organic” is used on the PDP or other labeling of an agricultural product that is not certified as “100 percent organic” or “organic,” this distinction is blurred and consumers may be misled. Therefore, products certified as “made with organic (specified ingredients or food groups),” brand or company names containing the term “organic” should not be used on the PDP of these products. See NOP Instruction 4012 (Appendix B).

## NOP Residue Testing

The authority for certifiers to test organic products for residues of prohibited substances has always been part of the NOP regulations, and beginning January 1, 2013, regulations went into effect requiring that certifying agents take samples from at least 5% of the operations they certify on an annual basis. This requirement is in addition to testing organic products when there is reason to believe they have been contaminated with prohibited substances. The final rule also clarifies that certifiers may sample and test organic products for any type of prohibited substance residue, including pesticides, solvents, processing aids, GMOs, antibiotics, heavy metals, and pathogenic organisms.

Organic operations must implement systems that prevent contamination of organic products, and residue sampling is an effective certification tool to assess the efficacy of these contamination prevention measures. Additionally, the regular monitoring of organic products for prohibited residues further deters fraud in the marketplace. From this perspective, residue testing has a dual role in organic certification. It provides a means for monitoring compliance with the USDA organic regulations and discouraging the mislabeling of agricultural products and it also provides State Organic Program and certifying agents with a tool for ensuring compliance.

The EPA establishes the maximum allowed levels of pesticides, or EPA tolerances, which may be present on foods. Although many of these pesticides are prohibited in organic production, there can be inadvertent indirect contact from neighboring conventional farms or shared handling facilities. To recognize that inadvertent or unavoidable contact with prohibited substances may occur, the USDA organic regulations allow residues of prohibited pesticides—up to 5% of the EPA tolerance level—if those residues are present due to unavoidable or inadvertent contact. If an organic producer applied a prohibited pesticide or didn’t take adequate steps to avoid contamination from it, any level of pesticide residues would be a violation of the organic standards.

To assist certifiers and industry in matters of testing residues, NOP has created extensive guidance that can be found in the NOP Handbook. The guidance includes sampling procedures for residue testing (NOP 2610), laboratory selection criteria (NOP 2611), a target list of prohibited pesticides that includes approximately 188 analytes (NOP 2611-1) and step-by-step instructions for responding to test results (NOP 2613).

All of the guidance documents may be viewed electronically and/or be downloaded through NOP’s website at: <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

## Potential Residue Testing Issues for Dietary Supplements

The NOP regulations allow residues of prohibited pesticides—up to 5% of the EPA tolerance level or Maximum Residue Limit (MRL) —if those residues are present due to unavoidable or inadvertent



contact. Although MRLs have been established for most commonly used culinary herbs and spices, other agricultural products used as ingredients in dietary supplements are minor crops that often do not have an MRL established. This poses challenges when trace amounts of residues are found, and a zero-tolerance approach must be taken. Some of these ingredients used exclusively in supplements can also be challenging for laboratories to analyze, and some laboratories have not established protocols for certain crops that are not tested often. This can make it challenging for companies to find laboratories that can provide residue analyses with high confidence levels on certain dietary supplements and their ingredients.

Additionally, when a supplement is comprised of a wide variety of botanicals it may not be possible to determine which botanical may be the source of the pesticide detection and therefore it will be challenging to determine which MRL to apply since the MRL value corresponds to a particular crop or commodity.

Another issue arises for highly concentrated botanical extracts. When a supplement is composed of botanical extracts where the botanical has been highly concentrated, the pesticide residue in the source botanical may also become concentrated, though some extraction processes have been reported to remove or greatly reduce the pesticide level. Based on the current pesticide regulations, there isn't a consideration given to normalization of the pesticide result to extrapolate the result back to the botanical source.

For assistance with these issues and others, certified operations will want to ensure they are utilizing NOP's Guidance on residue testing as well as individuals, laboratories and trade organizations with expertise in finding laboratories that can conduct proper analysis, brainstorming on how to avoid residues in the future and navigating the organic requirements when residues are found on crops for which an EPA tolerance has not been established.

## Other Issues

Solid, organized and thorough documentation is essential in verifying that products have been produced in compliance with the NOP regulation. For example, documenting the disposition/reuse of the scrap gelatin netting that results after capsules are punched out is often overlooked. As a function of the certification process, certifiers will typically require that a product-in / product-out mass balance is conducted during the inspection to determine whether an operator has sufficient organic supply to produce the organic products being sold. Keeping track of and documenting the incoming, outgoing and disposal activity of all inputs (organic and non-organic) is therefore necessary.

## Conclusion

This document provides guidance to companies that wish to market organically labeled dietary supplements in the United States. Consumer demand for organic products has never been higher. A recent survey of more than 18,000 households throughout the country, found that more than eight in ten (82%) U.S. families say they buy organic sometimes<sup>14</sup>, and the \$1.2 billion organic supplement

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<sup>14</sup> Organic Trade Association, *2017 U.S. Families' Organic Attitudes and Behaviors Study*.



category reported 10.7% growth in 2016, which is much stronger than the 6.0% reported for all dietary supplements.<sup>15</sup>

This demand, plus the multiple country equivalency agreements with the United States, make it easier to identify and source certified organic inputs and are great incentives for dietary supplement manufacturers to research how to make organic products.

This document does not, however, serve as a substitute for a thorough understanding of the NOP rule as codified in Title 7 of the Code of Federal Regulations, Part 205 (7 CFR 205), or any other federal or state law or regulation. It is essential that any company that markets organic dietary supplements be familiar with the relevant sections of these regulations, either directly or through the services of a qualified consultant or knowledgeable legal counsel.

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<sup>15</sup> Organic Trade Association, *2016 Organic Industry Survey*.

