

European Union comments, 14.09.2020

QUESTIONNAIRE

Management of unsupported compounds without public health concerns scheduled for periodic review by JMPR

CX/PR 20/52/17, Appendix I, Section I	Comments provided by European Union
<u>TOR (i) - Investigate the circumstances that lead to unsupported compounds without public health concerns and obstacles that prevent providing support</u>	
<u>Question 1</u> Which are the circumstances that leads to unsupported compounds without public health concerns scheduled for periodic review?	See earlier EU comments to eWG, no further comments.
<u>Question 2</u> Which are the obstacles that prevent providing support to these compounds?	See earlier EU comments to eWG, no further comments.
<u>Question 3</u> Are Codex members and observers sufficiently aware of what information and data are required to support the periodic review of a pesticide?	See earlier EU comments to eWG, no further comments.
<u>Question 4</u> 4.1 Are Codex members and observers sufficiently aware of the consequences of the lack of support for a pesticide scheduled for periodic review and its uses, especially the loss of CXLs.	See earlier EU comments to eWG, no further comments.
<u>TOR (ii) - Explore options for efficient data support</u>	
<u>Question 1</u> What kind of collaborative activities can efficiently be developed within the framework of <ul style="list-style-type: none"> (a) Codex, (b) FAO, WHO and other international organizations, (c) relevant government agencies (i.e. twinning activities between Codex members), (d) industry / trading companies, and (e) other relevant parties (if any) to assist Codex members, currently lacking the capacity to independently support pesticides/uses important to their production systems, to provide the required data package for the JMPR periodic review?	(a) Codex Codex can provide a platform for the exchange of views, information and data between all interested parties. (b) FAO, WHO and other international organizations FAO and WHO can provide information on what data is available and more important on what data is missing. This is necessary to define the workload for those who will provide the missing data. (c) relevant government agencies (i.e. twinning activities between Codex members) Relevant government agencies can provide their latest evaluation as far as available and where the assessment was performed not longer than 5 years ago. Concerning further capacity building, the EU remains available for bilateral meetings to exchange

	<p>on issues related to capacity building and to identify opportunities to provide support.</p> <p>(d) industry / trading companies</p> <p>Concerned members should strengthen their efforts to bring interested small and medium enterprises (SME) together that produce substances and/or formulations, to facilitate shared data generation. As they have a commercial interest and benefit from the continued existence of pertinent CXLs, the EU considers it also their duty to support the CXLs. While a single SME may not be able to do all the work alone, it is necessary that they join forces to share the burden.</p> <p>The EU emphasises the growing importance of contacts between trading companies, trading associations, food associations and agricultural organisations on the one hand and relevant government agencies on the other hand to ensure an essential flow of information, not least in view of the currently changing agricultural environment.</p> <p>(e) other relevant parties (if any)</p> <p>Other international agencies may provide projects for capacity building, while research institutes may be willing to conduct some studies.</p> <p>Other relevant parties are trading companies, trading associations, food associations and agricultural organisations to ensure the flow of information between farmers, national agencies and main exporting countries.</p>
<p><u>Question 2</u></p> <p>2.1 Is there any possibility to reduce the minimum data requirements for a JMPR periodic review of a pesticide without a registered public health concern?</p> <p>2.2 If so, what are the minimum data requirements that could be considered appropriate?</p>	<p>The minimum data requirements for a JMPR re-evaluation should not be further reduced, as that may compromise JMPR's ability to assess the safety of a substance. Moreover, in view of the partial differences between JMPR minimum data requirements and national minimum data requirements, reductions to JMPR requirements may lead to decreasing acceptance of CXLs by members. Ultimately, this would undermine the aim of all ongoing efforts on unsupported substances.</p>
<p><u>TOR (iii) - Explore the advantages and challenges that arise from the options 2b and 3</u></p>	
<p><u>Option 2b</u>: Only those CXLs for which there are registrations listed in the national registration database (NRD) will be retained</p>	
<p>Advantages</p>	<p>See earlier EU comments to eWG, no further comments.</p>
<p>Challenges</p>	<p>See earlier EU comments to eWG, no further comments.</p>
<p><u>Option 3</u>: Codex members and observers are granted 4 years to fulfil the data requirements to maintain the CXLs. (i.e., 4-year rule). If members or observers are unable to address the data requirements, all CXLs are to be revoked</p>	
<p>Advantages</p>	<p>See earlier EU comments to eWG, no further comments.</p>

Challenges	See earlier EU comments to eWG, no further comments.
CX/PR 20/52/17, Appendix I, Section II	
<u>TOR (iv) - Comment is invited on the measures described in CX/PR/20/52/17 that may be required in order to implement Option 2b or Option 3.</u>	
<p><u>Option 2b:</u></p> <ul style="list-style-type: none"> (a) Partial revision of the Risk Analysis Principles applied by CCPR¹ (including an outline of the changes needed) (b) Proper functioning of the national registration database² (NRD) (including a description of the elements to improve its functioning additional to those already agreed to by CCPR) (c) Other options (to be applied singly or in combination with one or more of the options above – please specify) 	<p>The EU does not support 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.</p> <p>The EU considers the proper functioning of the national registration database a prerequisite for both options under discussion by the eWG.</p>
<p><u>Option 3:</u></p> <ul style="list-style-type: none"> (a) Enhanced presentation of the information on the schedules and priority lists of pesticides for evaluation by JMPR prepared by the EWG/Priorities relevant to the periodic review (including a description of such enhancements) (b) Enhanced practices in addition to those currently applied by the EWG/Priorities in the elaboration of the schedules and priority lists of pesticides for evaluation by JMPR relevant to the periodic review (including a description of such enhancements) (c) Capacity building activities to strengthen capacities in Codex members to enable them to meet the requirements of Option 3 (including a description of such activities) (d) Establish of a forum that allow Codex members to share data and/or information available to assist Codex members with difficulties to gather the required data to support the periodic review (e) Other options (to be applied singly or in combination with one or more of the options 	<ul style="list-style-type: none"> (a) As soon as an active substance reaches the 15-year time limit (para 54 of the Risk Analysis Principles), it should be marked more clearly in the tables maintained by the eWG on Priorities. This point in time should be the starting point for enhanced practices (see point (b) below) leading to the formation of a working group among interested parties, where appropriate. (b) If no support is indicated for a substances that reached the 15-year time limit, 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. The composition of such an interest group may vary with the substance in question and the progress made. While the work done in the interest group is done outside the eWG on Priorities, it is important to report back from the interest group to the chair of the eWG Priorities to inform subsequent decisions on the scheduling or non-scheduling of the substance.

¹ Codex Alimentarius Procedural Manual, Section II (Risk Analysis):

² REP19/PR, paras. 216-233

above – please specify)

(c) See EU comments on TOR (ii), Question 1.

(d) See EU comments on TOR (ii), Question 1.

(e) Not an option, but a prerequisite for both options under discussion by the eWG: proper functioning of the national registration database.