

APPENDIX XII

TECHNICAL / RISK ASSESSMENT CHALLENGES THAT EITHER ARISE FROM THE POSSIBLE REVISION OF THE CURRENT IESTI EQUATIONS, OR ARE CURRENT CHALLENGES AS WELL. TO BE FORWARDED TO THE FAO/WHO WORKING GROUP¹

1	Developing further guidance on the derivation of conversion factors, and developing a database with conversion factors
2	Developing a database with processing factors,
3	A database with P97.5 large portion value derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight is needed. Internationally agreed criteria must be developed for dietary surveys, used for the assessment of consumer exposure. It is noted that this is ongoing work by WHO/ GEMS Food.
4	Information on bulking and blending practices needs to be gathered in order to decide on cases where a median residue instead of the MRL could be used in the dietary risk assessment, or a homogenization factor could be added (see item 13).
5	Clarify the influence of the number of supervised field trials used for the OECD MRL Calculator, where small data sets result in high MRL estimates. It is noted that this especially affects minor crops with low data requirements.
6	The suitability of common moiety residue definitions needs to be reconsidered when multiple active substances are included (e.g. CS ₂ for all dithiocarbamates) and one of those is potentially exceeding the ARfD.
7	The acute exposure assessment using the proposed IESTI will merely depend on the LP _{bw} values. Especially LP of children are crucial in risk assessment. The food consumption data are very heterogeneous and based on dietary survey studies of different design, quality and origin. An important reason for heterogeneity is also the preference of certain foods by the population. The more popular a particular food, the more data are available and the more reliable and robust are the P97.5 values. A pragmatic approach has to be established which addresses this issues; e.g. setting the same consumption value for a group of commodities (extrapolation rules).
8	Further guidance/decision making needed on the use of the variability factors relative to the MRL. The current use of the variability factor is not considered to be mathematically appropriate for use with an MRL by many members of the eWG. Using the MRL with current variability factors is considered to be overly conservative and leading to loss of MRLs and disruption of global trade. Since MRLs are now determined consistently by algorithms in the OECD MRL calculator simulation modeling to determine how single item residues might relate to the MRL could be useful. Others consider that the variability factor describes the inhomogeneity of residues on individual units from an unknown lot in relation to a composite sample collected according to Codex sampling procedures. The Codex sampling procedure is also the basis for MRL compliance testing – therefore the relative inhomogeneity (variability) in lots at or above the MRL is identical to lots with lower residues measured in a composite sample. The variability factor to be used remains unaffected. Also, the OECD MRL procedure only considered results from composite field trial samples and includes no extrapolation to individual units as it is described by the new IESTI case 2.
9	To quantify uncertainties related to the use of the IESTI equations as far as possible, and to qualitatively describe the uncertainties that cannot be quantified.
10	To estimate the impact of removing the unit weight from the equation and especially for case 1 and case 2 which distinction currently relies on the unit weight.

¹ REP18/PR, PARA. XXX

11	Reaching consensus regarding the approach to be used to evaluate the level of conservatism of proposed updated IESTI equations and how it compares to both the present set of IESTI equations and state-of-the-science probabilistic methods.
12	<p>Current consumption data on processed commodities in some territories of the world are not available.</p> <p>Many crops which are consumed in large amounts in the processed form (e.g. apples or citrus consumed as juice) will be disproportionately considered when estimating the acute exposure on the basis of consumption data of non-processed commodities only, hampering a meaningful estimate of the acute exposure. Therefore consumption data of processed commodities and recipe data need to be collected from a representative range of countries..</p>
13	For blended foods (e.g. fruit juice, seed/nut oil, flour, corn meal), it is suggested to add a homogenization factor (<1) to the equation to reflect the decreased variability in pesticide residues resulting from processing.
14	The comparison of the deterministic IESTI with probabilistic models is challenging. First the database itself needs to be identical. Second, the results will differ commodity by commodity – how are general conclusions drawn for the equation itself? Third, the probabilistic methodology requires careful preparation and agreement. Especially for the consumption data the aggregation of commodities should be the same for both approaches (e.g. LP for apples, raw vs. apples raw in probabilistic; not LP for total apples expressed as raw vs. all individual foods containing apple).