CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/RVDF 10/19/5**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOD

Nineteenth Session

Burlington, Vermont, United States of America 30 August - 3 September 2010

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

Comments at Step 6 (replies to CL 2009/22-RVDF)

(European Union, Iran, United States of America and IFAH)

European Union

Draft Codex MRLs for narasin in cattle and pig tissues at step 6

At the 18th session of CCRVDF, the proposed draft Codex MRLs for narasin in cattle and pig tissues were advanced only to step 5 on the request by the European Union (EU). This was because the full JECFA report came available very late and there was not enough time to review the JECFA safety evaluations. It was also signalled that the use of narasin in food producing animals for growth promotion purposes is not authorised in the EU and that narasin is authorised in the EU only for the control of coccidiosis in chicken.

The EU has now reviewed the JECFA safety evaluations. It was concluded that the draft Codex MRLs for narasin in cattle and pig tissues do not raise concerns purely from toxicological point of view. Nevertheless, the EU continues to have concerns about the draft Codex MRLs as narasin is used in cattle and pigs primarily for growth promotion. Such use is not authorised in the EU because of the general EU policy of not allowing the use of veterinary drugs for non-therapeutical purposes. The EU ban on the use of antimicrobial substances in food producing animals for growth promotion is also based on their potential to increase antimicrobial resistance.

Draft Codex MRLs for tilmicosin in chicken and turkey tissues at step 6

At the 18th session of CCRVDF, the EU objected the proposed draft Codex MRLs for tilmicosin in chicken and turkey tissues based on public health concerns. The EU concerns arose from the fact that the theoretical maximum daily intake (TMDI) calculated using the proposed draft Codex MRLs equated to over 300% of the established EU ADI. The proposed draft MRLs were submitted to the 32nd CAC which adopted them at step 5 and advanced them to Step 6 with the EU reservation.

The EU has now reviewed new scientific data concerning tilmicosin. It was concluded that the new data would allow deriving a higher ADI for tilmicosin than the one currently established in the EU. Taking this into account, the EU considers that the draft Codex MRLs do not represent a consumer safety concern as the TMDI calculated using the draft Codex MRLs is below the ADI that would be established using the new data. Therefore, the EU can accept the draft Codex MRLs for tilmicosin in chicken and turkey tissues.

Iran

Iran supports the Proposed Draft Maximum Residue Limits (MRLs) for veterinary drugs (Narasin & Tilmicosin) in Appendices IV of Alinorm 09/32/31

United States of America

The United States supports the draft MRLs for narasin (in cattle and pig tissues) and tilmicosin (in chicken and turkey tissues) at Step 6 for advancement to Step 8.

IFAH (International Federation for Animal Health)

The International Federation for Animal Health (IFAH) provides the following comments for two veterinary drugs at step 6:

Narasin – IFAH supports advancing the draft MRLs for narasin in pigs to step 8. IFAH supports retaining the temporary MRLs in cattle at step 6 until a suitable analytical method is submitted and reviewed by JECFA. A method is being developed by the sponsor to monitor residues of narasin in cattle tissues at the recommended, temporary MRLs.

Tilmicosin – IFAH supports advancing the draft MRLs for tilmicosin in tissues of chicken and turkey to step 8. As agreed at the 18th Session of CCRVDF, the committee advanced the proposed draft MRLs for adoption at step 5 with the understanding that, if no new data would be submitted by the European Community to support JECFA re-evaluation, these MRLs would be advanced for adoption at Step 8 at its next Session. IFAH is unaware that any new data has been submitted and tilmicosin has not been added to the priority list.