JMPR - Procedures behind the establishment of MRLs

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JMPR Composition / Topics

Joint FAO / WHO Meeting on Pesticide Residues

FAO	WHO
20 Experts, 13 countries (recent e.g.)	21 Experts, 11 countries
Field trials (GAP), residue levels, metabolites	Toxicology data, parent + metabolites

MRLs,

Residue definition

ADI, ARfD

Exposure / intake estimates. Risk assessment – does the MRL present a safety concern.

No Hazard based risk management aspects

Information provision

- Compounds CCPR Priority list
 - New compounds / Periodic reviews / additional uses
- Data on residues and toxicology
 - Confidential study reports from sponsors
 - Published literature
 - Better database = more reliable assessment
- No formal (tick-box) data requirements
 - Minimum standards for quality and quantity.
 - Sufficient detail to permit an independent assessment to agreed scientific standards.
- Intake data from WHO GEMS food database (and trial using CIFOCOSS)

Outputs



Summary report - key outcomes – available soon after Meeting finishes

MRLs feed into CCPR system

Recent / potential changes in methodology / approaches (1)

- Normally covered in 'General considerations' in JMPR reports
- Increased emphasis on metabolites versus just the parent compound
 - More metabolites being found and test data generated
 - WHO flow chart for metabolite assessment is in the monographers guide
 - Major rat metabolite / threshold of toxicological concern (TTC)
- New scientific approaches
 - BMD uses all dose response data not just a single dose level in the study as a PoD
 - Maximum dose setting potential to move from MTD to kinetic basis
 - in silico prediction, in vitro testing.
 - JMPR has an open mind on evaluating new approaches and encouraged their submission.
 - Combined assessments for groups of compounds with similar toxicological profiles.
 - In 2019 JMPR proposed a pilot project on combined assessment.

Recent / potential changes in methodology / approaches (2)

- New exposure assessment by WHO (trial exercise)
 - Global Estimate of Chronic Dietary Exposure (GECDE) and less than lifetime exposures for critical groups for certain compounds.
 - Consistent with that used by JECFA vet. drugs.
 - In parallel to traditional approach IEDI / IESTI.
 - Uses the CIFOCOSS database not GEMS food.
- Possibility of using monitoring data for certain MRLs (e.g. spices)
- Consideration of microbiological effects
- Elements of the IESTI equation are regularly being revisited.
 - JMPR keeps abreast of these and will consider adoption based on scientific merit

Recurring Problematic Aspects

- Increased workload for each compound
 - Assessments more complex especially metabolites
- Incomplete dossier submissions extra data sent to other agencies
 - Identified late or in concern forms
- Superfluous data not relevant to MRL assessment
 - Takes time to review for no purpose (groundwater / non-oral exposure)
- Multiple codes / names for the same metabolite
 - Toxicity data on XAB-1245; residue description is desmethyl-XAB-116
 - Simple read across table
- Field trials not in line with critical GAP as specified.

Links to information sources

- JMPR reports / monographs
 - https://www.who.int/groups/joint-fao-who-meeting-on-pesticide-residues- (jmpr)/publications/reports
 - https://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/
- WHO monographer guide
 - https://www.who.int/groups/joint-fao-who-meeting-on-pesticide-residues-(jmpr)/publications
- FAO manual
 - https://www.fao.org/publications/card/en/c/3829b88a-c721-434f-92c1-08e1675e8141/
- Environmental Health Criteria 240
 - https://inchem.org/documents/ehc/ehc/ehc240 index.htm

Thank you for your attention.