
<232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures

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Pursuant to a Revision Bulletin posted on November 15, 2012 and updated on November 21, 2012, and in accordance with the Rules and Procedures of the 2010–2015 Council of Experts, the Executive Committee of the Council of Experts (CoE EC) postponed the official dates of <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures. The purpose for the postponement was to allow adequate time for the CoE EC to adjudicate and render a decision on three appeals related to the two general chapters. Due to the similarity of issues raised, these appeals were consolidated and considered simultaneously as a single appeal. As noted in the prior Revision Bulletin, the portion of the appeal that was allowed to proceed and was considered by the CoE EC was that related to the content of the general chapters and their official dates. The portion of the appeal that related to the planned implementation of these chapters effective May 2014 through a proposed General Notices provision was denied as untimely, as the General Notices proposal at issue had not yet appeared in Pharmacopeial Forum (PF) for public notice and comment.

The CoE EC met on January 7, 2013 to consider the combined appeal on General Chapters <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures. The Executive Committee was provided with the appeal documents in their entirety, information outlining the prior consideration of appellants' issues, and a comprehensive record of the standards-setting activities related to <232> and <233>. At its meeting, the Executive Committee reviewed the standards-setting record, the key points of each appeal, and how the Expert Panel and Expert Committee addressed each appellant concern. The Executive Committee determined that the information presented was sufficient for it to rule on the appeal.

The Executive Committee voted to uphold the general chapters, finding that 1) the Expert Committee and Expert Panel appropriately followed their processes and adequately considered appellants' prior comments, and there was no new data or evidence presented that justifies further consideration by the Expert Committee or Expert Panel, and 2) an official date should be re-established for the chapters, ending their postponement. They further determined this official date to be February 1, 2013.

As previously noted, USP intends to implement these general chapters through a proposed provision in the General Notices that would make <232> and <233> applicable to all articles in the compendia (except where noted otherwise) on May 1, 2014 (*USP 37–NF 32*). Conformance with <232> and <233> in applicable monographs will thus be required as of this date. This implementation approach for the general chapters also includes removal of all references to USP General Chapter <231> Heavy Metals from monographs in the *USP–NF*, also proposed in PF 39(1) for public comment. Note that <231> remains applicable until it is omitted.

This provision currently is proposed in Pharmacopoeial Forum (PF) 39(1) [Jan–Feb 2013] for public comment. Stakeholders may submit comments on the General Notices proposal until March 31, 2013 for consideration by the Executive Committee, which is responsible for revisions to General Notices.

It is important to note that although General Chapters <232> and <233> will become official on February 1, 2013, there will be no requirement for an article covered by an applicable *USP–NF* monograph to comply with their provisions on this date. 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 named in *USP–NF*. Typically, a standard becomes official six months after publication in a book or supplement, and implementation is required as of that official date. In this case, however, the official date is separate from the implementation date, as implementation cannot occur until the general chapters are referenced in a monograph or in General Notices.

The Executive Committee acknowledges that there may be particular issues relating to application of <232> and <233> to specific articles that may need to be addressed through monograph revisions or other vehicles. In these instances, the Executive Committee encourages appellants to provide specific data and information and work with USP and its relevant Expert Committees to resolve these issues prior to the May 1, 2014 planned implementation of the general chapters.

The Executive Committee notes that this decision upholding General Chapters <232> and <233> as official as of February 1, 2013, does not preclude their further revision based on new information, including new information arising from the International Conference on Harmonization (ICH), once ICH concludes its deliberations in the matter and national/regional adoption has occurred in accordance with US national procedures. The Expert Panel meets January 2013 to consider the status of these deliberations, as well as to consider several comments that are editorial in nature from the Food and Drug Administration.

This Revision Bulletin for <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures supersedes the Revision Bulletin posted

on November 15, 2012 and updated on November 21, 2012 and the currently published general chapters in the Second Supplement to the *USP 35–NF 30*, which originally had become official on December 1, 2012.

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

- [Download the Elemental Impurities Standards-setting Record](#)
- [Download Minutes of the January 7, 2013 Meeting of the Council of Experts Executive Committee](#)