

Annex A

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

<i>Submitted by: The European Union</i>			
<i>Date: March 2021</i>			
<i>Pesticide / Pesticide Code Number:</i>	<i>Food(s) / Food Code Number(s)</i>	<i>MRL (mg/kg)</i>	<i>Present Step</i>
<i>Benomyl (69) Carbendazim (72) Thiophanate-methyl (77)</i>	<i>All commodities</i>	<i>All MRLs</i>	<i>CXL</i>
<b><i>Is this a request for clarification?</i></b>			
yes			
<b><i>Request for clarification</i></b> (Specific statement of clarification requested)			
<p>Benomyl was initially evaluated by JMPR before 1995 and reviewed a few times for toxicology and residues (last review in 1998 for residues; in 1995 for toxicology).</p> <p>Carbendazim was initially evaluated by JMPR before 1973 and reviewed several times for toxicology and residues (last review in 2005). A toxicological periodic review took place in 1995; in 2005 only an Assessment concerning an ARfD was done.</p> <p>Thiophanate-methyl was initially evaluated by JMPR in 1973 and reviewed several times for toxicology and residues (last periodic review in 1998 for residues; in 2017 for toxicology). The JMPR in 2017 noted that it did not receive any information on the toxicology of carbendazim. The meeting was unable to complete its evaluation for residues.</p> <p>In 2003 it was decided to combine the residue definitions for benomyl, carbendazim and thiophanate-methyl to "Sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim". At that time, Germany noted "that benomyl is no longer supported in the EU and the USA, but was also advised that benomyl still had uses in Australia. The delegation of Germany also pointed out that the majority of MRLs came from the use of benomyl and that in its opinion all the MRLs should be reconsidered." (ALINORM 03/24A).</p> <p>At the same time benomyl and thiophanate-methyl were transferred to table 1 "LIST OF PESTICIDES WHOSE MRLS(CXLS) OR GLS HAVE BEEN DELETED BY THE CODEX ALIMENTARIUS COMMISSION AND FOR WHICH NO MRLS HAVE BEEN PROPOSED" with the note "see Carbendazim" within the document on DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS IN FOODS AND FEEDS AT STEPS 7 AND 4. This is misleading due to the heading of the table but correct since CXLS were not deleted yet. As a result, both substances are no longer part of table 3 in the priority lists!</p> <p>The EU is seeking advice on the following questions:</p> <ul style="list-style-type: none"> <li>• In case the entries in Table 1 of DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS IN FOODS AND FEEDS AT STEPS 7 AND 4 are correct why do we have qualifiers for benomyl and</li> </ul>			

<p>thiophanate-methyl in the list of CXLs for Carbendazim?</p> <ul style="list-style-type: none"> <li>In case the entries in Table 1 of DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS IN FOODS AND FEEDS AT STEPS 7 AND 4 are not correct how is it possible to perform a periodic re-evaluation for toxicology and residues for benomyl as the substance is no longer part in the priority lists? How was it possible to perform a periodic re-evaluation for toxicology for thiophanate-methyl in 2017 as the substance is no longer part in the priority lists?</li> </ul>
<p><b><i>Is this a concern?</i></b></p> <p>yes</p>
<p><b><i>Is this a continuing concern?</i></b></p> <p>No</p>
<p><b><i>Concern</i></b> (Specific statement of reason for concern to the advancement of the proposed MRL)</p> <p>As stated above in 2003 it was mentioned that benomyl is no longer approved in the EU and USA. EU takes note on the fact that the toxicological evaluation for thiophanate-methyl could not be finalized due to a missing actual evaluation of the toxicology of carbendazim.</p> <p>EU acknowledges that carbendazim is scheduled for periodic review in 2022. This substance is no longer approved in the EU since 2014. It is also noted that up to now no information was made available how the results of the toxicological re-evaluation of carbendazim will fit into the toxicological review of thiophanate-methyl and benomyl.</p> <p>The re-evaluation process for thiophanate-methyl in the EU was terminated in 2020, following the withdrawal of the application for renewal of approval by the applicant. The substance is thus no longer approved in the EU.</p> <p>A re-evaluation of the toxicological properties and MRLs for carbendazim and thiophanate-methyl in the EU is ongoing, taking into account information available under different legal frameworks and for both substances. The opinion of the European Food Safety Authority is expected to be published in the third quarter of 2021.</p>
<p><b><i>Do you wish this concern to be noted in the CCPR Report?</i></b></p> <p>Yes</p>
<p><b><i>Data/Information</i></b> (Description of each separate piece of data/information which will be provided to the appropriate JMPR secretary within one month of the CCPR meeting)</p>