Council of the European Union
General Secretariat

Brussels, 07 April 2026

WK 5072/2026 INIT

LIMITE

AGRI
CODEX

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

INFORMATION

From:	General Secretariat of the Council
To:	Working Party on International Food and Agricultural Questions (Codex - CCPR)
Subject:	CCPR57 - Management of unsupported compounds without public health concern(s) scheduled for periodic review by JMPR - Final EU comments

Delegations will find in annex the final comments of the European Union to the eWG on the "*Management of unsupported compounds without public health concern(s) scheduled for periodic review by JMPR*", as submitted to the Codex secretariat via the OCS by the Commission services.

Comments from the European Union

Please note that the comments of the EU as a member of this electronic working group do not prejudice the coordinated position officially and finally taken by the EU when requested by the Codex Secretariat. "

Part 1. ToR (i), ToR (ii)

(i) To examine carbaryl (008); methyl bromide (052); disulfoton (074); flumethrin (195), which were unsupported compounds identified under Agenda item 9 (Establishment of Codex schedules and priority lists of pesticides for evaluation/re-evaluation by JMPR);

(ii) Additionally, to examine ethoxyquin (035) identified under Agenda item 6.1 (MRLs for pesticides in food and feed (at Steps 7 and 4))

Nº	Commenter[1]	Comment	Rationale[2]
1	EU	**carbaryl** (008); the absence of a public health concern should be demonstrated	The last toxicological JMPR evaluation was in 2001 (ADI 0.008 mg/kg bw/day; ARfD 0.2 mg/kg bw). CXLs are in place for a wide range of commodities; they have been adopted in 2004 and 2011, based on JMPR assessments of 2002, 2007 and 2010. The latest acute and chronic risk assessment of JMPR reflecting the current CXLs could not be retrieved. Since 2007, carbaryl is no longer approved in the EU, since - based on the available data - it has not been demonstrated that the consumer exposure is acceptable. The information available indicates concerns for metabolites which are at the same level of toxicity as the active substance, and their presence at levels which might be of toxicological concerns cannot be excluded. The metabolites of

[1] **EWG Member/Observer**

[2] **Provide a rationale for your comment(s).**

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			concern are 4- and 5-hydroxycarbaryl. The European Food Safety Authority (EFSA) concluded, on the basis of available metabolism and residue data, that these metabolites are likely to occur in the same order of magnitude as the parent compound and should therefore be included in the residue definition for risk assessment. Moreover, there are concerns on potential carcinogenic properties of the active substance (recital 5 of Commission Decision 2007/355/EC)[3]. In order to decide whether the substance carbaryl meets the definition of unsupported substances without public health concern, we suggest that JMPR verifies that for the existing CXLs a consumer health concern can be excluded. We were unable to retrieve this information from the published JMPR assessments. If the absence of a public health concern cannot be demonstrated, the compound does not qualify to enter the CCPR process for management of unsupported compounds without public health concern.
2	EU	methyl bromide (052); No support for the inclusion in the work of the EWG on unsupported compounds without public health concern	In 1991, a number of Codex guideline levels were derived. They were retained at step 4 of the step procedure, since JMPR could not conclude on the toxicological profile of the a.s. ("Not cleared toxicologically by JMPR"). It is also unclear, which residue definition was established. Although these MRL proposals have never been formally adopted as Codex MRLs, they were erroneously presented

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007D0355.

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			in the Codex MRL database (see CX/PR 19/51/5-Part 3, List of Pesticides for which guideline levels have been set). In CCPR 55 (2024), it was agreed to revise the "GLs" of methyl bromide to "MRLs retained at Step 4" and update the Codex database to reflect the change and add methyl bromide to the Priority List – Table 2A, awaiting the sponsor's data submission. Bromide ion is the main marker substance in crops treated with methyl bromide. For bromide ion, separate CXLs had been established in the past (compound number 47, Bromide ion). The last evaluation by JMPR of bromide residues in crops grown in methyl bromide treated soil and in commodities fumigated post-harvest with methyl bromide has been performed in 1992[4], but no new Codex MRL proposals were derived. However, bromide ion was identified as an unsupported substance, as there was no commitment by a sponsor to support the CXLs. In 2021, CCPR decided to remove bromide ion (47) from the CCPR Pesticide list of compounds. In CCPR 56 (2025), as no sponsor made a commitment to submit a dossier of methyl bromide, the a.s. was included in the ToR of the EWG on the Management of unsupported compounds without public health concerns.

[4] https://openknowledge.fao.org/server/api/core/bitstreams/d43fe29d-03bb-49a0-8f81-0a17533dc886/content

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			In the EU, methyl bromide is not approved as a plant protection product. Methyl bromide is a controlled ozone-depleting substance listed in Annex E of the Montreal Protocol[5], for which a phasing out plan was defined under Article 2H. Use of methyl bromide for quarantine and pre-shipment applications are not affected by this phase-out plan. From a food safety perspective, the parent compound methyl bromide is unsuitable as a residue marker due to its rapid decomposition, making enforcement of the parent compound impractical; instead, bromide ion is used as the relevant marker. At EU level, MRLs are set for the residue definition bromide ion; a review of these MRLs is currently ongoing. We do not support that methyl bromide is dealt with by the EWG of unsupported compounds without public health concerns because of the following reasons: • Lacking valid ADI/ARfD values, it was never demonstrated that the Codex MRL proposals retained at step 4 do not pose a public health concern. The absence of a public health concerns is a prerequisite for referring the compound to the EWG.

[5] https://ozone.unep.org/treaties/montreal-protocol/montreal-protocol-substances-deplete-ozone-layer

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			• Considering that CXLs for bromide ion is the marker substance for methyl bromide uses, and keeping in mind that bromide ion (47) was removed from the Codex database in 2021 as there was no support from a sponsor, it is our understanding that since 2021 it is clear that sponsors do not support uses of methyl bromide. To keep the CXL proposals for a longer period at step 4 is unlikely to lead to a different situation. In addition, we do not support retaining Codex MRL proposals in the Codex system in view of a future establishment of CXLs for a compound restricted by the Montreal Protocol due to its effects on the ozone layer. One of the purposes of setting CXLs is the removal of trade barriers which might promote the use of the substance. In the interest of the protection of the ozone layer, in accordance with the Montreal Protocol, the use should not be promoted but should be further restricted.
3	EU	disulfoton (074); the absence of a public health concern should be demonstrated	The last comprehensive toxicological review of disulfoton was performed by JMPR in 1996, where JMPR established confirmed the ADI of 0.0003 mg/kg bw/day, which was derived in1991. In addition, an ARfD of 0.003 mg/kg bw was set, which reflects the potent cholinesterase inhibiting profile of disulfoton. The last comprehensive review of the residue assessment was performed in 1991. In 1994 and 1998, new uses were assessed. However, since JMPR noted that chronic and acute exposure exceeds the ADI, some of the MRL proposals were retained in the step

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			procedure for some years, before they were withdrawn. In 2003, a number of new CXLs were endorsed. The residue definition derived by JMPR for MRL enforcement and for dietary assessment covers the sum of disulfoton, demeton-S and their sulfoxides and sulfones, expressed as disulfoton**,** acknowledging that oxidised/oxon species may represent a substantial fraction of residues. In the available documentation of JMPR, we could not retrieve a comprehensive dietary risk assessment (chronic and acute risk assessment) reflecting all the current CXLs. In the EU, disulfoton is no longer approved. Health based guidance values (ADI/ARfD) are not established. Conclusion: In order to decide whether the substance disulfoton meets the definition of unsupported substances without public health concern, we propose that JMPR verifies that for the existing CXLs a consumer health concern can be excluded. We were unable to retrieve this information from the published JMPR assessments.
4	EU	flumethrin (195) no information on authorized uses of flumethrin as plant protection product. To be discussed by the joint JECFA/JMPR expert group to decide whether CXLs are required	The last comprehensive assessment by JMPR was performed in 1996. For the substance, an ADI of 0.004 mg/kg bw was derived. In 1996, the assessment of ARfDs was not yet routinely established. In 1996, JMPR also assessed uses on ectoparasite control on cattle, sheep and goats and of the use of flumethrin in honey-bee colonies. CXLs for cattle milk (0.05 mg/kg) and cattle meat (fat) (0.2 mg/kg) have been established in 1999 by CAC, based on the JMPR evaluation of 1996. As honey was not included in the Codex food classification, it was not possible to establish a CXL for this

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			commodity, but JMPR noted that a MRL of 0.005 mg/kg (equal to the limit of quantification) would be appropriate in view of the veterinary uses of flumethrin. Plant protection uses on crops have not been reported/assessed. In 2017, JECFA assessed veterinary uses against varroa mites in honey bee colonies. Although no quantifiable residues were found in honey after treatment with flumethrin products, JECFA recommended to set an MRL for honey at twice the LOQ, i.e. 0.06 mg/kg.[6] In 2019, JECFA assessed flumethrin and confirmed the previously derived ADI of 0.004 mg/kg bw per day. In addition, an ARfD of 0.005 mg/kg was established. MRLs for veterinary uses were not derived. JECFA also evaluated the substance with a view to recommend MRLs for cattle edible tissues and milk. JECFA concluded that it would not be possible to recommend MRLs with the available data, as there was an incomplete determination of the metabolic profile in cattle. (insufficient data on the identity and the toxicological profile of the metabolites, unknown metabolite in milk etc.). JECFA therefore concluded that in order to recommend MRLs for flumethrin in cattle tissues and milk, the data gaps should be addressed.[7] In 2021, CCRVDF concluded that residues resulting from the use of this substance as an insecticide in accordance with good practices

[6] https://openknowledge.fao.org/server/api/core/bitstreams/82a0eaf2-375d-4f9b-8613-f4398123e004/content
[7] https://www.who.int/publications/i/item/9789241210324

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			for veterinary drug are unlikely to pose a hazard to human health and therefore the setting of an MRL was considered unnecessary[8]. In the EU, flumethrin is not covered by the pesticide legislation. The use of flumethrin for topical treatment of livestock falls under the veterinary legislation. In 1998, The European Medicines Agency assessed this active substance and derived MRLs for bovine muscle, fat, liver, kidney and milk.[9] MRLs were established in Regulation (EU) 37/2010 for bovine and ovine muscle, fat, liver kidney and milk (bovine only). Conclusion: From the available information it seems that uses of flumethrin as plant protection product are not authorised. The existing CXLs reported in the Codex pesticide database are therefore not necessary and the substance should therefore be deleted from the list of pesticides. If, however, there is evidence that the CXLs for cattle meat (fat) and cattle milk are still required due to the use of a plant protection product (which is unlikely, since no MRLs for treated crops are in place), it is necessary to perform a risk assessment, taking int account the ADI/ARfD derived by JECFA in 2019 to demonstrate that the existing CXLs do not pose a public health concern. We recommend to discus flumethrin by the joint JECFA/JMPR expert group to decide whether CXLs are required, taking into account the previous assessments of JECFA.

[8] https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/vetdrugs/veterinary-drug-detail/en/?d_id=116
[9] https://www.ema.europa.eu/en/documents/mrl-report/flumethrin-summary-report-1-committee-veterinary-medicinal-products_en.pdf

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
5	EU	ethoxyquin (035) No support for the inclusion in the work of the EWG on unsupported compounds	The only CXL established for ethoxyquin is the one on pears (3 mg/kg), which reflects a post-harvest use. It was established in 2009, based on a JMPR evaluation of 2008. The last comprehensive toxicological assessment by JMPR was performed in 2005; the previously established ADI of 0.004 mg/kg bw was confirmed. In addition, an ARfD of 0.5 mg/kg bw was derived. The ADI and the ARfD are applicable to parent ethoxyquin and to its metabolites MEQ (methylethoxyquin), DHMEQ (dehydromethyl-ethoxyquin) and DHEQ (dihydroethoxyquin). Toxicological data on the dimers, which were also identified as the major metabolites/degradation products in pears, were not assessed/available. In the 2008 evaluation, JMPR concluded on the residue definitions (parent ethoxyquin for MRL compliance and ethoxyquin plus degradation products MEQ, DHEQ and DHMEQ for dietary risk assessment), taking into account the toxicological assessment performed in 2005. In addition, JMPR recommended the CXL of 3 mg/kg which is still in place today. The lack of toxicological data on the C-N and N-N dimers was not discussed in the JMPR assessment. In the 2024 JMPR periodic review, a plant metabolism study in pears (post-harvest treatment) was assessed, where the metabolic pattern was determined on the day of the treatment and after storage at -0.2±2°C for up to 33 weeks. After 33 weeks of cold storage,

Comments from the European Union

Nº	Commenter[1]	Comment	Rationale[2]
			ethoxyquin dimers (1,8-EQDM, N-N-dimer, methyl C-N-dimer) accounted for the majority of the residues. In a second post-harvest metabolism study in apples and pears, in addition, parent ethoxyquin, ethoxyquin quinone imine (EQI) and dehydrodemethyl-ethoxyquin (DHMEQ) were identified as major constituents of the residue in post-harvest treated fruits. For MRL enforcement, JMPR proposed the parent compound. However, due to deficiencies in the metabolism studies, JMPR could not agree on a residue definition for risk assessment. Consequently, JMPR did not derive a recommendation for the use of ethoxyquin in pears and did not conduct a dietary risk assessment. We would like to highlight that in the JMPR toxicological assessments the information on the toxicological properties of some of the metabolites/degradation products is not available (e.g. 1,8-EQDM, N-N-dimer, methy C-N-dimer, EQI). In the EU, a decision on the non-approval of ethoxyquin was taken in 2011 (Commission Decision 2011/143/EU[10]), due to the lack of a complete toxicological data package and insufficient data to set a residue definition. It was concluded that key endpoints such as long-term toxicity and carcinogenicity, neurotoxicity, reproductive toxicity and developmental toxicity in rabbits were not addressed by original studies. In addition, EFSA confirmed the previous conclusion that the

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011D0143

Nº	Commenter[1]	Comment	Rationale[2]
			toxicity of ethoxyquin was not adequately addressed in 2013[11] and MRLs were lowered to LOQ. Ethoxyquin was authorised in the EU as a feed additive for all animal species and categories until 2017. Following an EFSA opinion published in 2015[12] the authorisation was suspended due to an overall lack of data and the presence of a possible mutagenic impurity (p-phenetidine). In addition, EFSA highlighted concerns on the metabolite ethoxyquin quinone imine as potentially genotoxic. Conclusion: In light of these unresolved issues, we are of the opinion that the substance ethoxyquin does not meet the definition of an unsupported compound without public health concern.

Part 2. ToR (iii)

Review of APPENDIX XII (REP23_PR54e) MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW (For internal use by CCPR).

Nº	Commenter[13]	Paragraph	Line	Comment[14]	Rationale[15]
1	EU	general		We appreciate the work undertaken by Chile, Australia, Ecuador and Kenya as	

Comments from the European Union

Nº	Commenter[13]	Paragraph	Line	Comment[14]	Rationale[15]
				Chair and co-Charis of the EWG on the management of unsupported compounds without public health concern scheduled for periodic review and support the overall approach. We would like to share some suggestions to further strengthen the procedure in order to improve transparency, consistency and efficiency of implementation. It should also be confirmed that, after the final call for support, unsupported CXLs should be withdrawn unless a concrete commitment to provide the necessary data has been identified.	
2	EU		9-10		The definition for unsupported compounds without public health concern should be

[11] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3231
[12] https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2015.4272
[13] EWG Member/Observer

[14] Add text/remove text comments are preferred. Suggested text should be bold and underlined, removed text should be strikethrough text.

[15] Provide a rationale for your comment(s).

Comments from the European Union

Nº	Commenter[13]	Paragraph	Line	Comment[14]	Rationale[15]
					reconsidered: currently, a substance is considered to be "without public health concerns" as long as no concern form has been lodged or JMPR has not indicated a public health concern. However, the procedure on the consultation of JMPR on a possible public health concern is unclear. It is therefore suggested that JMPR should be explicitly consulted at the beginning. of the discussion whether a compound would comply with the definition of compounds without public health concern (PHC), and be asked to share the latest dietary risk assessment reflecting the current CXLs to demonstrate the absence of a PHC. In the framework of the consultation on the 5 compounds for which the EWG invited for comments, it turned out that it is not always easy to retrieve the information on the dietary risk assessment from the published documentation, as in the past the information was not presented in the same

Comments from the European Union

Nº	Commenter[13]	Paragraph	Line	Comment[14]	Rationale[15]
					clear and transparent manner as it is the current JMPR practice, where such information is clearly presented in the JMPR reports. The level of details presented in previous JMPR reports/evaluations, in particular in reports dating back to the 1990ies, was low and does not meet the current requirements.
3			11-14		We recommend that the management approach be supplemented by a structured progress report for each unsupported compound and its relevant CXLs, indicating at least the following: (i) the date on which the compound was placed in Table 2B; (ii) whether support has been identified and, if so, whether such support covers all CXLs or only specific ones, iii) the data required for re-evaluation (iv) the applicable timeline for follow-up by CCPR
4			21	look to the compounds to see which are supported and which are unsupported ***with special attention to the cases***	We propose to highlight those cases in which the revocation of a CXL may affect another compound, residue definition or compliance situation should be identified

Comments from the European Union

Nº	Commenter[13]	Paragraph	Line	Comment[14]	Rationale[15]
				where the revocation of a CXL may affect another compound.	separately and considered on a case-by-case basis before revocation is endorsed (e.g methamidophos/acephate)
5			33-34		We support the early engagement of the JMPR Secretariat and suggests that, before a timeline is accepted, the data package required for re-evaluation should be identified as precisely as possible, including whether toxicological data, residue data and/or methods of analysis are needed
6			38-39		For transparency and consistency reasons, we suggest to clarify the criteria (e.g trade relevance, past uses, linked residue definitions, etc) used to determine whether advancing in the search for possible support is justified.
7			51-53	For substances where support for one or more CXL for an unsupported substance is announced and support can be realized as described before, ***all*** the remaining unsupported CXL will be ***identified before being*** revoked after renewal of the compound.	It may be clarified that, where support is identified only for specific CXLs, all remaining unsupported CXLs should be clearly identified at an early stage so that their revocation can proceed without unnecessary delay

Comments from the European Union