NSF Standard(s) Impacted: NSF 173

Background:
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.

The dietary supplement industry is currently undertaking several voluntary initiatives to bring attention to the importance of supply chain management and the proper identification of botanical species used to product ingredients for these products. This topic extends to the appropriateness of the analytical techniques used to make the botanical identification.

This proposal is intended to clarify the requirements of section 6.1.1 for identification test methods for botanicals, as the selection of appropriate methods is highly dependent on the type of sample being identified.

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.

6.1 Identification test methods

6.1.1 Botanicals

The identity of botanical dietary ingredients shall be verified with one or more tests or examinations in accordance with the most appropriate analytical method(s) as described in 6.1.1.1 through 6.1.1.3. The selected test(s) or examination(s) shall be performed by an appropriately qualified individual using documented procedures, and shall be scientifically valid and fit for the purpose of analysis of the specific sample type being tested. Selection of the test method(s) shall consider the least burdensome analytical approach necessary to confirm identity of the specific sample being verified.

6.1.1.1 Macroscopic and organoleptic/sensory evaluation

Macroscopic and organoleptic/sensory test methods used for verifying the identity of unprocessed botanical dietary ingredients (whole plants or identifiable plant parts) shall be evaluated based on the information contained in applicable monographs (AHP, BHP, EP*, PPRC*; USP and other compendial references; except that, when no applicable compendial monograph exists, the qualified individual shall confirm identity based on the information contained in one or more alternative scientific references developed based on well-established principles of macroscopic assessment such as are presented in classic botanical pharmacognosy literature, and shall identify and record the alternative reference(s) used.

*NOTE: The two additional compendial references identified here are not yet included in 173's Normative References; this Issue Paper is peripherally proposing the current editions of these two documents be added to the Normative References – the European Pharmacopoeia (EP) and the Pharmacopoeia of the People’s Republic of China (PPRC).

6.1.1.2 Microscopic test methods
Microscopic test methods used for verifying the identity of non-extract botanical ingredients (whole plants, identifiable plant parts, cut or powdered forms) shall be evaluated based on the information contained in applicable monographs (AHP, BHP, EP*, PPRC*, USP and other compendial references; except that, when no applicable compendial monograph exists, the qualified individual shall confirm identity based on the information contained in one or more alternative scientific references developed based on well-established principles of microscopic assessment such as are presented in classic botanical pharmacognosy literature, and shall identify and record the alternative reference(s) used.

6.1.1.3 Chemical test methods

Chemical test methods used for verifying the identity of botanical dietary ingredients (all forms) shall be evaluated using methods that are scientifically valid and suitable for the intended purpose. Sources for methods should include based on the information contained in applicable references (AOAC International, AHP, USP, EP*, PPRC*, and other method sources); except that modification modification of an existing method to better suit the sample under test is allowable. If, and if no appropriate method exists development of a new method is allowable. The use of any modified or new method shall require that an assessment be performed which includes evaluation of the method specificity.

Supplementary Materials (photographs, diagrams, reports, etc.):
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: 9/23/16

Please submit to: Joint Committee Secretariat, Rachel Brooker at rbrooker@nsf.org or to standards@nsf.org

*Type written name will suffice as signature