CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4a **CRD19**

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ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

51st Session
Macao SAR, P.R. China, 8-13 April 2019

European Union Comments

Matters of Interest arising from FAO and WHO in addition to the 2018 JMPR activities

Acute probabilistic dietary exposure assessment for pesticides
CX/PR 19/51/3-Add.2

Mixed competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the World Health Organisation for the preparation of this document which is a valuable contribution to the discussion on the IESTI equation (see also discussion under Agenda Item 9). The EUMS believe that further clarifications and more detail on the methodology used are essential to fully understand the results and to make use of them. These comments are therefore considered preliminary on the basis of our current understanding of the results. Further to our comments the EUMS would also like to share some recent assessment performed by Germany which is shown in comparison of the results obtained in the WHO assessment.

Annex 1- Methodology:

Comment on the chapter "Hypothesis related to variation in residues"

This section would need to be better explained to make fully transparent which methods/approaches were applied and how exactly this was done. This is important as especially for the high percentiles, the combination of high mean residues of composite samples and unit-to-unit variability may become a significant driver of the exposure.

In particular, it is not clear how the “between sample variability” (= variability between individual units of one composite sample) was dealt with. Sample variability was not included, which seems an underestimation of potential acute exposure scenarios. Two points were made to justify this decision:

1) “*The sample variability is generally accounted for by using a probabilistic approach that selected a concentration level at random from the reported distribution of residue level measurements for that commodity*.”

   It should be better explained how this argument can solve the sample variability issue. A probabilistic (Monte-Carlo?) selection of means from a measured data population remains limited to the boundaries of the values. The idea of taking into account the sample variability by using the variability factor (or a distribution of variability factors) is to extrapolate the data to likely concentrations in single units beyond the mean concentrations measured.

2) “*For US data, these results were compared to the ones based on a selection of US concentration levels in a Lognormal distribution of mean the measured residue level and of variance parametrized such as the P97.5th value equals to 3 times the mean*.”

   We would like to better understand the methodology used and what the expression “*these results*” refers to. Also, the described procedure of using US concentrations with a LogNormal distribution (intended to match the basis of a variability factor of P97.5÷Mean=3) only describes the distribution of mean values from composite samples - not of individual units.

Annex 3 – Tables 3-12 and chapter 3 of main text "Results":

Comment on the selected upper percentile for reporting (P99)

At international level, no quantitative consumer protection goals have been established yet, thus a selection was made by the authors. It should be noted that at least in the USA (U.S. EPA Office of Pesticide Programs 2000[1]) the P99.9 was decided as regulatory threshold. This is also the currently proposed threshold in the EU for probabilistic cumulative risk assessment. For this reason it might be worthwhile to additionally report the P99.9 results in the report to enable countries using other percentiles to compare.

In light of the practices used in some member countries, the EU MS see a need to first agree and decide on the percentile that would be sufficiently conservative for a probabilistic assessment.

Annex 3- Tables 3-12:

Request for clarification on the expression "% of consumers" used in the headings of the tables:

The EU MS would like to seek clarification whether the notion of "% consumers" refers to person days or real consumers. Since most of the surveys reported more than one day for each individual, this may become important to judge on the true Level of Protection. As an example, if one individual was exposed on only one of the two reported days, would the resulting "% of consumers" be equal to 100 % or to 50 %?

Annex 3 - Table 1:

Methodology for selection of monitoring data

In table 1 the summary description of national residue surveys in food is presented. It should be clarified whether for all the countries that provided data only those monitoring data were selected where the national MRL is equal to the CXL. If monitoring results for food products with higher or lower national MRLs and results for food commodities for which no CXLs are established were not taken into account in the calculation, this should also be clearly stated. This is important since not all CXLs are taken over in EU legislation and EU MRLs may be in place for which there are no CXLs. Thus, restricting the exposure calculation to the food commodities with matching CXLs does not give a comprehensive picture of the overall exposure.

Annex 3 - Table 1 and 2:

Methodology for selection of consumption data

In table 2 the summary of the consumption data used for the probabilistic exposure calculation is reported. According to the last column the number of food items taken into account ranged form 11 (Italy) to 119 (Canada). Also in table 1 the number of foods is reported, which ranged from 20 (Australia) to 150 (EU countries). The EU seeks clarification whether this means that for calculating e.g. the exposure of Italian consumers, among the 150 food products for which monitoring data were reported from the EU, the results for the 11 food products for which consumption data were available, were taken into account. It would be important to understand which commodities were used for the different diets to get an understanding whether the results cover the most important food items in the diet and therefore are sufficiently representative for the actual exposure. Reading Table 13, where the most important contributors to the total exposure are listed, the Italian results for example repot cattle milk, sunflower seed, lentils (dry), walnuts. From our experience, these commodities are usually not the main contributors in the exposure. Similar comment is true for the other European countries (Netherlands, France, and Czech Republic). Thus, in order to derive a conclusion on the actual exposure situation, it is important that the main food products in the diet and the related residues are included in the exposure calculation.

Comparison of results of WHO Acute Probabilistic Dietary Exposure Assessment for Pesticides and of the Probabilistic dietary Risk assessment for the German population (Sieke et al. 2017[2])

The EUMS have specific data available from Germany that are displayed in the table below as an example. In the table, the range of results from the WHO assessment was compared to the P99 and the P99.9 estimated for the same compounds for the German population. It is noted that for several compounds the ARfD was established at different levels which needs to be considered.

[1] U.S. Environmental Protection Agency (EPA) - Office of Pesticide Programs (2000). Choosing a percentile of acute dietary exposure as a threshold of regulatory concern. Washington, D.C. (USA), EPA

[2] Sieke, C., et al. (2017). "Probabilistic dietary risk assessment of pesticide residues in foods for the German population based on food monitoring data from 2009 to 2014." Journal Of Exposure Science And Environmental Epidemiology 28: 46

Overall the results are within a comparable range for most compounds (taking into account different ARfDs). Deviations are likely to occur since a different model, different consumption data, different recipe data for RAC conversion and different monitoring data were used. In view of the complexity of the approach and the strong differences in the underlying data, the correlation is surprisingly good.

Major deviations were observed for carbofuran, which has a much lower ARfD in the EU and required the inclusion of relevant metabolites in the assessment carried out by Germany. Since the exposure in the selected scenario is mainly driven by the LOQ, the sum of all LOQs used in the assessment carried out by Germany provides an unrealistically high estimate of exposure and it was concluded to use a higher tier assessment for this compound. For phorate, the same ARfD was used both by WHO and Germany, but again the German assessment considered potential metabolites at LOQ level resulting in an overestimation in the scenario used.

Comparison table between the WHO probabilistic assessment and a probabilistic assessment carried out by Germany based on monitoring data from 2009-2014 (Sieke et al. 2017)

Compound	**Range of P99s in FAO Assessment 100% use (expressed in % ARfD)**	**P99 Sieke et al. Scenario LOQ × 1 (expressed in % ARfD)**	**P99.9 Sieke et al. Scenario LOQ × 1 (expressed in % ARfD)**
Buprofezin	0.03 – 0.22	0.3 %	0.9 %
Carbofuran	1.1 - 37	944 % (EU ARfD ~7x lower)	1850 % (EU ARfD ~7x lower)
Chlorpyrifos-methyl	0.07 – 0.88	0.8 %	1.5 %
Chlothianidin	0.02 – 0.28	1.7 % (EU ARfD 6x lower)	2.5 % (EU ARfD 6x lower)
Cyfluthrin/beta-Cyfluthrin	0.19 - 40	15 % (EU ARfD 2x lower)	29 % (EU ARfD 2x lower)
Cypermethrins	0.25 – 42.5	2.0 % (EU ARfD 5x higher)	3.9 % (EU ARfD 5x higher)
Cyproconazole	0.13 – 0.88	7.9 % (EU ARfD 3x lower)	16 % (EU ARfD 3x lower)
Cyromanzine	0.01 - 2	1.4 %	2.7 %
Dichlorvos	0.02 – 1.8	152 % (EU ARfD 50x lower)	256 % (EU ARfD 50x lower)
Difenoconazole	0.03 – 0.43	0.7 % (EU ARfD ~2x lower)	1.6 % (EU ARfD ~2x lower)
Dimethomorph	0.01 – 0.14	0.3 %	0.5 %
Diquat	0 – 0.1	- (EU ARfD n.n.)	- (EU ARfD n.n.)
Dithianon	0.08 – 2.5	2.0 % (EU ARfD 1.2x higher)	3.9 % (EU ARfD 1.2x higher)
Emamectin-benzoate	0.42 – 4.55	6.0 % (EU ARfD 2x lower)	8.2 % (EU ARfD 2x lower)
Etofenprox	0.01 – 0.21	0.2 %	0.2 %
Fenbuconazole	0.03 – 0.35	0.7 % (EU ARfD 1.5x higher)	1.6 % (EU ARfD 1.5x higher)
Fenpropathrin	0.25 – 20.33	4.0 %	6.3 %
Fenpyroximate	0.65 – 2.8	3.4 %	7.3 %
Fluopyram	0 – 0.11	0.1 %	0.3 %
Flutriafol	0.18 – 1.8	3.8 %	8.6 %
Fluxapyroxad	0.02 – 0.29	0.2 % (EU ARfD 16% lower)	0.4 % (EU ARfD 16% lower)
Imidacloprid	0.02 – 0.73	2.4 % (EU ARfD 5x lower)	4.2 % (EU ARfD 5x lower)
Indoxacarb	0.18 – 1.7	1.5 % (EU ARfD 1.25x higher)	2.3 % (EU ARfD 1.25x higher)
Malathion	0.01 – 0.05	0.5 % (EU ARfD 3x lower)	1.0% (EU ARfD 3x lower)
Methoxyfenozide	0.01 – 0.1	0.4 % (EU ARfD 4.5x lower)	0.9 % (EU ARfD 4.5x lower)
Phorate	2,6 - 27	62 %	145 %
Phosmet	0.05 – 1.4	7.1 % (EU ARfD ~4x lower)	12 % (EU ARfD ~4x lower)

Compound	Range of P99s in FAO Assessment 100% use (expressed in % ARfD)	P99 Sieke et al. Scenario LOQ × 1 (expressed in % ARfD)	P99.9 Sieke et al. Scenario LOQ × 1 (expressed in % ARfD)
Profenofos	0.01 – 0.19	< 0.1 %	0.2 %
Prothioconazole	0.89 - 34	13 %	26 %
Pyraclostrobin	0.17 - 5	4.7 % (EU ARfD ~2x lower)	12 % (EU ARfD ~2x lower)
Sedaxane	0.01 – 0.02	Not considered	Not considered
Sulfloxaflor	0.02 – 0.25	Not considered	Not considered
Tebuconazole	0.02 – 0.63	6.1 % (EU ARfD 10x lower)	12 % (EU ARfD 10x lower)
Thiamethoxam	0.01 – 0.33	0.4 % (EU ARfD 2x lower)	0.6 % (EU ARfD 2x lower)
Triadimenol	0.03 – 1.38	5.3 % (EU ARfD ~2x lower)	14 % (EU ARfD ~2x lower)
Triflumizole	0.03 – 0.18	7.9 % (EU ARfD 3x lower)	1.5 % (EU ARfD 3x lower)