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Joint Committee on Dietary Supplements

August 6, 2025

Proposed revision to NSF/ANSI 173 – Dietary Supplements (173i119r1)

Revision 1 of NSF/ANSI 173, issue 119 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by August 27, 2025** via the NSF Online Workspace.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

Purpose

The proposed revision will 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

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

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[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 grey 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 Nutrition and Wellness –

Dietary Supplements

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, and to help ensure products do not contain ingredients at levels that pose a serious or undisclosed risk to consumer health.

This standard provides criteria for determining that good manufacturing practices (GMP) were followed in the production of dietary supplements.

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5.2 Quantity

5.2.1 Dietary ingredients

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5.2.1.1 Ingredient acceptability

Product ingredients shall be reviewed by the certifying body to help ensure each ingredient can be reasonably expected to be safe for its intended use in dietary supplements. For each dietary ingredient within a product formulation, the dietary ingredient's maximum use level (MUL) shall not exceed established upper safe levels (USLs) or typical use levels (TULs).[1] USLs and TULs shall be relevant to the specified dietary ingredient under the conditions of use indicated on the label for the intended population.

[1] An informational ingredient acceptability review process flow may be referenced under Informative Annex 3.

When a USL or TUL from an authoritative body is not available, other scientific assessments may be considered to establish the USL or TUL. USLs shall be based on a scientific review of the available safety data while TULs shall be established using a history of safe use (HoSU) approach. A safety assessment is required when the MUL exceeds the established USL or TUL for the dietary ingredient.

An MUL above the established USL or TUL may be acceptable, with or without additional statements, if a safety assessment can substantiate safe use at the proposed MUL. If a safety assessment identifies a risk of adverse health effects at the MUL, the product label or product ingredient disclosure shall include a statement that addresses any relevant health risks identified. The statement shall be agreed upon between the certifying body and the company seeking certification. The certifying body maintains the ability to deny certification if a safety assessment identifies a serious risk to health.

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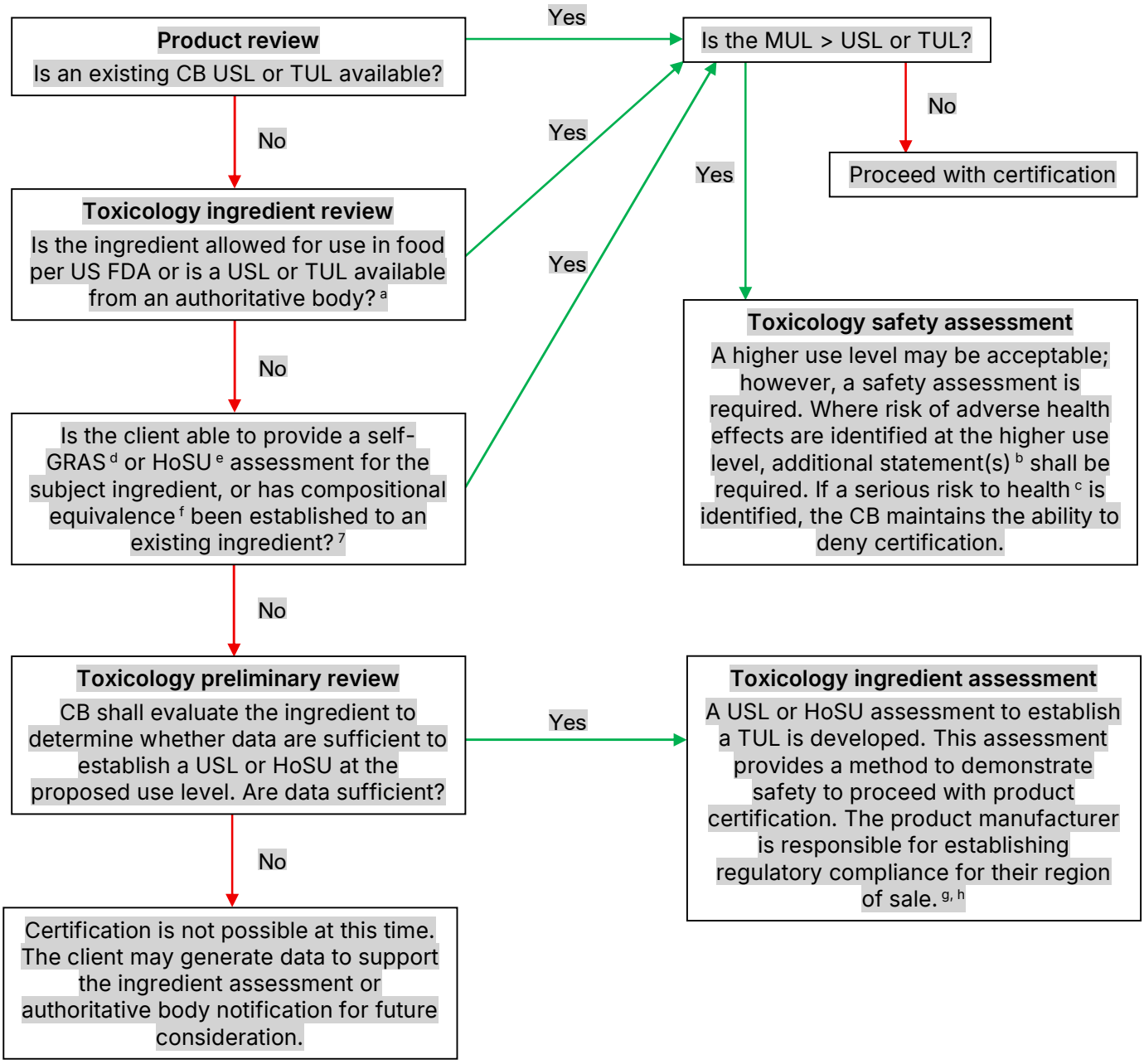
Figure X

Ingredient acceptability review process



Note 1. Prerequisite to the use of this process is that the dietary ingredient has been characterized as to its chemical identity, source, and manufacturing process in sufficient detail to allow for an ingredient acceptability evaluation.

Note 2. CB = Certifying Body, HoSU = history of safe use, MUL = maximum use level (maximum daily intake based on the product label), TUL = typical use level, USL = upper safe level

[a] Authoritative body means any global health agency but does not include trade associations or other industry bodies. In addition, the ingredient specification should be consistent with the authoritative review (i.e. source, species, and production process).

[b] Should a safety assessment identify risk of adverse health effects at the MUL, the product label or product ingredient disclosure shall include a statement that addresses any relevant health risks identified. The statement shall be agreed upon between the certifying body and the company seeking certification.

[c] Serious risk to health is defined as effects that may result in irreversible damage to the body, physical impairment, hospitalization or that otherwise may increase the risk of life-threatening events.

[d] A full self-affirmed GRAS dossiers reviewed by an expert panel may be used to demonstrate safety at the MUL; standalone GRAS statements without supporting documentation are not considered sufficient.

[e] Old dietary ingredient status (ingredients listed per UNPA, CRN, or NNFA) may be used to establish HoSU; however, ODI status shall be substantiated with supporting data.

[f] Compositional equivalence may be established based on chemical analysis, supported by an ingredient fingerprint using NMR, MS, etc.

[g] Client-provided assessments and ingredient assessments need to be independently peer-reviewed by experts qualified to evaluate ingredient safety.

[h] Demonstration of regulatory compliance is not in scope of the standard and is the responsibility of product manufacturers. The interim ingredient assessment is intended to establish safe use of the ingredient to protect consumer health and prevent the certification of unsafe ingredients.