CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5a **CRD15**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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

Comments on Revision of the IESTI Equation, submitted by Croplife

Agenda item 5a (General Considerations): Revision of the IESTI Equation

CropLife International has reviewed the conclusions and proposals of the 2015 scientific workshop of revision of the IESTI equations organized by EFSA and RIVM (co-sponsored by FAO and WHO),as summarized in the General Considerations section 2.1 of the 2015 JMPR report.We are concerned that these proposals if implemented will have a significant impact on MRL setting in Codex.

As pointed out in the General Considerations, the workshop proposals recommend to replace STMR and HR by MRL, use a variability factor of 3 and include conversion factors to account for differences between the Definition ofResidue (DoR) for risk assessment and monitoring. In addition, it is proposed to remove the unit weight from the equation, which would assume that the full food portion consumed always contains residue levels at the MRL level.

For about 70% of all substances reviewed in the last 15 years by the JMPR, ARfDs have been set. Therefore, it can be expected that the risk assessment for the large majority of new and periodically reviewed substances will become much more conservative.

These potential changes lead to 3 observations:

> Especially for medium sized commodities in ‘case 2a’we expect that a significant number of MRLs could be lost or would need to be revised if the workshop proposals are adopted.
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> For all commodities the assessment becomes more conservative. And, for blended commodities, the estimated exposure can become 5 to 20 times higher.
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> The proposed changes lead to much higher theoretical consumer intakeswhich in themselves will present considerable challenge for risk communication with consumers and food chain members, possibly leading to more and stricter secondary standards.

In the food monitoring programs of many countries MRL/Tolerance exceedance is low, typically 1% as reported.These programs show that a significant percentage of samples contain no quantifiable or residue levels below the MRL. Using the MRL instead of the HR or STMRoverestimates dietary exposure, especially when used in combination with the other changes proposed for these equations.

In the official risk communication of many developed countries there is no indication of a need for a higher consumer protection level. Therefore, we do not see an urgent need for an immediate revision.CropLife International supports JMPR’s view that if the IESTI equations are to be revised then all parameters of the equations must be carefully investigated.

In case the CCPR supports the review of the IESTI equations we suggest to use a 3 step approach:

- First, establish aneWG on behalf CCPRto define clear protection goalsfor short term dietary exposure assessment for discussion and agreement by the CCPR. Without internationally agreed objectives for consumer protection it is impossible to state whether currently used or future IESTI approaches are sufficient or unrealistically overly protective.This proposal is similar to recommendation 2 of CRD 03 (prepared by the EU and Australia). We believe that protection goals must be defined and agreed by the CCPR as the first step to enabling risk assessors to develop the

adequate methodology. In addition, risk communication messages need to be developed to explain protection goals to the general public.

- Second, perform a scientific/statistical review of all parameters of the IESTI equations to analyse their cumulative effect on the requested level of consumer protection and MRL setting. Criteria for good quality consumption data and guidance on theiruse by risk assessors and risk managers need to be developed, as well as advice to risk managers on the feasibility of including new parameters requiring international harmonization into the equations.

- Third, the CCPR, as with any proposed change to be adopted,needs to considerconsumer protection needs, potential losses of MRLs, impact on local growers, international tradeimplications for agricultural commodities and risk communication needs.

CropLife in a side-event will provide a more detailed analysis of the proposed revisions of the IESTI equations.