



## AHPA Guidance Policy

AHPA develops guidance policies to promote responsible commerce in herbal supplements. 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.

### **Microbiology & Mycotoxins** (adopted June 2003; last revised July 2012)

Food ingredient suppliers, dietary ingredient suppliers, and dietary supplement manufacturers determine what, if any, tests or examinations are appropriate for their ingredients and products, whether to meet specifications established for these ingredients and products or for other purposes.

With respect to herbal ingredients and supplements, there are a variety of microbiological characteristics and mycotoxins for which companies may consider implementing tests or examinations, if appropriate. This guidance discusses some of the more commonly used ones. Not all of these, however, are applicable to every herbal ingredient and supplement, and others not included here may be relevant for some herbal ingredients or supplements.

Where manufacturers choose to establish one or more microbiological and/or mycotoxin specifications for herbal ingredients or dietary supplements identified in this guidance, AHPA provides the following as guidance on maximum quantitative limits:

(a) (i) for dried, unprocessed herbs for use as ingredients in dietary supplements, and (ii) for herbal supplements in solid form consisting of dried, unprocessed herbs:

- Total aerobic plate count:  $10^7$  colony forming units/gram
- Total yeasts and molds:  $10^5$  colony forming units/gram
- Total coliforms:  $10^4$  colony forming units/gram
- *Salmonella* spp.: not detected in 25 grams
- *Escherichia coli*: not detected in 10 grams
- Total aflatoxins (B<sub>1</sub> + B<sub>2</sub> + G<sub>1</sub> + G<sub>2</sub>): 20 µg/kg (ppb)
- Aflatoxin B<sub>1</sub>: 5 µg/kg (ppb)

and (b) (i) for powdered extracts and for soft extracts, and (ii) for herbal supplements in solid form consisting of powdered extracts or soft extracts:

- Total aerobic plate count:  $10^4$  colony forming units/gram
- Total yeasts and molds:  $10^3$  colony forming units/gram
- Total coliforms:  $10^2$  colony forming units/gram

- *Salmonella* spp.: not detected in 25 grams
- *Escherichia coli*: not detected in 10 grams
- Total aflatoxins (B<sub>1</sub> + B<sub>2</sub> + G<sub>1</sub> + G<sub>2</sub>): 20 µg/kg (ppb)
- Aflatoxin B<sub>1</sub>: 5 µg/kg (ppb)

**For purposes of this guidance the following definitions apply:**

- “Dried unprocessed herb” *means* an herb or other botanical that is dehydrated from its fresh state and that has not been subjected to any further processing other than cleaning, grading, or size reduction (e.g., cutting or powdering).
- “Dietary supplement” *has the same meaning as* described in 21 U.S.C. 321 (ff). For purposes of this guidance a dietary supplement is a product in finished form ready for consumer use.
- “Herbal supplement” *means* a dietary supplement, as described in 21 U.S.C. 321 (ff), that contains one or more herbal ingredients (i.e., an herb or other botanical, or a concentrate, extract, or combination of an herb or other botanical). An herbal supplement may or may not contain additional non-herbal dietary ingredients (e.g., vitamins, minerals, amino acids, etc.) or excipients.
- “Botanical extract” *means* the complex, multi-component mixture obtained after using a solvent to dissolve components of an herbal or other botanical biomass. Botanical extracts may be in dry, liquid or semi-solid form. Excipients may be added to botanical extracts for various technical purposes (e.g., to adjust concentration; enhance stability; limit microbial growth; or improve drying, flow or other manufacturing characteristics). Botanical extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents (though it should be noted that some chemical modifications might occur as the natural consequence of the extraction process).
- “Powdered extract” *means* a botanical extract that has been dried into a powder.
- “Soft (a.k.a. pilular, semi-solid, or solid) extract” *means* a botanical extract having a consistency of a thick liquid or paste.

**In addition, for purposes of this guidance the following limitations and conditions apply:**

- This guidance is not intended to suggest that manufacturers should establish specifications for any or all of the identified microbiological characteristics or mycotoxins in any specific herbal ingredient or supplement, but is rather intended to provide guidance for limits in the event any such specifications are set. This guidance is not, in fact, applicable for some herbal ingredients and supplements. In addition, it may not be relevant to test any specific herbal ingredient or supplement to determine the level of any or all of the microbiological characteristics or mycotoxins identified in this guidance.
- In determining whether *Salmonella* spp. and *E. coli* are not detected, the sample size may vary depending on the method used.

- Depending on the analytical methods used to detect *Salmonella* spp. or *E. coli*, failure to detect a microorganism may be reported as “absent,” “not detected,” “negative,” or “less than” the detection limit.
- For dried, unprocessed herbs for use as ingredients in dietary supplements, the above quantitative limits may be exceeded in either of the following circumstances:
  - When, due to naturally occurring conditions, an individual herb requires higher limits on total aerobic plate count, total yeasts and molds, and/or total coliforms. When acceptable techniques, such as steam sterilization, will be employed in subsequent processing to eliminate pathogens.
  - However, such treatment is not acceptable if the untreated materials are spoiled prior to such treatment.
- For herbal products in solid form, the above quantitative limits do not apply to products where boiling water is added before use, and may not apply to products containing other dietary ingredients (such as vitamins and minerals) and excipients.