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## Need for Clear Regulation of Pesticide Residue Limits for Articles of Botanical Origin

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### Need for Clear Regulation of Pesticide Residue Limits for Articles of Botanical Origin

Botanical Dietary Supplements and Herbal Medicines Expert Committee,<sup>a</sup> and USP Staff<sup>a,b</sup>

**ABSTRACT** *Articles of Botanical Origin* (561) provides limits for common contaminants, including pesticides, aflatoxins, and elemental impurities. The *USP* limits for pesticides specified in this chapter are applicable to botanical drugs, but since dietary supplements (DS) in the United States are regulated as a subset of foods, the U.S. limits for pesticides in botanical DS are set to the same levels as those for food by the Environmental Protection Agency (EPA), or the Food and Drug Administration (FDA) action levels determined on a case-by-case basis.

This creates a divide between two different standards for the same article of botanical origin, which results from the unintended consequences of U.S. regulations initially established for food crops, but now also applicable to botanical ingredients that fall within the DS regulatory framework. In the absence of EPA-established limits for an article, compliance with the *USP* limits is permitted for drugs, whereas zero tolerance is applied when the same ingredient is labeled as a food or as a DS.

The intent of this *Stimuli* article is to provide background about the need for rational limits for pesticides, to ensure the quality of articles of botanical origin, engage the stakeholders to strengthen *USP* standards with regard to contaminants, and solicit public comments that will be reviewed and considered by USP's Botanical Dietary Supplements and Herbal Medicines Expert Committee. It is recommended that *USP*-specified limits for DS be adopted as part of the Good Manufacturing Practices for Dietary Supplements in 21 CFR 111.

## Problem Statement

- ▶ Articles from an estimated 3,000 botanical species are in commerce.
- ▶ Majority of species have no EPA-established tolerances.
- ▶ Residues of “legacy” and “current use pesticides” (CUPs) now detected in Arctic ice caps (long range atmospheric transport).
- ▶ Non-point source pesticide detection an increasing problem even with certified organically grown and/or wild-collected botanicals.
- ▶ Nearly half of organically grown crops now show trace - yet detectable - levels of pesticide residues of unknown origin (CFIA ).
- ▶ European (exporting) and U.S. (importing) companies believe that enforcement for botanicals without EPA-tolerances is an increasing risk and threat to business.
- ▶ U.S. regulatory framework did not envision these new realities. A more rational and scientific approach to articles of botanical origin is needed.

- ▶ Environmental Protection Agency (EPA): 40 CFR Part 180 Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food.
- ▶ Food and Drug Administration (FDA): 21 CFR Part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Final Rule.
- ▶ United States Department of Agriculture (USDA): 7 CFR Part 205 National Organic Program Section §205.671 Exclusion from organic sale.

- ▶ United States Pharmacopeia (USP) <561>: Within the U.S., many botanicals are treated as dietary supplements and are subject to the statutory provisions of the FD&C Act that governs foods but not drugs. Limits for pesticides for foods are determined by the EPA, and where no limit is set, the limit is zero.
- ▶ USP limits, therefore, are not applicable in the U.S. when articles of botanical origin are labeled for food or dietary supplement purposes.
- ▶ USP limits are presently applicable only when the article is a botanical drug and are applicable in countries where USP limits are accepted such as Canada and Australia, among others.

## Zero Tolerance Not a Rational Approach

- ❑ Unfortunately, pesticide residues can now be detected the world over,
  - ❑ in the air, ice, snow, soil and water;
  - ❑ on crops from certified organic land where no pesticides have been applied;
  - ❑ and even in the remotest areas where wild plant species are gathered for domestic consumption and export trade.
  
- ❑ Full enforcement for botanicals without EPA-tolerances would have a significant negative impact on the global herb trade (U.S. is one of the major importers).
  
- ❑ Zero tolerance for the majority of botanical species in commerce is not a rational approach.
  - ❑ Risks of doing business with U.S. companies given the uncertainties of FDA detention for pesticides
  - ❑ Supply interruptions and out-of-stocking finished products

- ▶ EPA establish rational pesticide residue tolerances for each of the botanicals of commerce presently not specified in 40CFR Part 180 – is it realistic?
- ▶ Adoption of USP limits for botanicals as part of the GMPs for Dietary Supplements in 21 CFR 111 would:
  - help to resolve a major unintended omission in the U.S. regulatory framework;
  - provide a rational, scientific approach to regulation that would serve the public interest while reducing undue risk to businesses using herbal ingredients;
  - put the U.S. in line with trading partners like Canada where *USP* <561> is accepted for NHP ingredient specifications and with the EU where the comparable European Pharmacopoeia pesticide residue limits are applied for botanical raw materials.



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# Discussions





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# Thank You