30/01/2023

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
26th Session

Portland, the United States, 13-17 February 2023

European Union comments on

Agenda Item 8

Criteria and procedures for the establishment of action levels for unintended and unavoidable carryover of veterinary drugs from feed to food of animal origin

(CX/RVDF 23/26/8 and CL 2022/77-RVDF)

European Union Competence
European Union Vote

The European Union (EU) would like to thank Australia and Canada for leading the work on action levels.

General comment

The criteria and procedures for the establishment of action levels for unintended and unavoidable carry-over of veterinary drugs from feed to food of animal origin as presented in document CX/RVDF 23/26/8 are overall acceptable for the EU. However, they should in a first phase be limited to veterinary drugs other than antimicrobial active substances. The unintended and unavoidable carry over of antimicrobial active substances could then be considered in a second phase in which, besides food safety concerns related to residues in edible parts of non-target animal species, would also consider the avoidance of antimicrobial resistance (AMR) as a public health outcome, in conjunction with other relevant Codex texts on AMR.

Specific comments

Q1: No comment

Q2: No comment

Q3: The proposed criteria are acceptable.

Q4: As regards the options for animal dietary exposure assessments, it seems appropriate to consider hypothetical carry-over rates of x% of the highest authorised dose (1 %, 2.5% or 3 %). The rate of 5 % should not be considered as this rate is too high in case all good practices, including the application of appropriate mitigation steps, at the different stages of the feed chain are applied.

If monitoring data provide evidence that lower levels of carry-over can be achieved than the hypothetical carry-over rates, then these lower levels of carry-over should be considered. In case effective data indicate higher levels of carry-over than the hypothetical carry-over rates, then the hypothetical carry-over rate are to be used and feed business will have to strengthen their good practices, including the application of appropriate mitigation steps, to achieve these hypothetical carry-over rates. Experience in the EU have demonstrated that when good practices are applied the carry over rates of 1 and 3 % (depending on the mitigation measures applied) are achievable and this independently from the size and the nature of the feed manufacturing plants.

Q5: No comment

Q6:

- For the data on the carry over in feed: see the reply to Q4.

- For the residue levels in food of animal origin: in case extensive monitoring data demonstrate that the levels of residues are (much) lower than the calculated action levels using estimated TF factors, then the used assumptions as regards carry-over level in non-target feed and for the calculation of the TF factor might need closer examination and reconsideration. In case monitoring data indicate higher levels than the calculated action level, then an examination of the assumptions can also be done but much more cautiously given that there is no evidence that these monitoring data are the result of applying good practices, including the appropriate mitigation measures, all along the feed chain.

Q7: No comment

Q8: Antimicrobial active substances should be excluded from the scope of this document because in addition to food safety concerns, AMR concerns as a consequence of carry over antimicrobial active substances need to be considered.

In addition, a prioritisation of new work proposals of action levels should be considered. A valid criterion for prioritisation should be the proven occurrence (combined with frequency of occurrence) of residues of the veterinary drug in edible commodities from non-target animals.

Q9: The proposed roles and responsibilities are acceptable.

Q10: Although CCRVDF and Codex do not deal with animal health, it would be appropriate to mention explicitly that the necessity to limit the unintended cross-contamination of non-target feed is not only very important for food safety/public health but also for animal health as certain non-target animal species might be very sensitive to the presence of traces of certain veterinary drugs. To do so, as an overarching principle, it could be mentioned that relevant World Organisation for Animal Health (WOAH, founded as OIE) standards need to be considered for all animal health aspects.