CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4(a) **CX/PR 16/48/3**
April 2016

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

48th Session
Chongqing, P.R. China, 25 - 30 April 2016

MATTERS OF INTEREST ARISING FROM FAO AND WHO IN ADDITION TO 2015 JMPR ACTIVITIES

(Prepared by FAO and WHO)

Feedback from the 81st JECFA

1. The 81st meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Rome, Italy, from 17 to 26 November 2015. The purpose of the meeting was to evaluate residues of certain veterinary drugs in food. The Committee raised conclusions of interest for JMPR and CCPR:

2. Coordination of the agendas of JECFA and JMPR. JMPR evaluates residues of pesticides in food, whereas JECFA (veterinary drug residues) evaluates residues of veterinary drugs in food. In general, although there are many assessment principles in common – and these are being harmonized to the extent possible – the groups tend to operate largely independently. There are some substances that are used both as pesticides and as veterinary drugs – for example, teflubenzuron at the present meeting. Because of differences in their residue profiles and exposures when used, respectively, as a pesticide and a veterinary drug, both JMPR and JECFA will be asked to assess such compounds for both their toxicology and their residues. In general, different experts are involved in the assessment of the compounds by JECFA and JMPR, and hence it is quite possible that there will be some differences in the interpretation of data and the conclusions reached. It is also possible that there are different sponsors for the substance when used as a pesticide and when used as a veterinary drug, which could lead to differences in the data made available to the respective experts. Indeed, this might even happen when the sponsor is the same, but different departments are responsible for pesticide and veterinary use. In the event that this leads to different outcomes or recommendations – for example, the ADI established – this would lead to confusion among those relying on such assessments. As such, JECFA 81st recommended that where dual use substances are to be evaluated by both JMPR and JECFA, CCPR and CCRVDF coordinate the prioritization of such substances for evaluation by the respective experts.

- Approach for dietary exposure assessment of compounds used for multiple purposes (i.e. veterinary drugs and pesticides). As a consequence of its consideration of two veterinary drugs (teflubenzuron and diflubenzuron) at the present meeting, the Committee identified the issue of how to estimate chronic dietary exposure to residues of substances used as both veterinary drugs and pesticides. The Committee noted that it has been common practice to assess the chronic exposure of pesticide and veterinary drug residues using different approaches that have been developed after consideration of the types of substances of interest, duration of exposure, exposure in different subgroups and the type of estimate needed, based on the information available. However, the Committee expressed the view that it may be necessary to estimate the total chronic exposure from both sources. In response to that, FAO and WHO established a working group on this topic.
- Diflubenzuron (insecticide last evaluated by JMPR in 2001). In the absence of adequate information on exposure to 4-chloroaniline (PCA), a genotoxic and carcinogenic metabolite and/or degradate of diflubenzuron, the Committee was unable to establish 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.
- Teflubenzuron (insecticide last evaluated by JMPR in 1994, ADI 0-0.01 mg/kg bw). The Committee established an ADI of 0–0.005 mg/kg bw on the basis of a lower 95% confidence limit on the benchmark dose for a 10% response (BMDL10) of 0.54 mg/kg body weight per day for hepatocellular hypertrophy in male mice observed in a carcinogenicity study, with application of an uncertainty factor of 100 to account for interspecies and intraspecies variability.