

**Codex Task Force on Antimicrobial Resistance**  
**Draft Antimicrobial Resistance Risk Assessment Guidance Document**  
**Points for further discussion/consideration**

1. Formatting and structure of the document: Are there gaps in the document?
2. What are the views of the WG on whether the definitions used in this draft are sufficient and appropriate? Are any terms missing?
3. Qualitative versus Quantitative Risk Assessment: What are the views of the WG as to the emphasis that should be given to Qualitative versus Quantitative Risk Assessment within this document?
4. Are the figures provided in the document useful and do they add clarity? Suggestions for improvement are welcome.
5. How should the antimicrobial categorization lists of importance in human medicine (FAO/OIE/WHO, 2008) be incorporated into this document, particularly in relationship to the hazard characterization on the severity of the adverse health effect consequence? Suggestions would be also welcome on how to capture the fact that there will be differences in the WHO categorization scheme vs. various national/regional categorizations.
6. Suggestions would be appreciated on how to capture and emphasize the impact of the cumulative effects of resistance in the document.
7. Suggestions would be welcome on the need to specify the areas where uncertainty estimates would be necessary or should be included?
8. Suggestions would be welcome in improving the decision power of each step of the AMR-RA as described in the guidance document.
9. Under the Exposure Assessment are the pre-harvest/post-harvest data tables (Section 6.2, tables 2 and 3) useful for this document? Are the terms “pre-harvest” and “post-harvest” appropriate as used in this document?
10. Is Appendix 1 (Qualitative Ranking of the Outputs of AMR-RA) useful?
11. Is the outline of information for AMR-RA provided in Appendix 2 necessary/useful?
12. The main objective of this document is to provide guidance on how to estimate the risk to the general population from the non-human use of antimicrobials. However, it could be adapted to conduct a pre- or post-market human safety assessment of an antimicrobial drug product intended for non-human use, or to conduct a risk assessment to estimate the risk from imported food products. Does this document provide clarity with respect to its intended applications in different scenarios and should these scenarios be listed?