14.09.2020

European Union Comments

Circular Letter CL 2020/40-PR

Request for comments on the management of unsupported compounds without public health concerns scheduled for periodic review

European Union Competence

European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) on unsupported compounds without public health concerns scheduled for periodic review chaired by Chile and co-chaired by Australia, India and Kenya for the preparation of the discussion paper on the management of unsupported compounds without public health concerns scheduled for periodic review with reference CX/PR 20/52/17.

As already indicated in its comments on CX/PR 19/51/17, regarding the management of unsupported compounds without public health concern, the EU considers that option 3 (described in paragraph 19 of CX/PR 19/51/17) is fully in line with the risk analysis principles. The EU supports the path proposed in option 3.

The EU understands the conclusions presented in CX/PR 20/52/17 to stick to the two options (2b and 3) included by CCPR51 (2019) in the terms of reference, and hence the alternatives presented in section 2 of the conclusions (para 22-27) to describe possible actions within these two options, rather than to be independent third and fourth options.

Please find below detailed comments per paragraph of CX/PR 20/52/17:

para 14: The EU does not support the proposal to reduce the data requirements for JMPR evaluations, as it would compromise JMPR's ability to fully assess the safety of a substance. During a periodic review, an "old" substance should be evaluated against the same safety criteria as a "new" substance evaluated by JMPR for the first time.

para 15: The EU does not agree with the notion that “the primary toxicological assessment is still valid”. As noted by the previous eWG in para 20 of CX/PR 19/51/17: “After 25 years the toxicological evaluation may be outdated and no longer reliable. Health concerns cannot be excluded in this case.” This is also acknowledged as a challenge for option 2b by the current eWG in para 17 of CX/PR 20/52/17: “The main points identified are related to the fact that some CXLs may be considered outdated in terms of the underlying risk assessment, because their GAP (= good agricultural practice) could have changed or have obsolete toxicological evaluation and, therefore, lead to possible health problems.”

para 19: The EU agrees with the advantages identified by the eWG.

para 21: Capacity necessary for data generation is needed in at least three domains:

- Organisational capacity: to anticipate future periodic reviews, identify the interest among members and observers to support some or all existing CXLs, and identify the data to be resubmitted or generated as appropriate. The EU considers that time should not be a crucial factor, as it is known from Table 3 (record of review) maintained by the eWG on Priorities when the JMPR last evaluated a given substance and thus when the 15- and 25-year timelines will be met, so that preparation may begin well before the 4-year rule is applied. See also the EU comments on para 24/25 for additional measures to address organisational capacity issues.

- Technical capacity: to plan, carry out and report the studies necessary for newly generated data. In view of the highly specialised nature of these studies, the EU considers that existing facilities should be used, rather than building capacity from scratch. Such facilities can be private (manufacturer, contract research organisation, etc.) or public, dependent on the parties interested in supporting a given substance.

- Financial capacity: to provide the financial resources necessary to generate data and compile a dossier. Actors at various stages of the production chain benefit from the existence of a CXL: manufacturers of plant protection products, growers, traders, countries in which the use is registered, etc. While the EU acknowledges the obstacles related to protection of intellectual property identified in section 1 of the conclusions, it considers that the overall economic benefit of a CXL related to the use of a plant protection product on a commodity moving in international trade should be sufficiently large to support the compilation of a complete dossier for evaluation by JMPR every 25 years.

para 22: The EU does not support option 2b and does not agree to an amendment of the Risk Analysis Principles regarding periodic reviews. It is not a problem of the Risk Analysis Principles, but of the practical implementation of those principles for certain substances. The EU considers that the preparation of a proposal for amendment for consideration by CCPR52 (2021) exceeds the terms of reference of the current eWG. It would also divert resources from pursuing more promising ways forward.

para 24: The EU supports option 3 and appreciates the proposals of the eWG to improve compliance with it. The EU invites the eWG to focus its future efforts on elaborating on measures to turn unsupported compounds into supported compounds, rather than on measures to exempt unsupported compounds from the consequences set out in the Risk Analysis Principles. The EU agrees with the eWG that established practices exist in the work of the eWG on Priorities to draw the attention of Codex members and observers on compounds (to be) scheduled for periodic review. See also the EU comments on para 21 regarding Table 3 (record of review).

para 25: The EU agrees with the proposal of the eWG, which would effectively help to "identify the interest among members and observers to support some or all existing CXLs", as indicated in the EU comments on para 21 (organisational capacity). In more concrete terms, the EU invites the eWG to consider the following suggested procedures:

- As soon as an active substance reaches the 15-year time limit (para 54 of the Risk Analysis Principles), the chair of the eWG on Priorities asks members and observers (a) to support this active substance, and/or (b) to provide authorised uses, and forwards a timetable when to send such information. This is similar to ongoing practice.

- If no support is indicated, but authorised uses indicate interest by members, an interest group is established, based on a request by the chair of the eWG on Priorities, to collect nominations. Interested parties, especially from those members having evaluated the active substance and/or authorised uses during a period not longer than 5 years ago and those members having an interest in keeping the substance in the Codex system, will discuss opportunities.

- A crucial step is to define what has changed since the last JMPR evaluation covering toxicology and residue behaviour, as it will define the amount of work to be done. The engagement of JMPR at this early stage of the procedure is essential, both to avoid that the dossier to be prepared will be found incomplete, and to avoid unnecessary repetition of studies. This is all the more important for vertebrate studies.

- Starting such work at the 15-year time limit ensures that interested members and observers would have a total of 10 years to take decisions and generate the necessary data. Concerned members should also strengthen their efforts to bring interested small and medium enterprises together that produce substances and/or formulations and have a commercial interest, to facilitate shared data generation.

- In case data is provided before the 25-year limit, CCPR can proceed with the normal procedure of an evaluation by the JMPR.

- In case no or incomplete data is provided by the 25-year limit, all CXLs are withdrawn and the active substance is deleted from the list of Codex substances, at the next CCPR meeting following the year when the 25-year time limit (para 74 of the Risk Analysis Principles) was reached, without any further discussion, as described in the Risk Analysis Principles.

- To increase transparency, it should be considered to flag active substances in Tables 2A and 2B whose last JMPR evaluation covering toxicology and residue behaviour is 20 years old or more, by adding a column indicating the anticipated year of deletion, in case the substance remains unsupported. Moreover, two years before the anticipated year of deletion, a note on the impending deletion should be included in the list of Codex MRLs.

para 26: In view of the highly specialised nature of these studies, the EU considers that existing facilities should be used, rather than building capacity from scratch, as indicated in the EU comments on para 21 (technical capacity).

para 27: The EU agrees with the proposal of the eWG, and suggests that the eWG recommend to explore whether the platform “forum.codex-alimentarius.net” could be used for this purpose.