# CODEX COMMITTEE ON PESTICIDES RESIDUES 55<sup>th</sup> Session

# Chengdu, Sichuan province, P.R. China 3-8 June 2024

### **European Union comments on**

## Agenda Item 7

# Draft Guidelines for monitoring the purity and stability of reference materials and related stock solutions of pesticides during prolonged storage

### (<u>CX/PR 24/55/6 – CL 2024/45-PR</u>)

European Union Competence European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) chaired by India and co-chaired by Argentina and Singapore for preparation of the on the Guidelines for monitoring the Purity and Stability of Reference Materials (RMs) of pesticides (CX/PR 24/55/6).

The EU generally supports the proposed guidelines with some comments in response to the Circular Letter CL 2024/45-PR.

Appendix I, CX/PR 24/55/6

- **Page 5, General criteria:** The EU suggests continuing the numeration of the paragraphs after the heading "general criteria" ("10. 1. The analysis should be conducted in an ISO/IEC 17025 accredited laboratory")
- **Page 5, paragraph 7:** The EU suggests changing the footnotes "6,7" to "1,2"

Another study revealed the stability of pesticide reference standard up to 15 years or in stock solution up to 10 years<sup>6,7],2</sup>."

• **Page 5, paragraph 8:** The EU proposes to include the option to keep the reference materials (RMs) in the refrigerator. For some RMs, standard providers recommend storage temperatures above zero; thus, refrigerator storage is also suitable. In addition, the EU propose to replace the word "better" by "more protective".

"8. To avoid any cross contamination or degradation of RMs, the vials must be placed in airtight capped tube/sealed pouch and immediately stored in the freezer/<u>refrigerator</u> at conditions <del>better</del>-more protective</u> than those recommended by RMPs; preferably at subzero temperature."

• Page 5, paragraph 8 (Also in Page 6, paragraph 16 and page 7, paragraph 25): Since calibrated material should not be exposed to extreme temperature changes and should not be stored in the freezer or placed in the oven, the EU proposes to remove the recommendation to use volumetric flasks for storing the standard solutions:

"8. [...] The stock solutions must also be stored in airtight capped glassware (preferably volumetric flask)."

• **Page 6, paragraph 9:** The EU considers that number of footnotes 5,6 and 5 are not correct and that only one footnote (5) should remain (same as footnote 4)

"[...] provided the purity remains acceptable<sup>5,6,5.</sup> "

• Pages 6 and 7, paragraphs 12, 13 and 20: The EU suggests adding the term "...preferably <5%" to emphasize the need for having a very small variability in measurement and to have a higher confidence in the calculated deviation between the standard solutions.

"Perform a minimum of five replicate measurements to obtain a mean value of the peak area for the old standard with %RSD  $\le 10\%$ , <u>preferably  $\le 5\%$ ."</u>

"A minimum of five replicate measurements should be performed to obtain a mean value of percent purity and the %RSD should be  $\leq 10\%$ , <u>preferably <5%."</u>

• Pages 6 and 7, paragraphs 12 and 20: The EU considers that it is not necessary to analyse the compounds using all the techniques, therefore it is suggested to replace "and" by "or" in the following sentence:

"(HPLC -DAD /HPLC-UV/GC -FID /LC-MS and or GC-MS in full scan mode"

• **Page 6, paragraph 12:** The EU suggests including the explanation of the abbreviation LC in a footnote.