

MRLS for groups of fish species (further recommendation)

Agenda item 7

EWG hosted by Norway and Japan

Recommendation C

- ▶ No grouping, but discuss further guidance on national risk management options
 - ▶ Exclude GVP and withdrawal times from risk assessment/leaving GVP and withdrawal time to risk management
 - ▶ Possible to extrapolate and set MRLs for larger groups of fish, ex) finfish

An Example of Recommendation C

ADI=0-1mg/kg bw = 0-60mg/person

Food	Sum of MRL x Food intake/day	MRL
Fish	10 mg/day	Can be set*
Others	40 mg/day (Existing)	(Existing)
Total	50 mg/day < 60mg/day (Safe level)	

On the case Fish intake/day = 0.3kg/day

MRL (mg/kg) for fish = 10 (mg/day) / 0.3 (kg/day) = 33 mg/kg

Residue data of fish are not needed to set MRL for fish.

Present Situations of veterinary drugs in aquaculture

- ▶ Fish species and veterinary medicines for aquaculture seems to be limited based on the information from EWG members
 - 12 orders of fish/crustacean
 - 50 substances
- ▶ Registration system of veterinary medicine and GVP for using veterinary medicines for aquaculture seems to be not well-established in many Codex member countries/regions.

Advantages and Disadvantages of option C

Advantages	Disadvantages
<p>Promotion of making MRLs by limited data</p>	<p>Need to determine withdrawal periods for each fish species using residue depletion data for each fish, because the MRL is not based on the residue depletion data of each fish species</p>
<p>Enable to stop the sales/import of fish products containing veterinary medicines above MRL</p>	<p>Increase use of veterinary drugs without approval, and increase AMR?</p>
<p>Promotion of Food Trade?</p>	<p>Inconsistent with present “RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF” (See procedural Manual, p.151 & p.155)</p>
	<p>Inconsistent with present “RISK ASSESSMENT POLICY FOR RESIDUES OF VETERINARY DRUGS IN FOODS” (See procedural Manual, p.161)</p>

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- RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF

- ▶ (P.151) 15. Where CCRVDF considers the possible **extrapolation** of MRLs to other species, this should be clearly identified in the preliminary risk profile. Pre requisites include:
 - Comprehensive data packages or established MRLs for the veterinary drug are available for at least one animal species;
 - The drug is approved for use in the species for which MRL extrapolation is requested in at least one member country and Good Veterinary Practice has been established.
- ▶ (P.155) 30. The CCRVDF may:
 - recommend the MRLs based on the JECFA assessment;
 - recommend **extrapolation** of MRLs to one or more other species, here JECFA has identified that is scientifically justifiable and the uncertainties have been clearly defined;

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-RISK ASSESSMENT POLICY FOR RESIDUES OF VETERINARY DRUGS IN FOODS

▶ (P.161) (h) **While considering extrapolation of MRLs:**

- There should be a reasonable expectation that two food producing species that are **biologically/physiologically related** will generally exhibit a similar pattern of metabolism, distribution and depletion of veterinary drug residues (e.g., ruminant to ruminant).
- There should be a reasonable probability that **a unique metabolite(s) of toxicological concern is unlikely to occur** in species in which MRLs are being extrapolated;
- JECFA should, when requested, assess different risk management options and present, in its report the implications of these different risk management options for the CCRVDF to consider.

Proposal of Advanced Option C' (advanced option C)

No fish grouping based on science at present time



Data making by using VICH-GL57
Tentative fish grouping by order refer to VICH-GL57



Fish grouping based on science in the future

Comparison of Option C and Option C'

	Option C	Option C'
ADI	Necessary	Necessary
Exposure assessment for fish	Necessary	Necessary
Metabolism study in fish (to define marker residue)	1 fish species	1 fish species per 1 order
Marker residue depletion study for fish	(1 fish species)*	1 fish species per 1 order
Analytical Method for MRL	Necessary	Necessary
MRL	Same for all fish	For every Order

*Residue depletion study for each fish species are not needed to establish MRL, but it is needed to establish withdrawal period.