

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

CX/PR 21/52/5-Add.2

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

52nd Session

(Virtual)

26-30 July and 3 August 2021

PROPOSED MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOOD AND FEED

Comments at Step in reply to CL 2020/6-PR submitted by the United Kingdom

FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL OR REQUEST FOR CLARIFICATION OF CONCERNS

Submitted by: UK			
Date: 21 June 2021			
Pesticide/Pesticide Code Number	Food/Food Code Number	MRL (mg/kg)	Present Step
Chlorothalonil/ 081	Cranberry/ FB 0265	15	5
Is this a request for clarification? No			
Request for clarification (<i>Specific statement of clarification requested</i>) N/A			
Is this a concern? Yes			
Is this a continuing concern? No			
Concern (<i>Specific statement of reason for concern to the advancement of the proposed MRL</i>) The UK is concerned that the advancement of the proposed CXL for cranberries is not appropriate on the basis of the points set out below, and requests additional clarification and assurance on the scientific basis for the proposal: <ul style="list-style-type: none">• The chronic exposure estimated for the metabolite R613636 exceeded the threshold below which no adverse effects for human health are expected• The overall chronic exposure to the metabolite R613636 from all commodities has not been addressed• The acute exposure to the metabolite R613636 has not been addressed The metabolite R613636 was found to be a major degradation product on hydrolysis of chlorothalonil and therefore has the potential to be found in processed cranberries. In particular the residue levels in cranberry juice and sauce, rather than the fresh cranberries, is of a concern. The chronic exposure to this metabolite has been estimated on the basis of the hydrolysis study. The OECD test guideline 507 outlines the purposes of the hydrolysis study, which includes information on the nature of the residue in processed foods. The study is not designed to be used to estimate the magnitude of residue levels in processed foods. The levels of the metabolite R613636 in processed cranberries should be based on magnitude studies (i.e. OECD test guideline 508). The FAO manual is also clear that the purpose of the hydrolysis study is to determine whether or not breakdown or reaction products of residues in the raw commodities are formed during processing which may require a separate risk assessment. Processing factors derived under realistic conditions are required for MRL setting and/or refinement of the consumer exposure assessment.			

The UK would accept that using the hydrolysis study to provide an estimate of the exposure level would be an acceptable approach under specific circumstances. For example if the exposures estimated were significantly below the toxicological reference values or the generic threshold.

However, in this specific case the exposures were above the generic threshold and therefore data generated on the residue levels in processed cranberries (or suitable surrogates) would ensure more accurate exposures for the metabolite can be determined. This would provide the evidence to support the JMPR statement that there are unlikely to be public health concerns, even though the exposure exceeds the threshold, as it seems very unlikely that the daily diet contains a high percentage (> 50 %) of cranberries subject to high temperature treatment.

Specific toxicological reference values could not be established for this metabolite owing to the lack of toxicological data. The acceptability of the chronic exposure has therefore been assessed using the TTC (threshold of toxicological concern). The chronic exposure estimated by the JMPR exceeded the generic threshold of 1.5 µg/kg bw/day (for compounds categorised in Cramer class III).

In the Codex Alimentarius Commission procedural manual (27th edition) if either the IESTIs exceed the ARfD or the IEDIs exceed the ADI the JMPR should indicate additional data are necessary to refine the calculations. The same approach should be taken when the acceptability of the exposures have been determined on the basis of a generic threshold as analyte specific toxicological reference values cannot be established.

The UK fully supports the use of the TTC to determine the acceptability of the exposure to this metabolite. The TTC provides a conservative exposure threshold in the absence of sufficient chemical specific toxicological data. However, a fundamental principle of using the TTC is that where exposures are below the threshold further data are not required and where the exposures exceed the threshold then it must be a priority to provide further data. Setting additional thresholds above the established threshold is not appropriate for MRL setting and could undermine confidence in the Codex MRLs. In this specific case, as the exposure for the metabolite has only been estimated using the hydrolysis study, with no actual crop treated, there are additional uncertainties. In addition, Codex MRLs are currently established for a wide range of crops which can be processed. The new data assessed by the JMPR, including toxicological data, has led to the consideration of R613636 in the dietary exposure assessment. Therefore, the residue levels of this metabolite for all relevant commodities should be presented and hence the chronic exposure to all sources of this metabolite should be estimated. Based on the information provided the total chronic exposure for metabolite R613636 is not known.

The JMPR has not undertaken an acute exposure for metabolite R613636. Based on the information in the FAO manual it is not clear why an acute exposure assessment has not been presented. The FAO manual refers to the example of the TTC assessment for pymetrozine (JMPR, 2014). For pymetrozine it is implied that both chronic and acute exposures were undertaken for some metabolites.

Based on the highest IESTIs estimated by the JMPR for chlorothalonil/cranberries and using the formation fraction of 23 %, the acute exposure estimated for metabolite R613636 would be 13.03 µg/kg bw/day. This dietary exposure is for children (AU, Child, 2-16 yrs) and is 8.7 times higher than the threshold of 1.5 µg/kg bw/day or 2.7 times higher than the threshold of 5 µg/kg bw/day (threshold proposed for the acute exposure for substances categorised in Cramer Class III).

The proposed CXL for cranberries should not be advanced as the exposures estimated are based on a hydrolysis study and clearly exceed the thresholds. Additional information/data should be provided to refine the exposure assessments to show that the exposures are below the thresholds and hence there are no public health concerns.

Do you wish this concern to be noted in the CCPR Report?

Yes

Data/Information (Description of each separate piece of data/information which will be provided to the appropriate JMPR secretary within one month of the CCPR meeting)

N/A