
[<232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures](#)

Type of Posting: Revision Bulletin: POSTPONEMENT

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Official Date: Postponed

Expert Committee: Executive Committee of the Council of Experts

In accordance with the Rules and Procedures of the 2010–2015 Council of Experts, the Executive Committee of the Council of Experts has postponed the official dates of <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures. The purpose for the postponement is to allow adequate time for the Executive Committee of the Council of Experts to adjudicate and render a decision on three appeals related to the two general chapters.

There are two components of the elemental impurities standards involved in these appeals:

1. The two general chapters themselves (<232> and <233>) that were slated to become official on December 1, 2012 in Supplement 2 to *USP 35–NF 30* and
2. A planned General Notices proposal that will appear in Pharmacopoeial Forum (PF) 39(1) January–February 2013, which if it proceeds on schedule, will become official in *USP 37–NF 32* and make the two general chapters applicable to all monographed articles as of May 1, 2014.

USP's position is that until a general chapter is referenced in a monograph or in General Notices, it is not applicable to any article in the compendia and creates no mandatory requirements.

Appellants have raised two general objections. One relates to the technical content of the general chapters: that the general chapters themselves are deficient and appellants' comments were not appropriately addressed by the responsible Expert Committee. The second relates to timing: that

the general chapters should not be implemented until a related International Conference on Harmonization (ICH) standard is concluded.

With the consent of the Executive Committee of the Council of Experts, the Chair of the Council of Experts has allowed the portion of the appeal that relates to the technical content of the general chapters and their official dates to proceed. The Chair has denied the portion of the appeal that relates to the planned implementation of these chapters effective May 2014 through a proposed General Notices provision. This portion is untimely as the General Notices proposal that would accomplish this has not yet appeared in Pharmacopeial Forum (PF). The arguments made by appellants here should be submitted as comments to the PF proposal, and be considered by the Executive Committee of the Council of Experts as part of the notice and comment process along with comments received from other stakeholders. The Executive Committee of the Council of Experts itself is responsible for General Notices revisions.

The Executive Committee of the Council of Experts will first consider the appeal based on the documentation submitted. If the Executive Committee determines that additional information is needed to reach a decision on the appeal, they will consider conducting a hearing.

This Postponement via Revision Bulletin for <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures supersedes the currently published general chapters in the Second Supplement to the *USP 35–NF 31*, which were originally targeted to become official on December 1, 2012.

Please contact Mario Sindaco (301-816-8246 or mys@usp.org) should you have any questions.