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European Union Comments
CODEX COMMITTEE ON PESTICIDE RESIDUES
48th Session
Chongqing, 25 – 30 April 2016

AGENDA ITEM 10

Establishment of Codex Schedules and Priority List of Pesticides

Mixed Competence

European Union Vote

The European Union and its Member States (EUMS) would like to thank Australia for the preparation of the schedules and priority lists of pesticides (2017-2021). Our comments relate to two main issues:

a) General comments on the balance between new evaluations and periodic reviews

b) Specific comments on substances.

a) General comments on the balance between new evaluations and periodic reviews:

At the 2015 CCPR meeting, the EU delegation welcomed the proposal of the Chair of the electronic Working Group on Priorities (eWG) to review the ratio of new and old compounds, with a possible stronger focus on periodic reviews, and requested a thorough discussion on this point at the 2016 CCPR meeting.

In response to the broadcast e-mail sent by the Chair of the eWG, the EU submitted comments on the balance between new compound evaluations and periodic reviews. These comments included an analysis of the problems with the current approach and proposals to address them. The comments are reproduced below, as the analysis and proposals are still valid, and to provide the necessary context to Members and Observers who did not participate in the eWG.

The EUMS appreciate the clarification provided in CL 2016/PR, namely that the JMPR Secretariat has indicated a quota of 11 compounds for full evaluation (new compounds and periodic review) per year.

The EUMS welcome the shift in the ratio between new evaluations and periodic reviews proposed in CL 2016/PR, to about 1.25:1 (new compound: periodic reviews). However, while this is a step in the right direction, it does not go far enough. As acknowledged in CL 2016/PR, a ratio of 1.25:1 applied to a quota of 11 full evaluations per year would mean a maximum of 5 periodic reviews annually. Based on 200 pesticide compounds in the Codex system, this would result in an average time between reviews of about 40 years (and not yet taking into account that more new compounds are added every year).

The EUMS consider that such long periods between periodic reviews do not meet the requirements of the risk analysis principles, as explained in the comments to the eWG, and calls on the CCPR to shift the ratio further towards periodic reviews, while resuming discussions on possibilities to increase the evaluation capacity of JMPR.

Furthermore, as also highlighted in part b) of this comment, the EUMS are strongly in favour of a stringent approach for deleting compounds from the system that are no longer supported by a manufacturer. Consequent withdrawal of the corresponding Codex MRLs will contribute to reducing the number of substances for which a periodic review is overdue. The EUMS therefore very much welcome the recently increased efforts to regularly review the national registrations of substances and to push for revocation of the associated CXLs if substances are no longer supported. For substances in the periodic review table, manufacturers should be required to indicate their support in writing by a certain specific deadline. If this support is not provided, the compound should be removed from the list and all CXLs be revoked.

EU comments to the eWG:

"Currently, too few periodic reviews are scheduled to ensure that compounds are regularly re-assessed, i.e. every 15 years. Moreover, the Risk Analysis Principles state that the review schedule "seeks to provide a balance of new pesticides, new uses, other evaluations and periodic reviews". Given the more than 200 pesticide compounds in the Codex system[1], at least 13 periodic reviews per year are required to achieve a sufficient re-evaluation of substances[2]. In the past years however, only a fraction of the necessary periodic reviews was carried out[3], resulting in a backlog of more than 30 compounds whose last review took place before the year 2000.

The current scheduling approach falls even short of the 25-year period set out in the Risk Analysis Principles as a maximum that will trigger CCPR's attention with a view to scheduling, also in the absence of concerns and/or availability of data. Continuing the scheduling practice of the past years would result in an average time between reviews of about 50 years. That number would be exceeded to the extent that further new compounds are added.

It is hence clear that the current approach does not meet the requirements of the risk analysis principles, neither in terms of the 15- and 25-year rules for scheduling periodic reviews, nor to "provide a balance of new pesticides, new uses, other evaluations and periodic reviews"[4].

There is an imbalance between the ambition to set new Codex MRLs for a large number of compounds, and the ensuing responsibility to ensure that the standards that were set in the past remain safe for consumers also in the light of evolving scientific knowledge and technical standards. In this respect the absence of a re-evaluation for more than 15 years can in itself be seen as a concern. Furthermore, there is a mismatch between the needs for risk assessment of old and new compounds combined, and the currently available evaluation capacity of JMPR.

It is the view of the EU that it is necessary to address these problems. Not doing so may compromise the high level of consumer protection afforded by Codex standards and may undermine support from an increasingly critical public.

The EU proposes to address both problems outlined above.

In the short term, the ratio of new compound evaluations and periodic reviews should be readjusted, with a shift towards periodic reviews. While the numbers suggest that nearly all of JMPR's current capacity for full evaluations (new compounds and periodic reviews, but not new use evaluations) would be needed to ensure sufficiently regular re-assessments, the EU acknowledges that this would

[1] 279 pesticide compounds in total, of which 7 with EMRLs or guideline levels, and 72 without MRLs.
[2] Long-term average of 200 compounds divided by 15 years ≈ 13 compounds/year. Considering that currently about 8 new compounds are added every year, the average number of required periodic reviews is expected to rise by 1 every two years.
[3] 2010 JMPR: 5 periodic reviews, 2011: 4 PRs, 2012: 7 PRs, 2013: 3 PRs, 2014: 3 PRs, 2015: 4 PRs, 2016: 3 PRs scheduled plus 2 reserve status.
[4] JMPR evaluations in recent years covered ca. 35 compounds per year, of which ca. 14 as full evaluations (ca. 10 new compound and 4 periodic reviews) and 20 new use and other evaluations.

be difficult to achieve. However, the EU considers that a clear majority of full evaluations should be dedicated to periodic reviews, given the responsibility for consumer protection and the imbalance towards new compound evaluations in the past years. Identification of compounds no longer supported by a manufacturer and eventual withdrawal of the corresponding Codex MRLs might further contribute to reducing the number of substances for which a periodic review is overdue. The EU therefore very much welcomes the recently increased efforts to regularly review the national registrations of substances and to push for revocation of the associated CXLs if substances are no longer supported.

In the medium term, the evaluation capacity of JMPR should be increased to match the demand. While recent discussions in this regard did not deliver concrete results, further exploration of different options is necessary. Any gains in capacity should be to the benefit of both periodic reviews and new compound evaluations, until the balance required by the risk analysis principles is achieved."

b) Specific comments on substances:

The EUMS are grateful that the substances we proposed for prioritisation in the period review (amitraz, azinphos-methlyl, diazinon, phosalon and quintozen) have been taken up in the document "schedules and priority lists 2017-2021".
These substances are not approved in the EU due to health concerns (see Annex with main rationales for EU health concerns).

As outlined under point a) of our comments, the recent developments towards a more stringent procedure by which current registrations are systematically checked and CXLs withdrawn swiftly in the absence of support by manufacturers, is very welcome and is in our view urgently needed to free additional resources for periodic review of other substances.

In line with this principle, the EUMS would like to make the following specific comments:

- **bromopropylate and permethrin** (see para 12 of CL 2016/PR) remain unsupported for at least 5 years. CXL should therefore be withdrawn by CCPR 48 without the need to keep the substance in the 2018 schedule.
- **azinphos-methyl** (para 15 of CL 2016/PR) is no longer supported. This was confirmed at several previous meetings of the CCPR (since 2010[5]). The existing CXLs should be withdrawn by the CCPR 48 (2016) and without a need for a periodic review.
- **Table 2B:** The EUMS fully support the recommendation to CCPR 48 to remove the substances **aldicarb, tecnazene, tolylfluanid, diclofluanid and bioresmethrin** from the list and withdraw the CXLs for these substances. The EUMS wish to highlight that in addition the substances **fenthion, disulfoton and dinocap** are also no longer supported and should be recommended for deletion by CCPR 48. **Tolylfluanid and dichlofluanid** should consequently be deleted from the periodic review schedule for 2020.
- **Fenbuconazole, maleic hydrazide, amitrole, pyripoxyfen and malathion** are on the list of substances for which advice of manufacturers is awaited. The recommendation for deletion of these substances should be strongly announced now in CCPR 48. If in one year's time such advice is not given, they should be recommended for deletion by CCPR 49.
- For **2-phenyl-phenol, parathion-methyl, bitertanol, 2,4 D, diphenylamine, piperonlybutoxide, methomyl, fipronil, spinosad and imidacloprid** the same procedure

[5] 2010 CCPR, para 178; 2011 CCPR, Appendix X; 2012 CCPR, para 166; 2014 CCPR, Appendix XV; 2015 CCPR, Appendix XV.

should apply with a slightly longer timeline (i.e. strong announcement of a recommendation for deletion in CCPR 49 (2017) and subsequent withdrawal of CXLs if no longer supported).

- The EUMS welcome that an interim JMPR organised in spring 2016 will review **diazinone** based on concerns raised by IARC on the possible carcinogenic properties. Also the toxicological reference values set by JMPR should be reviewed. Both chronic and acute health risks have been identified for the substance, the EU ADI being 25 times lower than the JMPR ADI. Organising interim JMPR meetings between regular sessions may also be a solution to address the increasing backlog of substances for periodic review.
- The EUMS also request to **anticipate the review of amitraz** into an earlier schedule. With the existing CXLs exceedances of the acute reference dose occur in several commodities.

As regards the procedure of establishing the list of substances for evaluation, the EUMS wish to make one final comment: If the periodic review of a scheduled substance is postponed or cancelled, the emerging gap should be preferably filled with substances from the periodic review table. The EUMS were surprised to learn that following withdrawal resp. postponement of two compounds (MCPB and norflurazon), they were replaced by two reserve compounds from the new compounds table (pinoxaden and cyclaniliprole) instead of the two reserve compounds from the periodic review table (fenpropimorph and chlormequat). This seems inappropriate given the long delays and backlog of the periodic review exercise.

ANNEX

Code No.	Substance	Rationale
2	Azinphos-methyl Falls under the 15-year rule (listed in Table 2B). The EU proposes to include the substance in Table 2A based on public health concerns. A concern form was submitted in October 2015. Azinphos-methyl was re-evaluated concerning toxicology in 2007 with concerns mentioned by EU in CCPR 2008 due to the use of human data. The re-evaluation for residue behavior was announced for 2010 but then did not take place as the substance was no longer supported.	The substance is not authorised in the EU. It is of public health concern as the ARfD established by JMPR is exceeded for several commodities when using EU consumption data: • 185% of ARfD for pears • 135% oranges which might be of no concern taking into account distribution between peel and pulp • Peaches (120%) • Pine apples (105%) As the substance is falling under the 15 year rule and it has been confirmed at several meetings of the CCPR that it is no longer supported worldwide, the existing CXLs should urgently been withdrawn (2010 CCPR, para 178; 2011 CCPR, Appendix X; 2012 CCPR, para 166; 2014 CCPR, Appendix XV; 2015 CCPR, Appendix XV).
22	Diazinon Falls under the 15-year rule (listed in Table 2B), last evaluation in 1996. Diazinone is already scheduled for toxicological and residue assessment by an interim JMPR to be held in Spring 2016, based on concerns raised by IARC on the possible carcinogenic properties of the substance (see Summary Report JMPR2105).	The substance is not authorised in the EU. The EU-ADI of 0.0002 mg/kg bw/day) is much lower than the JMPR ADI (0.005 mg/kg bw/day). Using the existing CXLs and the EU ARfD/ADI in the EFSA PRIMo model, serious public health concerns are identified after long-term dietary exposure of diazinon. An acute dietary risk assessment was performed using CXLs. When using the JMPR IESTI model, the JMPR-ARfD is not exceeded. By using the EFSA PRIMo model and the CXLs, the EU-ARfD is exceeded (IESTI 1) in case of scarole (175%), plums (132%), carrots (127%), melons (121%), apples (118%), broccoli (117%), tomatoes (116%), pears (105%), head cabbage (105%), bovine meat (102%). Refinement (IESTI 2) of the variability factors would still lead to exceedances of the ARfD for scarole, melons, plums and bovine meat (102-175%). Use of the HR would lower the short term exposure by a factor of 2 which would not result in an exceedance of ARfD. Even without

Code No.	Substance	Rationale
		including the LOQs for the crops without MRLs, the highest calculated TMDI values in % (EU) ADI are 376-4990% in various populations (child, toddlers, general public) and countries, with meats, pome fruit, carrots and sugar beets conributing the most (all >>100 % of the ADI). It is acknowledged that the use of the STMRs would lower the long-term dietary exposure by approximately a factor of 4-5, but this would still lead to an exceedance of the ADI.
60	Phosalon Falls under the 15-year rule (listed in Table 2B), last evaluation in 1997.	The substance is not authorised in the EU. EU has established a lower ADI and ARfD than JMPR. Using the EU ARfD and ADI of 0.01 mg/kg, the EU MRLs and the Codex MRL for apple and pome fruit for phosalone leads to exceedance of ADI, with apple contributing most (114-639 %) in various populations. In the short-term dietary risk assessment these MRLs lead to exceedances of the EU ARfD not only in apples (490%), but also in pears (180%) and peaches (120%). The impact of the metabolite oxaphosalone has not been taken into account, but will only add to the dietary exposure. With the ARfD of the JMPR at 0.3 mg/kg bw and the ADI at 0.02 mg/kg bw/day, there are no exposure concerns.
64	Quintozene Falls under the 15-year rule (listed in Table 2B), last evaluation in 1995.	Quintozene containing more than 0.1% hexachlorobenzene is banned in the EU. For quintozene (containing less than 0.1% hexachlorobenzene), the necessity for deriving an ARfD has not been assessed (EU or JMPR). Using the CXLs, the JMPR IESTI model and the ADI as surrogate ARfD, an exceedance of the ARfD is found for ginger root (240%); no exceedance is found for the EFSA PRIMo model. Using the (temporary) ADI of 0.01 mg/kg bw/day, the TMDI in the long-term dietary risk assessment does not exceed the ADI using the Codex MRLs and the EFSA PRIMo model. However, there are many uncertainties regarding the metabolites that can be formed, depending on application of

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		the active substance at growth stage and on type of plant. There is a lack of sufficient data to exclude consumer risks.
122	Amitraz Falls under the 15-year rule (listed in Table 2B), last evaluation in 1998.	The EU and JMPR ARfD and ADI for amitraz are equal. All EU MRLs are set at LOQ. No EU evaluation of residue trials is available. Therefore the acute risk assessment was performed with the existing CXLs. However, when applied in the EFSA PRIMo model exceedances are observed for oranges (663%), apples (490%), pear (455%), peaches (297%), cucumber (292%), tomatoes (291%) for children. Refinement (IESTI 2) of the variability factors would still lead to exceedances of the ARfD for the same crops (211-480%). In addition, even without including the LOQs for the crops without MRLs, the highest calculated TMDI values in % ADI are 254 and 146 in DE and NL child, with pome fruit attributing the most (>100 % of the ADI). It is acknowledged that the use of the STMRs would lower the long-term dietary exposure by approximately a factor of 4-5, whereby exceedance of the ADI is no longer envisaged. Using the FAO IESTI spreadsheets and JMPR ARfD, the ARfD is exceeded in case of oranges (150-290%), apple (280-360%), pear (280-290%), peaches (150-260%), cucumber (130-200%), tomatoes (110-320%). It is acknowledged that the use of HRs would lower the dietary exposure by approximately a factor of 2, but this would still result in exceedances of the ARfD.