



## AHPA Guidance Policy

AHPA develops guidance policies to promote responsible commerce in herbal products. These policies address a variety of labeling and manufacturing issues and reflect the consensus of AHPA's members and its Board of Trustees. AHPA encourages its members and non-member companies to adopt these policies to establish consistent and informed trade practices.

### **Heavy metals (elemental impurities)** (adopted October 2008; last revised October 2020)

Dietary supplement manufacturers determine what, if any, tests or examinations are appropriate for their finished products, whether to meet specifications established for these products (21 CFR §§ 111.70 and 111.75) or for other purposes. Similarly, food manufacturers identify and evaluate known and reasonably foreseeable hazards, including chemical hazards, to determine those requiring preventive controls (21 CFR § 117.130).

With respect to herbal products, there are a number of non-essential heavy metals<sup>1</sup> that dietary supplement and food companies may consider in relation to their manufacturing and quality control operations, if appropriate. This guidance addresses four such elements. Not all of these, however, are applicable to every herbal food or supplement product, and others not included here may be relevant for some such products.

Where companies choose to establish specifications or make hazard determinations for one or more of the elements listed below for finished herbal products intended for oral consumption, AHPA provides the following as guidance on maximum quantitative limits:

- for inorganic arsenic: 10 mcg/day
- for cadmium: 4.1 mcg/day
- for lead: 6 mcg/day; 3 mcg/day for products intended to be used by children
- for methyl mercury: 2.0 mcg/day

#### **In this policy the following terms, limitations, and conditions apply:**

- The terms “herbal product,” “herbal supplement” and “herbal food” mean a finished product, a dietary supplement, or a food, respectively, that contains one or more herbal ingredients (i.e., an herb or other botanical, including fungi and algae, or a concentrate, extract or combination of an herb or other botanical). An herbal product may or may not also contain non-herbal ingredients.

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<sup>1</sup> There is some inconsistency in how the term “heavy metals” is defined, and some disagreement as to whether the term should even be used to describe certain metallic elements associated with adverse health effects. Alternative terms in use include “toxic elements” and “elemental contaminants.” In this policy the word “elements” is used to describe the subject substances, including methyl mercury, which is more accurately an organometallic compound.

- This guidance is not intended to suggest that companies should, for any or all of the elements identified here, establish specifications for any specific herbal supplement or determine these as hazards that require preventive controls for any specific herbal food. This guidance is not, in fact, applicable for some herbal products, but is instead intended to provide guidance for limits in the event any such specifications are set or such determinations are made. In addition, it may not be relevant to test any specific herbal product to determine the level of any or all of the elements identified in this guidance.
- The above quantitative limits may be determined at either the highest daily intake based on the highest labeled serving size or upon average daily consumption of a food or supplement.
- The above quantitative limits are most applicable to herbal products consumed in a total daily amount of 5 grams or less.
- A product in compliance with this guidance may require a warning in order to comply with California Proposition 65's listing of these chemicals. [Click this link for information on California Proposition 65.](#)