
[General Chapter <561> Articles of Botanical Origin](#)

Type of Posting: Intent to Revise

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Expert Committee: General Chapters—Chemical Analysis

In accordance with section 7.05 (c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the General Chapters—Chemical Analysis Expert Committee intends to revise General Chapter <561> Articles of Botanical Origin.

Based on the submissions and supporting data received from a manufacturer whose article is subject to the existing monograph (see General Notice section 5.40), the Expert Committee proposes to revise the limit of bromide under the section Pesticides of the General Chapter. The Expert Committee has recognized that because bromide is a natural occurrence in some pharmacopeial articles of botanical origin, it may exceed the currently official limit (50 µg/g). However, the Expert Committee is concerned with the toxicity arising from unknown methylated compounds derived from the practice of fumigation with methyl bromide as a pesticide. Therefore, the Expert Committee has decided to maintain a limit for bromide as an indication for the use of this fumigant. The proposed limit of 125 µg/g is harmonized with Environmental Protection Agency (EPA) requirements set in 40CFR180.123(a)(2)(i)(D) for processed foods not otherwise listed under 40CFR180.123(a)(2)(i) and under 40CFR180.521(a)(3), which would include some of the herbal drugs listed in this pharmacopeia.

It is anticipated that the proposed revision will be published in a Revision Bulletin that will be posted on USP's website on July 25, 2014 and become official August 1, 2014, pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Maria Monagas, Scientific Liaison to the General Chapters—Chemical Analysis Expert Committee at (301-230-7422 or MJM@USP.org).

