CODEX ALIMENTARIUS COMMISSION E

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Agenda Item 7.1 **CRD2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-third Session

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REPORT OF THE PHYSICAL WORKING GROUP ON UNINTENDED PRESENCE OF RESIDUES OF VETERINARY DRUGS IN FOOD COMMODITIES RESULTING FROM THE CARRY-OVER OF DRUG RESIDUES IN FEED

The physical working group (pWG) was co-chaired by Canada and the United States of America and attended by several member countries and organizations, as well as observers. The co-chairs presented the summary of work completed by the electronic working group (eWG), as included in CX/RVDF 16/23/7, and highlighted some of the key points to be discussed by the pWG.

The co-chairs reminded the working group that the scope of the work was to prepare a discussion paper for elaborating risk management recommendations in situations where low-level residues of a registered veterinary drug are detected regularly in certain foods, and trace-back inspections confirm the source to be unintended/unavoidable carry-over residues in feed.

The working group agreed to focus the discussions on risk management measures that the Committee could deliberate to address this issue.

1. Code of Practice to manage the risk of unintended residues of veterinary drugs in foods resulting from carry-over drug residues in feed:

The working group identified that the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) provides overarching principles that could cover the carry-over residue issue management. Specifically the paragraph 48 of the Code (see below) is considered important in this regard:

"48. Manufacturing procedures should be used to avoid cross-contamination (for example flushing, sequencing and physical clean-out) between batches of feed and feed ingredients containing restricted or otherwise potentially harmful materials (such as certain animal by-product meals, veterinary drugs). These procedures should also be used to minimise cross-contamination between medicated and non-medicated feed and other incompatible feed. In cases where the food safety risk associated with cross-contamination is high and the use of proper flushing and cleaning methods is deemed insufficient, consideration should be given to the use of completely separate production lines, transfer, storage and delivery equipment." (CAC/RCP 54-2004)

Outcome of the discussion: Participants were in general agreement that this Code of Practice provides overarching principles for the management of residues in food resulting from unintended carry-over residues in feeds. However, there was no consensus on whether this Code of Practice needed further elaboration to provide specific guidelines for member countries to manage these residues. Some participants suggested that no further revisions to the guidelines are required, as the current wording is general enough to cover the issue at hand; other participants suggested that specific guidelines to avoid/minimize unintended carry-over residues in feed could be elaborated either as an in-text revision or added as an annex. However, no details were brought forward on what aspects of the Code needed to be updated.

2. Elaborating risk management recommendations

It was suggested that low-level residues of certain veterinary drugs do occur in foods due to carry-over residues of drugs in feeds despite following/implementing the Good Manufacturing Practice (GMP) in feed manufacturing. Risk management recommendations (which may include numerical limits) may be required for certain drugs to address the human health concerns and/or trade issues.

However, there were several comments that the issue should be addressed first by GMP following the Code of Practice on Good Animal Feeding. Furthermore, there were several comments on the possible name for a numerical standard, if one is required and if it is established. There was general agreement that such a standard should not be called an MRL due to differences in the underlying principles.

Several members expressed the opinion that, if a risk management measure (including a numerical standard) is sought, it should be reserved for those specific situations where the risk of carry-over cannot be controlled by GMP alone and that criteria for identifying the need for a standard in food are clearly defined.

Participants also discussed whether this situation poses a safety issue or a trade issue or both. Some members identified this specific situation to be a trade issue and not a food safety risk. However, members also discussed that the Committee needs to consider food safety risk while addressing this trade issue.

Outcome of the discussion:

After extensive discussions, the physical working group agreed on the following:

a. Criteria for requesting risk management recommendations/measures:

- Only to be considered when Good Manufacturing Practices following the Code of Practice on Good Animal Feeding are insufficient to avoid residues from carry-over in food commodities
- There is an identified food safety/trade issue
- Only for veterinary drugs where JECFA already has an established ADI or the JECFA has been requested to establish an ADI
- There is a rationale justifying the need required – priority setting

b. General considerations for risk management recommendations/measures:

- Supporting data are available from the drug sponsor, academic publications, national monitoring data, *etc.*
- Potential principles applicable: Set limit as low as reasonably achievable while addressing the identified trade issue
- Evidence that implemented GMPs for Good Animal Feeding are insufficient to control carry-over

3. Define appropriate questions for scientific assessment body

The pWG also discussed how to frame the questions when the Committee requests the JECFA to provide risk management recommendations (including a numerical standard). The following was discussed:

- Will the presence of residue in food at levels associated with unavoidable carry-over in feed constitute a risk to human health?
- Can a risk management recommendation be elaborated? For example, what limit/standards could be established to address the trade issue while protecting human health.

Some countries noted that JECFA may be able to provide some advice on what additional data would be necessary if the submitted data were found to be insufficient to make a recommendation. In addition, members also discussed how these standards could be referenced and terms like Maximum Limits,or Maximum Unavoidable Levels were brought forward. Some members also suggested that the risk management advice could be in form of a footnote or risk management recommendation for a particular drug and there may not be a need to define a numerical standard.

4. Consideration for risk management recommendations, with specific reference to lasalocid in eggs

There were some discussions on whether lasalocid residues in eggs, due to carry-over of drug residues in feed, could be used as an example for determining if it meets the criteria specified and asking JECFA for risk management recommendations (including a numerical standard). There were suggestions that certain drugs, because of their specific chemical properties, have a higher tendency to transfer to the next batch of feeds (*e.g.*, ionophores (monensin, salinomycin), nicarbazin) should also be considered together.

5. Procedural manual changes

While this was identified as one of the possible discussion items, it was not discussed at the pWG.

Conclusions/Recommendations

The pWG could not reach consensus on whether the Code of Practice on Good Animal Feeding is sufficient to address the issue of carry-over in feed. If the Code of Practice is insufficient, the Committee should consider what specific revisions would be required.

The pWG recommended some criteria and general principles if the Committee is considering elaboration of a risk management measure to address the unintended presence of residues in food due to carryover in feed.