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Joint FAO/WHO Expert Committee on Food Additives (JECFA)

New JECFA Approach for evaluating dietary exposure to
veterinary drugs residues in food

23rd session of CCRVDF

History

Codex has been implementing risk analysis since its creation, then came ...



The WTO Agreements Series
Sanitary and
Phytosanitary Measures

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

Conclusion

International standards have to be developed according to risk analysis principles !



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Risk Analysis Framework

**Scientific
advice**



**Regulation
and control**

Dialog with all stakeholders

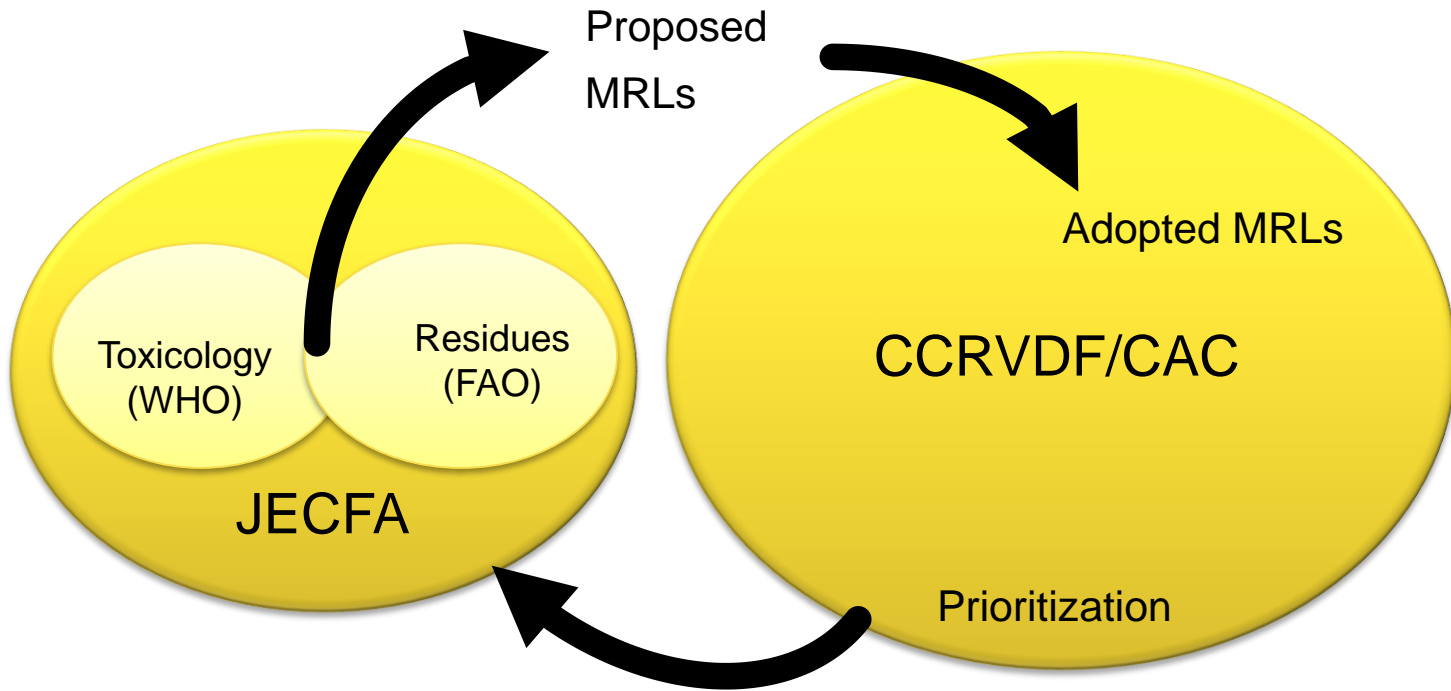


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General procedure

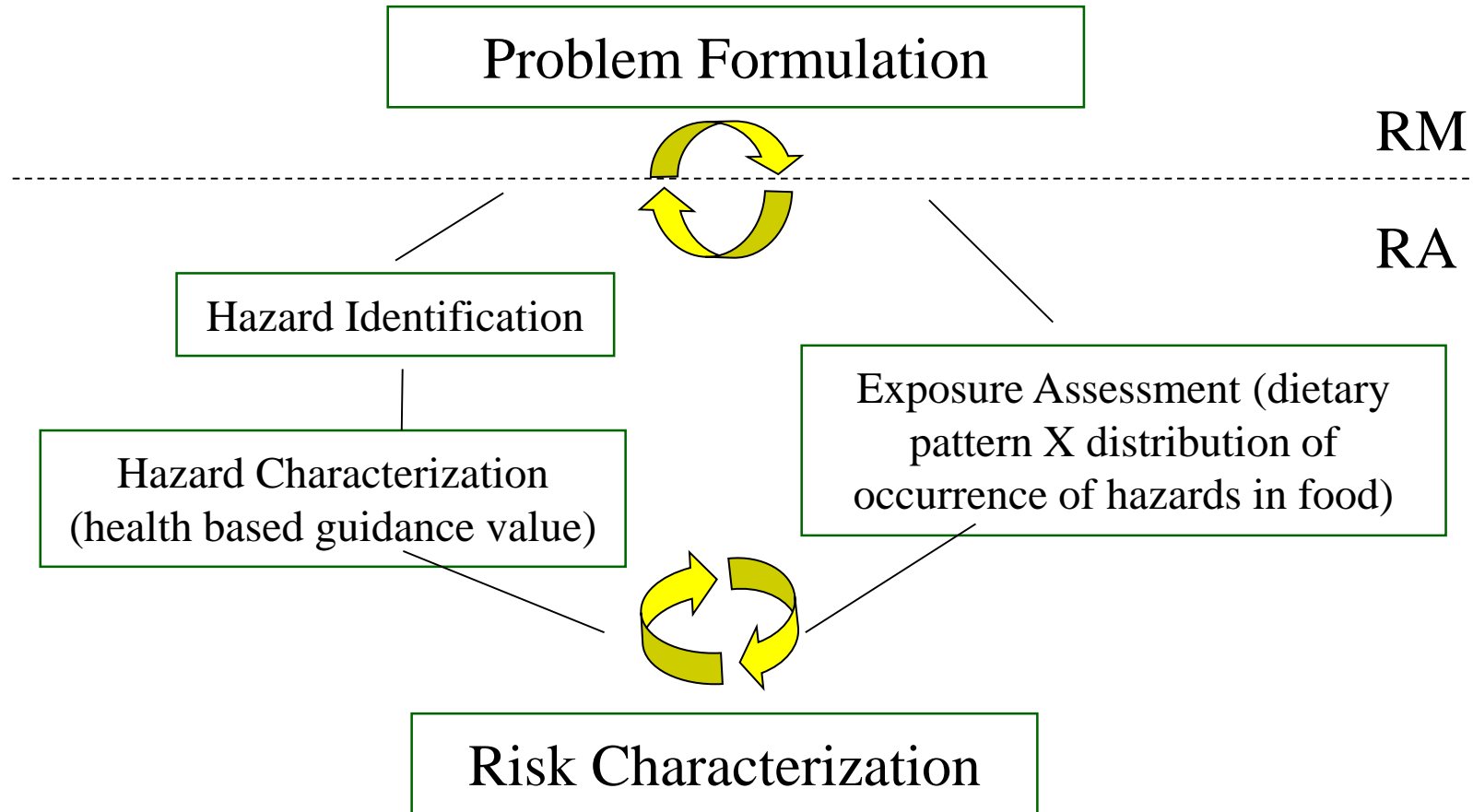


JECFA Terms of Reference on Vet Drugs

- elaborates principles for evaluating safety of vet drug residues and for quantifying their risks;
- establishes ADIs and other guidance values for acute exposure
- recommends maximum residue limits (MRLs) for target tissues; and
- determines appropriate criteria for and evaluates methods of analysis for detecting and/or quantifying residues in food



Risk Assessment procedure: A Scientific Process



Principles for risk assessment

- Step 1: Establishment of Health Based Guidance Values (HBGV)
 - Acute risk: an Acute Reference Dose (ARfD) should be established
 - ARfD – estimate of the amount of a substance in food and/or drinking water, expressed on a body-weight basis, that can be ingested in a period of 24h or less without appreciable risk to the consumer on the basis of all known facts at the time of evaluation. (JMPR 2002)
 - Chronic risk: an Acceptable Daily Intake (ADI) should be established.
 - ADI – estimate of the amount of a substance in food or drinking water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human 60kg). (WHO 1987)



Principles for risk assessment

● Step 2: Exposure assessment

- Various exposure scenarios should be estimated as a function of results from step 1
 - S1 (acute toxicity) Maximum exposure over 1 day i.e. a high portion of a food containing the chemical at high residue concentration.
 - S2 (chronic toxicity) Average and high dietary exposure on a lifetime basis for a diet containing the chemical at median residue concentration

● Step 3: Risk characterization

- When the exposure is $> ARfD$ or $> ADI$: adjust MRL or no MRLs recommended
- When the exposure is $< ARfD$ or $< ADI$: MRLs recommended



History of JECFA practices

- In 1988 the JECFA implemented the use of the TMDI based on a daily "food basket" (300 g of muscle, 100 g of liver, 50 g of kidney and fat, 1.5 kg of milk, 100 g of eggs and 20 g of honey) combined with MRLs residue concentration
- In 2006 the JECFA introduced the use of the median residue concentration to represent the best estimate of a central tendency over a prolonged period of time: the TMDI became the EDI with the same daily "food basket".
- In 2011 FAO/WHO organized an expert consultation to review the dietary exposure models considering in particular recent advances in methodology and data collection.



FAO/WHO expert consultation (2011)

- It was noted that :
 - The EDI is an approach for chronic dietary exposure.
 - The “food basket” used for EDI
 - Generally overestimates exposure and potentially leads to overly conservative risk assessments.
 - Is not always as conservative as previously assumed (Observed high consumption may be higher than reflected in the model diet)
 - does not considered data for tissues such as lung or intestine which had been reported to be consumed in some populations
 - assumes that all foods that are derived from the same tissue type are consumed in similar amounts e.g. the consumption amount of mammalian meat (muscle) is assumed to be the same as that for fin fish (muscle).
 - The food consumption amounts used in the food basket model are not suitable for estimating acute exposure.



FAO/WHO expert consultation (2011)

● It was recommended that

- JECFA's exposure approach evolve from the “food basket” to the use of appropriate food consumption data
- The food consumption data used in the new approach are derived from surveys conducted at the individual level.
- Food consumption data derived from surveys conducted at the individual level should ideally be used to provide a realistic representation of people's actual consumption patterns for different age and (target) population groups (e.g., infants, children)
- The new model should offers the possibility to assess exposure for sub-population groups (e.g. children, pregnant women...)



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New approach for Chronic Dietary Exposure 1/2

- For chronic exposure estimates, it is preferable to use surveys of more than 1 day's duration to represent “usual” consumption patterns
- Methodologies should take into consideration non-average individuals, such as those who consume regularly large portions of specific food items.
- It was decided to include separate data on infants and children, because the amount of food they consume in relation to body weight is higher than for older age groups.



New approach for Chronic Dietary Exposure 2/2

- The *new chronic dietary exposure model* for veterinary drug residues assumes that in the longer term, an individual might be a high-level consumer (97.5th percentile) of one food category only, and would be an average consumer of all the remaining relevant products.

$$\begin{array}{l} \text{Chronic dietary exposure} \\ \text{(mg/kg body weight per day or mg/day)} \end{array} = \begin{array}{l} \text{Highest exposure from one} \\ \text{animal product} \\ \text{(mg/kg body weight per day or mg/day)} \end{array} + \begin{array}{l} \text{Total mean exposure} \\ \text{from all other} \\ \text{products} \\ \text{(mg/kg body weight per day or} \\ \text{mg/day)} \end{array}$$



ARfD and Acute Dietary Exposure

- Till now the JECFA rarely established Acute Reference Dose for veterinary drugs: JECFA has now developed guidance for establishing ARfD for vet drugs
<http://www.who.int/foodsafety/chem/jecfa/ARfd/en/>
- In the past it was assumed that the TMDI could be used to cover both potential acute exposure as well as chronic exposure.
- The expert workshop confirmed that the "food basket" underestimates consumption for evaluation of acute exposure when compared with large portion size for numerous commodities in various regions.



New approach for Acute Dietary Exposure

- The expert workshop concluded that acute dietary exposure should combine high consumption with high residue figures as it is currently done by others FAO/WHO scientific risk assessment bodies (pesticides residues, additives, contaminants, toxins...).

Acute dietary exposure

(mg/kg body weight per day or mg/day)

$$= \frac{97.5\text{th percentile food consumption (1 person-day)} \times \text{High residue}_{\text{tissue}}}{\text{Body weight}}$$

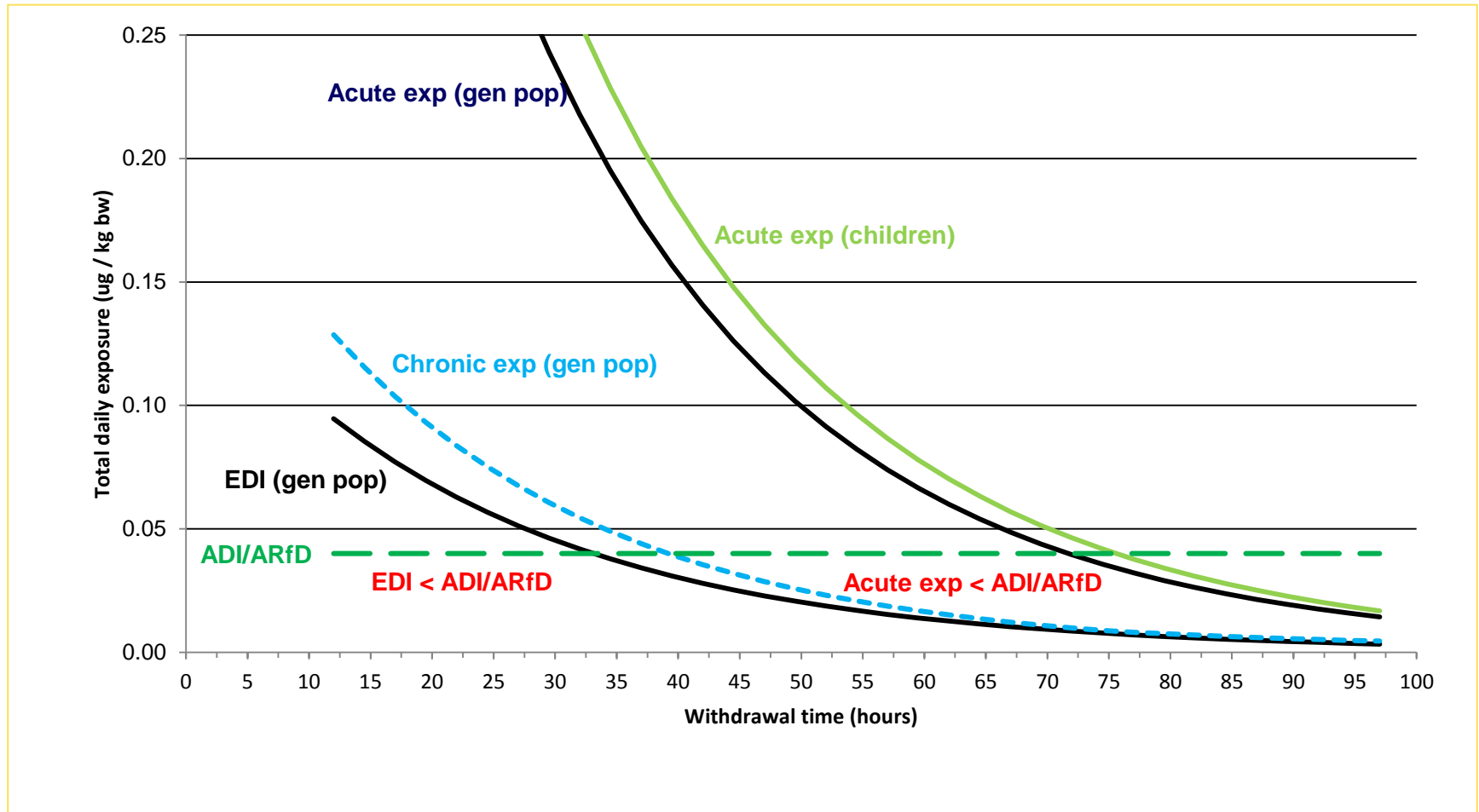


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EXAMPLE OF REFERENCE POINTS FOR MRL FOR THE ESTIMATED EXPOSURE TO VET DRUG RESIDUES



Future JECFA activities for improvement of the chronic dietary exposure approach (1/2)

- The 81st JECFA meeting identified the need to develop a combined dietary exposure approach for compounds that are used both as veterinary drug and pesticides
- The methodologies applied by JECFA and the JMPR to estimate chronic dietary exposures should be updated in a consistent way.



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Future JECFA activities for improvement of the chronic dietary exposure approach (2/2)

- The FAO/WHO Chronic individual food consumption database – Summary statistics (CIFOCOss)
<http://www.who.int/foodsafety/databases/en/>
- A joint FAO/WHO Electronic working group on harmonizing / combining exposure from veterinary drug and pesticide use has been established
<http://www.who.int/entity/foodsafety/RequestForExpressionOfInterest.pdf>



***Thank you for your
attention***



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