



# Guidance on Formulation and Marketing of Organic Dietary Supplements Under the National Organic Program

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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 and dietary supplement 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 food and supplement 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 traditional food products. The majority of the

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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).

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 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.

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

## Background on the National Organic Program (NOP)

Most products marketed in the U.S. as organic under the NOP are fresh or processed foods. 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. Since the NOP was developed with a primary focus on agricultural products, it is not surprising that these food products make up most of the organic products in the marketplace.

### 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>4</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>5</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 plants 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 2011 of organic dietary supplements were reported at \$739 million, an increase of 8.5 percent over the prior year.<sup>6</sup>

While the U.S. organic dietary supplement industry has experienced significant growth, other North American trade developments are also shaping market and sourcing opportunities. In June 2009, the U.S. and Canada signed an equivalency agreement which allows trade of organic products with few restrictions.<sup>7</sup> In June 2012, the U.S. and the European Union engaged in a similar equivalency agreement for organic agricultural products.<sup>8</sup> While these agreements have little impact on the international markets for finished dietary supplements, they expand the availability of certified

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<sup>4</sup> Federal Register, Vol. 65, No. 246, p. 80557. December 21, 2000.

<sup>5</sup> Robinson BC. Memorandum to all USDA accredited certifying agents. August 23, 2005.

<sup>6</sup> Organic Trade Association, *2011 Organic Industry Survey*.

<sup>7</sup> Details and supporting documents for the U.S. – Canada organic equivalency agreement can be found [here](#)., Accessed July 12, 2013.

<sup>8</sup> Details and supporting documents for the U.S. – European Union trade agreement can be found [here](#). Accessed July 12, 2013.

organic ingredients for use in these products. More information about the NOP's international partnerships can be found on the [NOP website](#).

## The National List

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 of Allowed and Prohibited Substances (the National List). This 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. When making an "organic" claim, 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.

Dietary supplements that are labeled as organic under the NOP and are available, but these products are much less prevalent than organic foods. 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.

Because the dietary supplement industry has generally been less involved in the development of the National List, some of the nonagricultural and nonorganic agricultural products used exclusively as ingredients in supplements 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 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>9</sup> for requesting consideration of an amendment to the National List is available on the NOP website.

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<sup>9</sup> Information on the process for filing a petition to amend the National List can be found [here](#). Accessed July 12, 2013.

## Labeling of Products as Organic Under the NOP

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

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>10</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, usually on 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><i>Cannot</i> 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</p>	<p>Can identify organic ingredients as organic in ingredients statement only</p> <p><i>Cannot</i> display:</p> <ul style="list-style-type: none"> <li>• Any other reference to organic content</li> <li>• The USDA organic seal</li> <li>• The certifier name or seal</li> </ul>

<sup>10</sup> For example, organic apple juice that is processed with organic rice hulls would comply with this organic labeling category.

## How Dietary Supplements Can Meet NOP Labeling Rules

The previous section discussed the four categories of organic labeling 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 options. For both the "organic" and the "made with organic" labeling options, 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>11</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 percent of the ingredients are certified organic herbs and certified organic flavors or sweeteners, so long as the remaining ingredients consist of either nonagricultural substances or nonorganically produced agricultural products included on the National Lists 7 CFR 205.605 or 7 CFR 205.606.
- ❑ 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 percent of the finished product and are included on the National Lists 7 CFR 205.605

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<sup>11</sup> Liquid extracts of certified organic raw materials in which the solvents are limited to water and 100 percent 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.



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.

- ❑ 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 percent certified organic raw agricultural herbs, or certified organic extracts, and not more than 5 percent of the weight of the ingredients at formulation of the tablet 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.

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

- ❑ Herbal teas in which at least 70 percent 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 percent 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 percent 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>12</sup>
- ❑ Encapsulated products (in either hard-shell or soft-gelatin capsules) in which the encapsulated ingredients consist of approximately 85 to 90 percent certified organic

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<sup>12</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.

raw agricultural herbs or extracts of certified organic herbs. The calculation to this higher percentage is based on the fact that the capsule itself constitutes approximately 20 percent of the finished weight of an encapsulated herbal product, increasing the required organic percent of the contained ingredients. 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 percent 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**

- ✘ Any herbal product that contains certified organic herbal ingredients, including teas, extracts, tablets, capsules, etc., 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.

## The Organic Dietary Supplement Certification Process

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.

- Agricultural crops and the land on which they are grown must be certified 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.
- All post-harvest and processing facilities that prepare, process or transform organic crops into ingredients must be 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 from each of the processors from whom it sources organic ingredients.
- 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]” claims on their products. No such requirement is applicable to companies that make products that are labeled only to identify individual organic ingredients in the ingredients statement.
- 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.

The NOP accredits certifiers around the globe to help ensure that ingredients and final products, entering or made in the U.S., which are labeled as meeting the requirements of the NOP are in fact truly organic. 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:

- **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 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 NOP was developed to address organic agricultural food production, although it is being used 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 does not differentiate with respect to product type. 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 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. Therefore, herbal ingredients cannot be used unless they are organic or are listed on 7 CFR 205.606.

Products making a “made with organic [specific ingredients]” claim must contain by weight (excluding water and salt) at least 70 percent 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:

- 🌱 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 includes enzymes, starches and vitamins.

- ❏ All ingredients and additives/processing aids must not be processed with irradiation. This includes herbs and spices.
- ❏ All nonorganic raw agricultural ingredients and additives/processing aids must not be produced with the use of sewage sludge as a fertility input.
- ❏ Vitamins and minerals listed in 21 CFR 104.20(d)(3)<sup>13</sup> may be added. Vitamins and minerals must be nonagricultural for their use to be covered under the National List 7 CFR 205.605.
- ❏ 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.
- ❏ Only those nutrients listed in 21 CFR 101.9 are approved by the FDA 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; 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.

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

## 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. The "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.

## 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.

## 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 study showed that 76 percent of consumers prefer a product that has been independently tested and certified as sustainable or green<sup>14</sup>, and U.S. sales of organic dietary supplements in 2011 increased of 8.5 percent over the prior year.<sup>15</sup>

This demand, plus U.S.-Canada and U.S.-EU equivalency agreements that make it easier to identify and source certified organic inputs, are great incentives for dietary supplement manufacturers to research how to make organic products.

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<sup>14</sup> 2012 NSF International Consumer Preference Survey

<sup>15</sup> Organic Trade Association, *2011 Organic Industry Survey*.