9 June 2023

CODEX COMMITTEE ON PESTICIDES RESIDUES

(Fifty-fourth Session)
Beijing, China
26 June – 01 July 2023

European Union comments on

Agenda Item 12

Monitoring the purity and stability of certified reference material of multi-class pesticides during prolonged storage

(CX/PR 23/54/14 and CL 2023/38-PR)

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on the Guidelines for monitoring the Purity and Stability of Reference Materials (RMs) of pesticides chaired by India and co-chaired by Argentina and Iran for the preparation of the Discussion Paper with reference CX/PR 23/54/14. The EU would like to submit its comments in the format instructed in CL 2023/38-PR, as follows:

(i) **With consideration to Appendix I**, the EU considers that it provides sufficient data/information that support the development of a guidance on monitoring the stability and purity of reference material of pesticides during prolonged storage.

In addition, the EU would like to provide comments as regards the current information, as follows:

Comment No I-1:

Appendix I, paragraph 1: The EU suggests providing clarification of the term "multi-class pesticide", possibly in section of definitions in the Annex of the document.

Comment No I-2:

Appendix I, paragraph 2: The EU suggests modifying the sentence

"Their stability can be assessed by creating quality control charts, comparing the certified values of expired RMs with fresh RMs, and through satisfactory performance in proficiency testing (Linsinger, 2019)" as follows:

"Their stability can be assessed by creating quality control charts and by comparison of the certified values of expired RMs with fresh RMs (Linsinger, 2019).

The reason is that satisfactory performance in proficiency tests is supporting evidence of the stability of the analytical standards, but not a proof.

Comment No I-3:

Appendix I, paragraph 3: The EU suggests deleting the whole paragraph, as the purpose of the proposed guidance document is to continue using the expired certified analytical standards for quantification of the samples. Thus, it is not relevant if the aforementioned standards can be used to demonstrate repeatability.

Comment No I-4:

Appendix I, paragraph 5: The EU suggests deleting the whole paragraph, as verification of the purity of Certified Reference Materials (CRMs) by participation in proficiency tests is not an appropriate approach. At most, questionable or unacceptable z scores might indicate problems with the analytical standard solutions, but not necessarily related to the purity of the (CRM).

Comment No I-5:

Appendix I, paragraph 8: The EU suggests deleting the whole paragraph, as proficiency tests are not relevant with regard to the evaluation of the purity of RMs.

(ii) (a) **With reference to Appendix II,** the EU acknowledges the need and the purpose of new work on this matter as a means to contribute to analytical cost reduction and to facilitate the work of analytical laboratories.

(b) **Regarding Appendix III**, the EU would like to provide more specific comments as follows:

Comment No III-1:

Considering the current wording of the title of the proposed guidance, the EU suggests clarifying whether the proposed guidance concerns the monitoring only of the stability or also of the purity of reference material, even though paragraphs 6 to 9 of the document suggest that the purity of reference material is also included.

Comment No III-2:

Appendix III, paragraph 5: the EU suggests modifying the whole sentence as follows: "To minimize the degradation of RMs, the vials must be placed in airtight capped tube/sealed pouch and immediately stored in the freezer at at $\leq$ -18^{o}C with the aim to reach even lower temperature (Sharma et al. 2020).

The reason is that in certain cases, degradation cannot be avoided, but can be minimised. In addition, freezers that work at -25°C are not so common, but most freezers reach temperatures of -18°C.

Comment No III-3:

Appendix III, paragraph 6: the EU suggests deleting paragraph 6 and proposes using the procedure explained in document SANTE/11312/2021[1] under "Testing and replacement of standards" (paragraphs F8-F11).

Comment No III-4:

Appendix III, paragraph 6, footnote 9: the EU suggests replacing "mass chromatography" with "mass spectrometry".

Comment No III-5:

Appendix III, paragraph 8: the EU suggests modifying the sentence "If the deviation in the purity of the RM after expiration is found within 5%, the analyte [...]" as follows: "If the deviation in the purity of the RM after expiration is found within 10%, the analyte [...]", as 5 % is very low and does not take into account the instrumental repeatability.

Comment No III-6:

Appendix III, paragraph 8: the EU suggests correcting the sentence "[…] acceptable and therefore be considered for continued use as a RM" as follows: "[…] acceptable and therefore can be considered for continued use as a RM."

(c) the EU agrees with the proposal to establish an eWG to prepare guidance on monitoring the stability of reference material purity of pesticides during prolonged storage based on the outline provided in Appendix III for consideration by CCPR55.

[1] https://food.ec.europa.eu/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf