Product Sustainability Standard: Health & Body Care

Supplements & Medicine

Version 1.0: September 2021

Reason for Standard

Dietary supplements and vitamins are loosely regulated by the Food and Drug Administration (FDA), but these regulations have many gaps and do not consider additives like preservatives, fillers, or artificial dyes, nor do they address concerns like the environmental impact of growing the source material or bioavailability of the form.[i] This results in many low quality and potentially harmful products being released onto the market, where consumers assume they are safe and "natural."[ii]

Medicines and first aid products, like balms for cuts and insect bites or eye drops, can contain many toxic "inactive" chemicals similar to those found in body care products, such as petroleum-based chemicals, artificial dyes, and preservatives. Much like personal care products, there has been a shift towards synthetic chemical mixtures to handle minor first aid and health concerns, from colds to scrapes and burns. As a result, over the counter medicines and first aid products can be a source of exposure to toxic chemicals, however, there is not as much attention paid on toxic chemicals in these types of products as there is for cosmetics and personal care products or processed foods.

While conventional products present concerns with the toxic chemicals they contain, more "natural" or alternative medicines must also be carefully reviewed and evaluated based on scientific evidence of their effectiveness and safety. Like supplements, many alternative medicines and natural remedies are not highly regulated by the FDA and can potentially be rife with greenwashing or misleading claims.[iii]

PCC has developed a standard for supplements, vitamins, and medicines to set transparent expectations and requirements for the products we sell, to ensure they are safe, effective, and made from ingredients that are high quality and responsibly produced.

Scope

This standard applies to supplements, vitamins, and any products making health claims or marketed to alleviate symptoms of health conditions or illness sold in the Health and Body Care (HBC) Department. For a detailed list of all product types within the scope of this standard, see Appendix-Section A.

Standard

1. Products and General Criteria

1.1. Products must not contain any substances on the List of Unacceptable Ingredients for the Health and Body Care Department unless the product qualifies for an ingredient exception.

1.2. Vendors must abide by PCC's Genetically Engineered (GE) Ingredient and Labeling Standard and any ingredients that are at high risk of being GE must be certified USDA organic or Non-GMO Project Verified.

1.3. Vendors must abide by PCC's Packaging Standard and are encouraged to minimize packaging and use materials that are compostable, made from recycled content, reusable and/or easily recycled by the consumer after use when possible.

1.4. Vendors must abide by PCC's Fair Labor Standard; PCC will not sell products from vendors with a documented history of human rights abuses in their supply chain.

1.5. Topical products, such as salves and balms, must adhere to the ingredient requirements under the Health and Body Care, Personal Care Products Standard.

1.6. PCC gives preference to products that are made locally in the Pacific Northwest, and which contain, when possible, locally sourced ingredients.

1.7. PCC gives preference for herbs and botanical supplements derived from sustainably grown, sustainably wild-harvested, or organically grown plants and crops.

1.8. PCC encourages the use of third-party certification systems and testing to verify any product claims, such as health benefits or sustainability attributes.

1.9. PCC expects suppliers to have truthful and verifiable label claims on products.

2. Requirements for Vitamins, Supplements, and Ingestible Products

2.1. PCC requires all vitamin and supplement products to be produced following Current Good Manufacturing Practices (CGMP) and/or NSF International certified.

2.2. PCC does not accept products that contain artificial dyes, flavorings, sweeteners, and preservatives.

2.3. PCC encourages minimal use of binding agents, thickeners, flow agents, and excipients in products.

2.4. PCC does not accept products that use common allergen carrier oils, including soybean, rice bran, or wheat germ.

2.5. PCC gives preference to vendors that provide transparency on the source material for gelatin used in gel capsules.

2.6. PCC prioritizes products that use more absorbable forms of vitamins, minerals, or other nutrients.

2.7. PCC does not accept products containing novel or patented ingredients for which health and safety data is unavailable.

Standard-Specific Glossary

CGMP refers to the Current Good Manufacturing Practice regulations promulgated by the U.S. Food and Drug Administration (FDA) under the authority of the Federal Food, Drug, and Cosmetic Act. These regulations require manufacturers, processors, and packagers of drugs, medical devices, and some food, to implement strategies in their operations to ensure their products are safe, pure, and effective by minimizing or eliminating instances of contamination, mix-ups, and errors.

Dietary supplements are defined under U.S. law as products taken by mouth that contain a "dietary ingredient." Examples of dietary ingredients include vitamins, minerals, amino acids, and herbs and botanicals.

Genetically Engineered (GE)/Genetically Modified Organism (GMO) does not have a standardized definition. (In part, this has created some of the problems for achieving GE transparency and reaching consensus on how best to identify and communicate this with consumers.) Many authorities, however, would define GE food or GMOs as a living organism whose genetic material (otherwise known as DNA) has been artificially manipulated in a laboratory through genetic engineering. Genetic engineering creates combinations of plant, animal, bacteria, and virus genes that do not occur in nature or through traditional crossbreeding methods.

High-Risk Genetically Engineered Crop Ingredients is based on the Non-GMO Project list of crops and inputs that are highly likely to be GE. These include, but are not limited to, canola, corn (except popcorn), papaya, soy, and sugar beet.

Homeopathic medicine is a form of alternative medicine that uses very small amounts of natural substances that in higher doses may cause a disease, reaction, and symptom. It was developed in the early 1800s and its acceptance in the

medical community is mixed. The principle of homeopathy is similar to how immunizations work that contain extremely small quantities of a virus, just enough to produce a response that builds immunity in the body. While the evidence of its effectiveness isn't fully conclusive, it is believed to be relatively safe in most cases. Homeopathic remedies are subject to the same requirements of approval, adulteration, and misbranding as other drugs under the Food and Drug Administration (FDA), although there are no products officially approved by the FDA.

Organic refers to the practices associated with organic food production and processing that prohibit the use of most synthetic inputs and pesticides and require other environmental and animal-friendly agricultural and food handling practices. Established by the Organic Foods Production Act (a federal law), the National Organic Program (NOP) within the U.S. Department of Agriculture manages the organic certification standards, enforcement, and accreditation of independent certifying bodies. Many other countries also have organic certification programs.

NSF International is an independent product testing, inspection, and certification organization based in the United States. NSF focuses on global consumer health and sets robust standards that products bearing their certification must meet. The NSF mark can be found on a range of products, from dietary supplements to water filters and dishwashers.

Appendix

Section A: Products within the scope of the HBC, Supplements and Medicine Standard

- Herbs and supplements
- Vitamins and minerals
- Functional foods, such as protein powders and collagen
- Cold and flu medicines and immune support
- Allergy medicines
- Eye drops
- Specialized topical treatments, such as CBD salves, muscle salves, or eczema treatments
- Homeopathic medicine products

[i] Center for Food Safety and Applied Nutrition, "Questions and Answers on Dietary Supplements," Food & Drug Administration (FDA) (FDA, June 30, 2020), https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements.

[ii] C. Lee Ventola, "Current Issues Regarding Complementary and Alternative Medicine (CAM) in the United States," *Pharmacy and Therapeutics* 35, no. 9 (September 2010): 514–22.

[iii] Center for Biologics Evaluation and Research, "Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration," U.S. Food and Drug Administration (May 6, 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/complementary-and-alternative-medicine-products-and-their-regulation-food-and-drug-administration.