TO: Joint Committee on GMP for Cosmetics
Joint Committee on GMP for Dietary Supplements
Joint Committee on GMP for Over-the-Counter Drugs

FROM: Rachel Brooker, Secretariat of the Joint Committees

DATE: August 04, 2023

SUBJECT: Proposed revision to NSF/ANSI 455-1 – *Terminology for the NSF/ANSI 455 portfolio of Standards* (455-1i4r1)

Revision 1 of NSF/ANSI 455-1, issue 4 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by August 25, 2023** via the NSF Online Workspace <www.standards.nsf.org>.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments using the comment template provided in the ballot whenever possible. Please note that if you are a member on more than one of the Joint Committees listed above and you vote on this issue in one JC ballot but not the other(s) your vote will carry over to the other JC(s) as well.

Purpose

The purpose of this ballot is to update the definition of dietary supplements.

Background

The current definition of dietary supplements is based on the US FD&C Act §321. This means that only products that meet this definition are considered in scope for the NSF/ANSI 455-2 scheme. This unintentionally excludes international manufacturers that do not distribute in the US as their products, although equivalent to dietary supplements, may not meet the US definition. The proposed change does not remove the requirement for dietary supplements sold in the US to meet the US definition for the product. Instead, it is now broadened to allow dietary supplements that meet the definition of the product at the country of manufacture or sale to be in scope for NSF/ANSI 455-2.

Examples of dietary supplements definitions in other countries:
Within the European Union dietary supplements are sold as 'food supplements' and defined as '*foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities*' (Directive 2002/46/EC).

In Canada, dietary supplements are known as natural health products. NHPs are often called "complementary" or "alternative" medicines and include probiotics, herbal remedies, vitamin and mineral supplements, homeopathic medicines, traditional medicines such as traditional Chinese medicines, and other products like amino acids and essential fatty acids. NHPs are used and marketed for a number of health reasons, like the prevention or treatment of an illness or condition, the reduction of health risks, or the maintenance of good health. (Regulation of Natural Health Products)

If you have any questions about the technical content of the ballot, you may contact me in care of:

Rachel Brooker
Joint Committee Secretariat
Tel: (734) 827-6866
Email: rbrooker@nsf.org

[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by gray highlighting. Rationale statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/ANSI Standard
for the NSF/ANSI 455 portfolio of Standards

Terminology for the NSF/ANSI 455 portfolio of Standards

•
•
•

3 Definitions

•
•
•

3.28 dietary supplements: A product (other than tobacco) that:

— is intended to supplement the diet and bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

— is intended for ingestion ~~in pill, capsule, tablet, powder, or liquid form~~;

— is not represented for use as a conventional food or as the sole item of a meal or diet;

—is labeled as a "dietary supplement" or has the word "dietary" deleted and replaced by the name of the dietary ingredient/s in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins); or labeled with alternative names that comply with specific regulations of the country of manufacture or sale;

~~— includes an article that is approved as a new drug under Section 505, certified as an antibiotic under Section 507, or licensed as a biologic under Section 351, of the Public Health Service Act (42 U.S.C. 262), and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary (U.S. Department of Health and Human Services, FDAP) has issued a regulation, after notice, and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f), and does not include an article that is approved as a new drug under Section 505, certified as an antibiotic under section 507, or licensed as a biologic under Section 351 of the Public Health Service Act (42 U.S.C. 262) or an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful.[7]~~

-
-
-