CONCERN FORM

Submitted by: European Union

Date: 27 March 2015

Veterinary drug: Lasalocid sodium

Commodity (species and tissues): Muscle, liver, kidney, skin + fat
Chicken, turkey, quail, pheasant

MRL (µg/kg):		
	Muscle	400
	Liver	1200
	Kidney	600
	Skin + fat	600

Present Step: Step 3

Description of the concern:

In the case of lasalocid sodium, JECFA identified a hazard that may occur following short term exposure to residues: a disruption of the colonisation barrier. The level of consumer exposure that JECFA considered not leading to a disruption of the colonisation was expressed as a microbiological ADI (8.4 µg/kg bw or 504 µg/person). Because this hazard may occur following a short term residue exposure, there must be assurance that even occasional, high residue intake will not exceed the microbiological ADI. The EDI cannot provide this assurance. JECFA is developing a complimentary approach for addressing short term exposure scenarios based on high residue intake. However, this work has not yet been finalised. Therefore JECFA was unable to assess this kind of exposure. If the TMDI approach is used for this purpose - which is the approach that JECFA has used in other cases where short term exposure may lead to a consumer safety concern - the proposed draft Codex MRLs for poultry tissues would be estimated to lead to a consumer exposure of 882.11 µg/person, which represents 175% of the JECFA microbiological ADI thus representing a risk to consumer health.

Summary of the supporting documentation that will be submitted to JECFA (e.g. toxicology, residue, microbiology, dietary exposure assessment): N/A