

IASC Update

## EFSA Releases Guidance Document on Assessment of Botanical Ingredient Safety

*September 16, 2009* – The European Food Safety Authority (EFSA) published Sept. 10 a document intended to provide guidance to food authorities on the assessment of the safety of botanical materials and preparations intended for use in dietary supplements.

In addition to the guidance document, EFSA also provides a document with several case studies on specific herbs and a compendium of botanicals reported to have constituents that may cause adverse health effects.

According to an announcement by EFSA, the work will “help food manufacturers in their consideration of the safety of ingredients that they may use in their products,” as well as assist government regulators in assessing the safety of botanical materials and preparations that are intended for use in dietary supplements. The guidance document,

- specifies data needed to carry out safety assessments
- suggests a two-tiered scientific approach to a safety assessment that depends on the existing level of knowledge on a given botanical and the substance(s) a botanical contains
- provides a set of criteria to help prioritize the safety assessment of botanical ingredients currently in use

The case studies on six botanical preparations provide “a number of examples explaining how the proposed approach could be applied under different circumstances,” and the compendium, “which will be regularly updated, is intended to assist manufacturers and food safety authorities by highlighting possible safety issues which may require further consideration.”

The work is slated to be presented and discussed with European Union Member States and other stakeholders during a November 2009 conference in Athens.

To access the documents and for additional information, please see the EFSA Web site: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902880387.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902880387.htm)