JOINT COMMITTEE ISSUE PAPER

NSF Standard(s) Impacted: 173

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.

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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 6.2 or 8.7.

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 their intended use in dietary supplements. For each dietary ingredient within a product formulation, the quantity of the dietary ingredient shall not exceed established or upper safe levels (USLs) or typical use levels (TULs) that are based on a scientific review of the available safety data relevant to the specified dietary ingredient under the conditions of use indicated on the label for the intended population unless a safety assessment concludes that a higher use level is acceptable, with or without label warning language. The dietary ingredient's maximum use level (MUL), which is the maximum daily intake based on the product label, should be informed by the USL or TUL for the dietary ingredient.

When established data from an authoritative body is not available, competent authority or other scientific assessments may be considered to establish the USL or TUL. A safety assessment is required when the MUL exceeds established USLs or TULs for the dietary ingredient. An informative ingredient acceptability review process flow may be referenced under Annex *<insert here>.*

If a safety assessment identifies a serious risk to health at the MUL, certification may be prohibited. If a safety assessment confirms there is no serious risk to health but identifies mild to moderate adverse health effects at the MUL, a caution statement should be added to the label in a format that is readily visible to the consumer: *"Caution: the recommended intake level for [ingredient] exceeds health authority recommendations for long-term use and may result in mild to moderate health effects (e.g. effects as appropriate for the ingredient) with chronic consumption. Periodic or short-term use under the advisement of a qualified healthcare professional is recommended."* An equivalent statement may also be used at the discretion of the certifying body.

*****There is a proposed Normative Annex, but I could not format it to include it on this issue paper. Please see the proposed new annex in the reference document section of this straw ballot.*****

Supplementary materials (photographs, diagrams, reports, etc.):

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If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

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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*

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