12/03/2015

European Union Comments

CODEX COMMITTEE ON PESTICIDE RESIDUES

47th Session

Beijing, China, 13 – 18 April 2015

AGENDA ITEM 10

Establishment of Codex Schedules and Priority List of Pesticides (CL 2015/3-PR)

Mixed Competence

European Union Vote

The European Union (EU) would like to thank Australia for the preparation of the schedules and priority lists of pesticides (2016-2019) and is grateful for the preparation of the new list for "candidates for inclusion in Table 2A based on public health concerns".

The EU acknowledges that its proposals have been included in that list of candidates and wishes to re-iterate its request for inclusion of the listed substances into Table 2A with priority. Public health concerns have been identified for the following substances as specified in the Annex:

- Acetamiprid
- Carbendazim/benomyl/thiophanate-methyl
- Ethoxyquin
- Guazatine
- Prochloraz
- The CXL for tolylfluanid should be revoked as it is no longer supported worldwide.

As a general point, the EU would like to seek clarification from the JMPR on the procedure for the periodic review as such. The EU fears that if the number of substances remains limited at only 4 substances per year, then the list of substances for review will become longer every year. The EU would like to seek for information as to how this problem will be addressed and managed in future.

Finally, the EU would like to complete the information on **current national registrations** (Table on page 34 of CL 2015/3-PR) with the following additional information:

Active substance	**Active substance approved?**	**Uses registered in EU**
Bromopropylate (70)	no	none
Methidathion (51)	no	none
Diclofluanid (82)	no	none

Permethrin (120)	no	none
Bromide ion (47) [1]	no	none [2]
Hydrogen phosphide (46) [3]	yes	numerous MS [3]
Fenarimol (192)	no	none
Dimethoate (027)	yes	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, MT, NL, PL, PT, RO, SI, SK, UK
Quintozene (64)	no	none

[1] active substance to be looked for: methyl bromide

[2] some emergency uses in place based on specific regulations

[3] active substances to be looked for:

- aluminium phosphide: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK
- calcium phosphide: AT, CZ, DE, HU, LU, LV, PL, SI
- magnesium phosphide: AT, BE, BG, CY, DE, EE, EL, ES, FR, HR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SI, UK
- phosphane (hydrogen phosphide): DE
- zinc phosphide: AT, CZ, DE, FR, HU, LU, PL, SI

ANNEX: SUBSTANCES FOR WHICH HEALTH CONCERNS HAVE BEEN IDENTIFIED

Code No.	Substance	Rationale
246	Acetamiprid (246)	Although acetamiprid was quite recently reviewed by JMRR (2011), there are new toxicological data on development neurotoxicity which may lead to a lowering of the current ARfD (0.1 mg/kg bw). EFSA, in its reasoned opinion on developmental neurotoxicity of acetamiprid and imidacloprid (December 2013) recommends a 4 times lower ARfD of 0.025 mg/kg bw. With such a lowered ARfD, the CXLs for apple, chard and citrus fruit would be of concern.
69, 72, 77	Carbendazim (072), Benomyl (69), Thiophanatemethyl (77)	The last periodic re-evaluation of carbendazim was in 1998. That is more than 15 years ago. In the meantime the active substances benomyl and thiophanate-methyl are no longer supported by the sponsor but the CXLs for carbendazim still cover uses of these two active substances meaning that a couple of CXLs are obsolete. Moreover, the EU has a lower ARfD. Acute health risks were identified for several commodities in the 2006 CCPR. In addition, the EU received an import tolerance application for the use of carbendazim in rice and it turned out that the existing CXL for rice is based likely on an obsolete US GAP on benomyl. In this case as well an acute risk could not be excluded
35	Ethoxyquin	The substance is not authorised in the EU and no import tolerances exist. EFSA concluded that the metabolism data used by JMPR for establishing the residue definition for enforcement and risk assessment could not be confirmed as the metabolism data showed deficiencies using the JMPR residue definition. EFSA concluded that the CXL for pears exceeded the ARfD (109%) and proposed to lower the EU MRL to the LOD. The last periodic review of residues was performed by JMPR in 1999 and of toxicology in 1998. This is approximately 15 years ago.
114	Guazatine	Only "guideline levels" (5 mg/kg) for citrus

Code No.	Substance	Rationale
		exist since the ADI was withdrawn in 1997. It was recommended that these guideline levels would remain until a new ADI is recommended.
142	Prochloraz	Last reviewed by JMPR in 2001. In 2011, Prochloraz was re-evaluated in the EU and a lower acute toxicological endpoint of 0.025 mg/kg/bw/d was established compared to a value of 0.1 set by JMPR in 2001. From the JMPR report (2004) the IESTI was calculated to be greater than 25% of the ARfD at 0.1 for several commodities. With a lowering of the ARfD by a factor of 4, the CXLs for banana, edible offal (mammalian), grapefruit, mandarin, orange, papaya, pineapple, shaddocks/pomelos are expected to be of concern. The EU values were derived from 2 studies that do not appear to have featured in the JMPR evaluation. The multi-generation rat study "Reader 1993" submitted as part of a dossier by a notifier and a 90 day dog study " Lancaster 1979" submitted by another notifier. In addition a change in the interpretation the significance of extended gestation in both the "Cozen 1980 study" and the "Reader 1993" study also impacted. It should also be noted the many papers reviewed as part of the literature search around prochloraz were also considered when the list of endpoints and critical values were set.
162	Tolylfluanid	EFSA identified an exceedance of the ARfD for apples, pears, table grapes and lettuce representing 159 %, 147 %, 146 % and 127 % of the ARfD, respectively. For grapes the CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. For quinces, medlar, loquat, strawberries, blackberries, raspberries, currants, tomatoes, peppers, cucumbers, leek and hops the existing CXLs are supported by data and no risk to consumers is identified. However these CXLs were initially based on an EU GAP which is no longer authorised; there are no relevant authorisations or import

Code No.	Substance	Rationale
		tolerances reported at EU level either. EU GAPs are no longer valid and the substance s no longer used worldwide. All MRLs were set to LOQ in the EU by Reg. 899/2012 and no comments were received during SPS notification. JMPR has a higher ARfD (0.5 mg/kg bw/d) than EFSA (0.25 mg/kg bw/day) but this is based on the same data. EFSA included two more metabolites in the RD than JMPR. The EU requests the revocation of the CXL for tolylfluanid.