NASC Preferred Supplier Program Focuses on Quality Standards in Animal Supplement Industry

The National Animal Supplement Council (NASC) is a California-based nonprofit industry advocacy and educational group that is dedicated to protecting and enhancing the health of companion animals (dogs, cats, and horses) in the United States.

Founded in 2002, the NASC is made up of more than 140 businesses that are committed to providing high-quality health supplements and nutritional supplements for these animals. Health supplements, such as those that contain glucosamine, chondroitin sulfate, methylsulfonylmethane (MSM), parsley (Petroselinum crispum, Apiaceae), and peppermint (Mentha × piperita, Lamiaceae), are intended to support maintenance of normal biological structures and functions. Nutritional supplements, such as those that contain vitamins and minerals, are intended to provide nutritional value as a component of a complete and balanced diet.^{1,2}

NASC members are located around the world, including in the United States, Canada, Europe, Australia, and China. An NASC Primary Supplier Member must be a manufacturer, formulator, bottler, labeler, or re-packer that markets its brand as the supplier of record. An NASC Associate Member may be involved in selling or distributing animal health/nutritional supplements as a distributor, dealer, retailer, veterinarian, or internet/catalog company.

All NASC members are vetted in a direct interview that presents and clarifies the requirements of the organization and the standards to uphold. In addition, most NASC members complete an independent NASC quality audit that, when passed, enables them to display the yellow

NASC Quality Seal on their packaging and marketing materials. NASC membership demonstrates a commitment to upholding specific quality standards, which the NASC hopes, in turn, will increase consumer confidence

in the animal supplement industry.²

Preferred Supplier Program Overview

The NASC Preferred Supplier Program is a self-regulatory program that was initiated to help extend responsibility, accountability, and



uniformity upstream to the beginning of the animal supplement supply chain. It also helps NASC members identify reputable suppliers of reliable raw materials. "With the increased scrutiny on suppliers and supply chain management, our intention has been, always, to keep our members ahead of the regulatory curve," said Bill Bookout, president of the NASC and chair of its board of directors (oral communication, August 31, 2016).

The NASC's Preferred Supplier Program helps all parties involved save time and money through data sharing. Suppliers avoid having to submit to audits for every

customer, and NASC members do not have to go through the process of qualifying each supplier. Thus, all parties contribute to the program and all parties benefit from the program, according to Bookout.

The program qualifies suppliers in four categories: Raw Material Suppliers, Contract Manufacturers (many NASC member companies that market their own brand of products rely on one or more thirdparty manufacturers to produce their products), Laboratories and Research, and Service Providers (e.g., insurance providers, packagers or providers of packaging components, legal service providers, web service providers, etc.). So, in the context of the NASC's program, the term "Preferred Supplier" encompasses a wide variety of product and service providers along the supply chain and is not limited only to suppliers of raw materials.³



Each company in the Preferred Supplier Program pays an annual fee, which covers the posting of all Preferred Supplier information in the "Members" section of the NASC's website, the posting of a company sales profile for all Preferred Suppliers, the opportunity to conduct webinars and/or educational programs for NASC members, the availability of contacts at NASC member companies, attendance at the Preferred Suppliers Only Meeting during the NASC Annual Conference, and the opportunity to provide input about the program.

Raw Material Suppliers and Contract Manufacturers must complete and submit a Preferred Supplier Data Sheet, which includes information about the manufacturing facility, testing information, current good manufacturing practice (cGMP) compliance details, and more. In addition, Raw Material Suppliers must complete and submit a Non-Botanical Ingredient Data Sheet or a Botanical Ingredient Data Sheet for each unique ingredient that the company supplies.

These data sheets are modeled after the data sheets of the Standardized Information on Dietary Ingredients (SIDI) protocol, but have been adapted for the animal supplement industry. The SIDI initiative is a voluntary, industry-wide protocol intended to standardize and streamline communication of information about dietary ingredients from raw material suppliers to finished product manufacturers. It is a cooperative effort among three of the leading trade associations for the dietary supplement industry: the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA).⁴

For each ingredient that is qualified by the NASC's

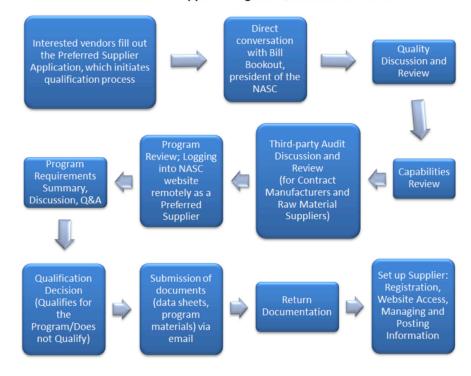
program, samples from five batch/ lot numbers (from one supplier) of that ingredient must be tested to verify the information on the respective certificate of analysis (COA) that accompanies each batch/lot. A COA is the supplier's test results for the batch/lot of raw material being supplied. The information provided on the COA depends on the raw material, but it usually includes information about quality, strength, purity, and composition. It may also include notation of the plant part(s) used (for botanical ingredients), the geographical source of the raw material, concentrations of marker compounds, and levels of potential contaminants (if detected), including microbial (e.g., Salmonella and Escherichia coli) count and heavy metal (e.g., lead, mercury, cadmium, and arsenic) count. In the case of boswellia (Boswellia spp., Burseraceae), for example, the COA could include boswellic acid content. For garlic (*Allium sativum*, Amaryllidaceae), it could include allicin yield. Methods of analysis are also noted.

Samples from the first two batch/lot numbers may be tested by the Raw Material Supplier from their own in-house laboratory or submitted by the Raw Material Supplier for testing by an NASC-approved laboratory. However, samples from the other three batch/lot numbers must be submitted either by an NASC member that sources the ingredient from that supplier, or by another customer of that supplier that uses the ingredient in its product formulations, for testing by an independent, third-party, NASC-approved analytical laboratory in the United States. The three independent tests, which are conducted at the expense of the supplier, break the chain of custody and eliminate sample bias. These tests may be performed by the laboratories that are listed as Preferred Suppliers on the NASC's website or by other reputable laboratories in the industry.

All raw materials must be tested using methodology that follows current established recommendations of the United States Pharmacopeia (USP), AOAC International, other recognized testing authorities, published monographs (including monographs of the American Herbal Pharmacopoeia [AHP]), or other published testing methods. Each raw material qualified by the NASC's program is subject to re-verification with one random test performed annually.

Raw Material Suppliers must meet these requirements for each individual ingredient in order for those ingredients to be qualified by the NASC's program, but there is no additional fee for qualifying additional ingredients.

NASC Preferred Supplier Program Qualification Process



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For Contract Manufacturers and Raw Material Suppliers, the NASC will recognize facility audits that have been conducted by NSF International, the Safe Quality Food (SQF) Institute, Underwriters Laboratories (UL), the Natural Products Association (NPA), and other auditing bodies that are accredited to confirm that manufacturing facilities are operating in accordance with dietary supplement cGMPs, as described in 21 CFR (Code of Federal Regulations) Part 111. This regulation requires "persons who manufacture, package, label, or hold a dietary supplement to establish and follow current good manufacturing practice[s] to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record."5

The NASC requires Contract Manufacturers and Raw Material Suppliers to have a current audit certificate. Typi-

cally, these certificates expire every one or two years. If a Contract Manufacturer or Raw Material Supplier has not been audited, the NASC can conduct a facility audit, but this takes more time.

Laboratories seeking qualification by the NASC's program must complete and submit an Analytical Laboratory Data Sheet. These laboratories must comply with good laboratory practices (GLPs) and good analytical methodology (as recommended by the USP, AOAC International, etc.). In addition, Service Providers must complete and submit a Service Provider Data Sheet.

The data sheets submitted by all of the Preferred Suppliers, along with the required testing information and any additional documentation (e.g., kosher statement, hormone statement, sterilization methods [irradiation, ethylene oxide] statement, genetically modified organism statement, and

Table 1: Top-Selling Pet Supplements Overall

Primary Ingredient	Sales	% Change from Previous Year
Glucosamine	\$21,244,413	-6.1%
Glucosamine/Chondroitin Combination	\$20,513,548	57.3%
Vitamin E (Not Ester-E)	\$6,998,649	108.6%
Multiple Vitamin (Adult)	\$4,630,069	-7.5%
Animal Protein (Whey and Casein)	\$3,934,666	127.0%
Parsley (Petroselinum crispum, Apiaceae)	\$2,794,133	-12.9%
Zinc	\$2,754,218	214.1%
Animal and Plant Protein Combination	\$2,544,139	19.5%
Chlorophyll/Chlorella	\$2,039,035	-62.3%

Source: SPINS / Cross-channel aggregate* for the 52-week period ending November 27, 2016

Table 2: Top-Selling Herbal Pet Supplements

Primary Ingredient	Sales	% Change from Previous Year
Parsley (Petroselinum crispum, Apiaceae)	\$2,794,133	-12.9%
Chlorophyll/Chlorella	\$2,039,035	-62.3%
Peppermint (Mentha × piperita, Lamiaceae) and Other Mints	\$1,831,908	38.2%
Pumpkin (<i>Cucurbita pepo</i> , Cucurbitaceae)	\$862,966	150.4%
Chamomile (<i>Matricaria recutita</i> , Asteraceae)	\$465,978	-32.6%
Flax (Linum usitatissimum, Linaceae) Seed and/or Oil	\$249,602	7.9%
Menthol (Derived from <i>Mentha</i> species)	\$173,344	-11.0%
Lavender (<i>Lavandula angustifolia</i> , Lamiaceae)	\$143,232	-0.4%
Garlic (Allium sativum, Amaryllidaceae)	\$124,020	-73.2%
Tea Tree (<i>Melaleuca alternifolia</i> , Myrtaceae) Oil	\$113,826	34.2%

Source: SPINS / Cross-channel aggregate* for the 52-week period ending November 27, 2016

organic certification statement, etc.) are available for NASC members to download on the NASC website. In addition, Preferred Suppliers may also choose to post liability insurance certificates.

Preferred Suppliers, however, are not required to post confidential information, such as proprietary processes or anything covered under trade secrets. Preferred Suppliers may choose to make certain information available to the NASC under a non-disclosure agreement (NDA). Additionally, distributors are not required to disclose their suppliers, since manufacturers could then cut them out and go directly to the supplier, but distributors must be able to verify how their suppliers were qualified.

Ingredients that have been qualified by the program are searchable by common name on the NASC website. Each common name listing includes all of the Raw Material Suppliers that have been qualified to supply that particular

ingredient, in addition to the required testing information and additional documentation.

Conclusion

Currently, more than 60 Preferred Suppliers, some of which are also NASC members and most of which are located in the United States, have been qualified by the NASC's program. These Preferred Suppliers are able to display the blue NASC Preferred Supplier Seal. "Our goal with the program is not to get every single company that possibly participates in this industry into the program," said Bookout (oral communication, December 15, 2016). "Our goal is to get quality suppliers into the program, to differentiate them from opportunistic suppliers, and to reduce the ever-increasing cost of quality and qualifying suppliers."



According to Bookout, the NASC's program has qualified most of the main ingredients commonly used in animal supplements (Table 1), such as glucosamine and chondroitin,† MSM,‡ and hyaluronic acid.** However, the NASC hopes to start qualifying more herbal ingredients (Table 2) under the program soon. According to data from the Chicago-based market research firm SPINS, cross-channel aggregate sales of animal supplements totaled almost \$110 million in the 52-week period that ended November 27, 2016, an 11.2% increase in sales from the previous year.

The Preferred Supplier Program officially began in 2014 and, in 2016, it grew significantly, according to Bookout. He also said that the feedback the NASC has received about the program has all been extremely positive.

* Includes sales in the Natural Channel, Specialty Gourmet Channel, and Conventional Channel. The SPINSscan Natural Channel includes products sold at full-format natural product supermarkets, small to mid-sized chains, and independent and cooperative stores across the continental United States (excluding sales at Whole Foods Market). The Specialty Gourmet Channel includes products sold at full-format supermarkets with more than \$2 million in annual sales, with SPINS-defined specialty items making up at least 25% of their overall volume. The Conventional Channel includes natural, organic, specialty, and wellness products sold at conventional outlets in the United States (data determined in collaboration with Information Resources Inc. [IRI Worldwide]).

[†] Glucosamine and chondroitin are compounds derived from cartilage and are often used in combination to treat conditions associated with osteoarthritis.⁶

[‡] MSM is a natural compound found in some primitive plants (e.g., *Equisetum arvense*, Equisetaceae) and other natural sources, and that can be prepared through oxidation of dimethyl sulfoxide. It is used to treat a variety of conditions, such as arthritis, joint inflammation, tendonitis, and musculoskeletal pain.⁷

** Hyaluronic acid is a compound found in the tissues and body fluids of vertebrates, and in some bacteria, that can help with joint lubrication, water homeostasis, filtering effects, and regulation of plasma protein distribution.8

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Bookout said the NASC is also planning to expand the program beyond dietary supplements for animals. "We are going to expand the program out to pet food and pet treats manufacturers as well," he said.

The NASC's Preferred Supplier Program was put together with the help of NSF International auditors. "I have been told by everyone who has looked at it that it will stand up to the independent scrutiny of a third-party audit," said Bookout. "At the end of the day, consumer confidence is increased, and, in our case, the animals benefit." HG

—Connor Yearsley

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Animal Supplement Industry Regulation in the United States

The NASC was established to provide a complete regulatory and compliance pathway for the animal supplement industry because of the absence of a legal category for animal dietary supplements and because of apparent efforts by regulatory bodies to remove many of these products from the market.⁹

In 1994, the Dietary Supplement Health and Education Act (DSHEA) was passed, and it classified dietary supplements as a category of food under the Federal Food, Drug, and Cosmetic Act. This meant that dietary ingredients could be used without premarket approval as long as they were marketed in dietary supplements before October 15, 1994.9-11 However, DSHEA did not address animal supplements, probably because that segment was very small at the time and because the purpose of the legislation was to address the increasing demand for human dietary supplements, 9 as well as consumer and industry concerns at the time about government regulations that would have limited access to many supplements.

In 1996, the Food and Drug Administration's (FDA's) Center for Veterinary Medicine (CVM), which is primarily responsible for the regulation of animal food and drugs, stated that DSHEA does not apply to animal products, reasoning that ingredients with a history of safe use in human dietary supplements may not necessarily be safe for animals. Different animal species require different nutrients, absorb and metabolize substances differently, and may exhibit different toxic reactions to substances.¹⁰

Therefore, products marketed as animal dietary supplements, which typically fall under the category of "animal feed," are still subject to the pre-DSHEA regulatory environment and usually must be made up of ingredients that are generally recognized as safe (GRAS), approved as food additives, or listed in the Official Publication of the Association of American Feed Control Officials.¹¹

Animal supplement claims are limited to those pertaining to the nutrition, taste, and/or aroma of the product. In some cases, the CVM allows claims of "nutritional support" of specific organs and/or body functions. As with human dietary supplements, animal supplements that claim to treat, mitigate, or prevent disease are considered unapproved new drugs.¹¹

The Food Safety Modernization Act (FSMA), which was passed in 2011 and emphasizes preventing contamination in the food chain instead of responding to it, established cGMPs for animal food production. So, animal supplements marketed as food are subject to FSMA rules.¹²