JOINT COMMITTEE ISSUE PAPER

NSF Standard(s) Impacted: Click or tap here to enter text.

Purpose and Background:
Provide a one or two sentence statement explaining the purpose of your recommendation. Also please provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc., and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Purpose:
This proposal would add an ingredient assessment guideline to mitigate the risk of unsafe products entering the market. Ingredient assessment provides consumers with additional assurances regarding product safety. In addition, adding safety to the purpose statement in 1.1.

Background:
The U.S. Food and Drug Administration's (FDA's) pre-market approval processes for food and color additives require an estimate of the *probable* consumer intake of the additive to determine whether its use or presence in a food at a given concentration is safe. The key determinant in the safety evaluation of a substance found in or added to the diet is the relation of its probable human intake to the level at which adverse effects are observed in toxicological studies.*

The standard would follow this structure to provide an assessment on whether ingredients meet an upper safety limit identified by a reputable international public health authority. Examples of reputable international public health authority should be listed in the standard.

*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food

Recommendation:
Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration, etc.

1 General

1.1 Purpose

This standard provides test methods and evaluation criteria for dietary supplement products to allow for the determination that the ingredients in the product are accurately identified, that the product contains the quantity of dietary ingredients and marker constituents declared on the product label, ~~and~~ that the product does not contain unacceptable quantities of contaminants to ensure quality and safe products for consumers. This standard provides criteria for determining that good manufacturing practices (GMP) were followed in the production of dietary supplements.

Item #: 173i119 (DS-2024-5)
(For NSF internal use)

•
•
•

5 Product requirements

•
•
•

5.2 Quantity

5.2.1 Dietary ingredients

COA claims for dietary ingredients shall be reviewed to determine a set of verification tests to confirm quantity of dietary ingredients and marker constituents in accordance with Section **Error! Reference source not found.** or **Error! Reference source not found.**.

Dietary ingredients tested shall meet minimum quantities (minus the measure of uncertainty of the analytical method) of ingredients and marker constituents as stated as a specification in the COA.

5.2.1.1 Ingredient Acceptability

Product ingredients must be reasonably expected to be safe for use in dietary supplements. For each active ingredient within a product formulation, the ingredient shall not exceed established acceptable daily intakes (ADIs) or upper safety limits (USLs) that are based in a comprehensive review of the available safety data where those data are demonstrated as relevant to the specified ingredient. Competent authority assessments may be considered to establish ADIs or USLs.

•
•
•

Supplementary materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

Click or tap here to enter text.

I hereby grant NSF the nonexclusive, royalty free rights, including nonexclusive, royalty free rights in copyright; in this item and I understand that I acquire no rights in any publication of NSF in which this item in this or another similar or analogous form is used.

Signature*: Heather Trinkle
Company: NSF
Telephone: 734-773-4269 Email: htrinkle@nsf.org
Is this a revision of a previous Issue Paper (if yes put original issue number): No
Submission date: 9/26/24

Please submit to: Joint Committee's Secretariat or to standards@nsf.org

**Type written name will suffice as signature*

Item #: 173i119 (DS-2024-5)
(For NSF internal use)