

## ANNEX B

FORM FOR EXPRESSING CONCERNS WITH PUBLIC HEALTH ON A  
PESTICIDE FOR PRIORITISATION OF PERIODIC REVIEW

<b>Submitted by: <i>The European Union</i></b>		
<b>Date: <i>29 June 2016</i></b>		
<b><i>Pesticide/Pesticide Code Number</i></b>	<b><i>Food/Food Code Number</i></b>	<b><i>CXL (mg/kg)</i></b>
<b>130 Diflubenzuron</b>	<b>All commodities</b>	<b>All CXLs</b>
<b><i>Is this a concern? Yes</i></b>		
<b><i>Is this a continuing concern? No</i></b>		
<b><i>The concern relates to which prioritisation criterion/criteria (Specific statement of concern)</i></b>		
<p>The active substance was last evaluated for toxicology in 2001 by JMPR resulting in an ADI of 0-0.02 mg/kg bw and an ARfD being not necessary. The active substance was last evaluated for residues in 2002 by JMPR resulting in a residue definition (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: diflubenzuron.</p> <p>The substance was evaluated in 2015 for toxicology by JECFA. In the absence of adequate information on exposure to 4-chloroaniline (PCA) JECFA was unable to propose an ADI for diflubenzuron because it was not possible to assure itself that there would be an adequate margin of safety from its use as a veterinary drug. The Committee also noted that it was not possible to calculate a margin of exposure for PCA in the absence of adequate information on exposure to PCA.</p> <p>It is expected that the same problems with ADI setting will occur when re-evaluating the substance for its pesticide use. In addition, a re-evaluation of diflubenzuron is necessary to evaluate the exposure of a genotoxic and carcinogenic metabolite 4-chloroaniline (PCA) after use of diflubenzuron.</p>		
<b><i>Is supporting data being provided?</i></b>		
<b><i>Data/Information (Description of each separate piece of data/information which is attached or will be provided to the EWG Priorities and the appropriate JMPR Secretary within one month of the CCPR meeting)</i></b>		
Toxicological evaluation of certain veterinary drug residues in food. WHO Food Additives Series, No.		

## Section IV: Risk Analysis

72, 2016. Toxicological Monographs of the 81st meeting.

EFSA Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance diflubenzuron. EFSA Journal 2012;10(9):2870 [26 pp.].  
<http://www.efsa.europa.eu/en/efsajournal/pub/2870>

EFSA Peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA. EFSA Journal 2015;13(12):4222 [30 pp.].  
<http://www.efsa.europa.eu/en/efsajournal/pub/4222>

***Is this a continuing concern? No***

***Outline ongoing concern and provide supporting data***