CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/RVDF 12/20/2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES

MATTERS ARISING FROM THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Standards and Related Texts adopted at Steps 8 and 5/8[1]

1. The 34th Session adopted the Maximum Residue Limits (MRLs) for narasin in pig tissues and for tilmicosin in chicken tissues, as recommended by the CCRVDF.

Approval of new work for the elaboration of new standards and related texts[2]

2. The 34th Session of the Commission approved the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA and the elaboration of Performance criteria for multi-residue analytical methods for veterinary drug residue analyses (Appendix to the *Guidelines for the design and implementation of national regulatory food safety assurance programmes associated with the use of veterinary drugs in food producing animals*- (CAC/GL 71-2009), as proposed by the 19th Session of the CCRVDF.

Amendments to Codex Standards and related texts[3]

3. The 34th Session of the Commission adopted the amendments presented by the CCRVDF to correct the references in several Codex texts to: *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993) and *Code of Practice for Control of the Use of Veterinary Drugs* (CAC/RCP 38-1993), superseded by the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009).

OTHER MATTERS

Standards and Related Texts Held at the Commission at Steps 8[4]

Draft MRLs for Bovine Somatotropin[5]

4. The 34th Session agreed to consider the draft MRLs for bovine somatotropins (bSTs) at its next session. In order to facilitate its discussion, the Commission requested the Codex Secretariat to prepare a paper, which would describe the history of development and discussion of the MRLs in Codex, including a summary of the JECFA evaluation.

Draft MRLs for Ractopamine[6]

5. The 34th Session of the Commission retained the draft MRLs for ractopamine in bovine and pigs tissues at Step 8. An excerpt of the discussion on the draft MRLs for ractopamine is included in the Annex to this document.

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[1] REP11/CAC, para. 23 and Appendix III
[2] REP 11/CAC, para. 127
[3] REP 11/CAC, para. 131 and Appendix VI
[4] REP11/CAC, para. 23 and Appendix III
[5] ALINORM 95/31, Appendix II
[6] ALINORM 08/31/31 para. 47 and Appendix II

Antimicrobial Resistance[7]

6. The 34th Session of the Commission adopted the draft *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*, elaborated by *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance. The Task Force having completed its work was dissolved.

MATTERS ARISING FROM THE 65TH SESSION OF THE EXECUTIVE COMMITTEE

Critical Review for the Elaboration of Codex Standards and Related Texts – Monitoring of Standard Development[8]

7. The 65th Session of the Executive Committee invited the CCRVDF to set a target date for the completion of the Proposed Draft Sampling Plans for Residue Control of Aquatic Animal Products and Derived Edible Products of Aquatic Origin.

MATTERS ARISING FROM OTHER COMMITTEES AND TASK FORCES

Committee on Pesticide Residues (CCPR)[9]

8. With regard to the development of performance characteristics for multi-residue analysis methods for veterinary drugs in foods (request of the 19th CCRVDF), the 43rd CCPR agreed that a clearly described request and more background information were necessary for making any specific recommendations for discussion at is future sessions.

[7] REP11/CAC, paras 25-26 and Appendix III
[8] ALINORM 10/33/3 paras 15-17
[9] REP11/PR, para. 10

Annex

Excerpt of the discussion of the 34th Session of the Codex Alimentarius Commission on the draft MRLs for Ractopamine n the draft (REP11/CAC, paras 90-115)

***Draft MRLs for Ractopamine*[10]**

90. The Chairperson recalled that at the 33rd session of the Commission it had not been possible to reach consensus on the draft MRLs for ractopamine and that the Commission had accepted the proposal of the Chairperson to serve as facilitator to a discussion on possible solutions through a technique, used in FAO, WTO and other UN organizations, to establish an informal group called "Friends of the Chair" (FOTC). The FOTC comprised 11 members: Brazil, China, Canada, European Union, Ghana, Japan, Mexico, Norway, South Africa, Tunisia, and the United States of America, and 2 observers: IFAH and CI.

91. The Chairperson further noted that, as indicated in document CX/CAC 11/34/4-Add.3, the FOTC had met several times and had established an agreement for the way to work. However, despite open and frank discussion, the FTOC had been unable to reach a consensus but made two proposals, which left the Commission in the same position as it was at its 33rd session.

92. The Chairperson also explained that a delegation raised a question on the transparency in the way the FOTC had operated even though she had striven to ensure transparency throughout the process.

93. Several delegations appreciated the efforts of the FOTC to find solutions. The Delegation of Ghana, which participated in the FOTC, expressed their appreciation for the process, which had brought to light critical issues concerning Codex and regretted that the discussion had not resulted in a resolution. Other delegations expressed their appreciation for the efforts of the FOTC. The Delegation of the European Union stated its view that they had participated constructively and positively in the FOTC but noted that, after a promising start, it was their view that a number of irregularities in the conduct of the process had appeared and that transparency and that neutrality had not always been ensured. Another delegation, while in principle in favour of using the FOTC to reach consensus, was of the view that it should be used in accordance with the Codex guidance, should be unbiased and that Codex work should be open, transparent and inclusive.

94. The Commission had an extensive discussion on the adoption of the draft MRLs for ractopamine, which mirrored positions and arguments at its 33rd Session, with a number of delegations supporting the adoption of the draft MRLs and a number of other delegations supporting discontinuation of work or proposing to hold the draft MRLs at Step 8.

95. The delegations which supported the adoption of the draft MRLs emphasized that JECFA had reviewed the MRLs three times and fulfilled its task by considering all available data and noted that these MRLs could be reviewed in the future in the light of new scientific data. It was also pointed out that the draft MRLs were based on JECFA risk assessment, as prescribed in the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods* included in the Procedural Manual, and that the concern of China regarding residues in lung was not within the scope of the draft MRLs currently under discussion. These delegations also underlined the conclusion of JECFA that these MRLs were compliant with the ADI and safe and reiterated their confidence in the science-based work of JECFA, and expressed concern about the precedent that could be set, undermining the work of JECFA and risk assessment.

96. These delegations further highlighted their concerns on the long delay to adopt the MRLs based on non-scientific factors and stressed the need for Codex to base its decisions on science, in view of the status of Codex standards under the WTO SPS Agreement. They recalled that many countries used Codex standards as the basis for their national legislation and that failure to adopt the MRLs for ractopamine could negatively impact on food security as the establishment of MRLs for ractopamine would allow the safe use of new technologies to meet the increasing demand for food production foreseen by FAO. It was also stated by many delegations that all Codex steps had been followed in the elaboration of the MRL for ractopamine.

97. The Delegation of the United States of America noted that no government would be required to permit the use of ractopamine but would be able to allow imports, confident that the imported meats are safe for consumers when the exporting country has produced the food according to Codex standards.

98. The delegations which opposed to the adoption of the draft MRLs continued to be concerned with the safety of ractopamine, as there were still unanswered safety questions, particularly with respect to the residues in lung tissue and scientific concerns linked to the use of ractopamine, which required further studies. It was noted that many countries did not allow the use of veterinary drugs solely for growth promotion, without any therapeutic purposes and that Codex, as

[10] ALINORM 08/31/31 para. 47 and Appendix II

risk management body, should base its decision not only on science but also take into account other factors, such as consumer concerns. They further noted that it was essential for Codex to base its decision on a broad consensus not to undermine its credibility.

99. The Delegation of the European Union underlined that they highly respected the work of JECFA but could not ignore the opinion provided by EFSA, which is at the basis of their food safety system, established according to the principles of risk analysis. The Delegation of China pointed out that they were the largest producer and consumers of pork; it was further pointed out that China and the European Union represented together 70% of the pork production in the world and that more than 70% of the pork was consumed in these countries; therefore, adopting a standard without the support of these two major actors would undermine the credibility of Codex.

100. The Delegation of China referred to their experiment findings on residues in pig lungs and voiced their concern with the safety of ractopamine, especially their concern with the risks related to residues in lung tissue and other offal tissues. Therefore, China expressed the view that if the relevant risk assessment is completed and safety issues are fully addressed, the adoption of ractopamine MRLs could be considered.

101. The WHO JECFA Secretary recalled that JECFA had evaluated an extensive toxicological database, including human studies at its 62nd meeting (2004) and established an ADI 0-1 µg/kg bw. Extensive residue data were also assessed and formed the base for the MRLs recommended for tissues of pig and cattle (i.e. muscle, liver, kidney and fat), as requested by the CCRVDF. At the 66th meeting (2006), JECFA reviewed the establishment of the ADI on request of the 15th CCRVDF and confirmed the scientific basis and soundness of its previous decision.

102. The analysis conducted by JECFA in 2010 of additional residue studies in pigs, submitted by the People's Republic of China, confirmed the previously recommended MRLs. Estimated dietary exposure taking the food basket and standard tissues into account led to about 50% of the safe intake level (the ADI). Data on residues in non-standard tissues, including lungs, from these new studies were also evaluated. However, it was noted that residues in these tissues were not routinely measured and were not available from the previous studies assessed at the 62nd and 66th meetings of JECFA. The JECFA Secretary further noted that, when consumed, lung and other non standard tissues generally replaced the standard tissues (e.g. muscle meat) and were not added to the daily consumption of products of animal origin. Even if residue levels in lung were higher than in the other tissues, based on the estimated dietary exposure, they did not indicate a health concern.

103. The JECFA Secretariat emphasized that JECFA's mandate was to evaluate residues in foods when veterinary drugs were used in accordance with good veterinary practice, i.e. used as recommended, while residues due to misuse could not be considered. Setting an MRL was one aspect of risk management, but the important responsibility of Governments was to put appropriate control and surveillance measures in place.

104. The JECFA Secretariat further clarified that EFSA had not undertaken a risk assessment by considering the original raw data, but had undertaken a review of the JECFA assessment based on the published JECFA evaluation.

105. The Chairperson noted that the extensive debate had essentially presented three main options on the way to proceed, i.e.: (i) continue to hold the draft MRLs at Step 8; (ii) discontinue work on the draft MRLs; and (iii) vote on the adoption of the draft MRLs. The Chairperson clarified that, in case of voting, the question to be answered was whether every effort had been made to achieve consensus.

106. The Delegation of the United States of America called for a roll call vote on the adoption of the draft MRLs for ractopamine.

107. The Chairperson raised the question whether every effort had been made to reach consensus before proceeding with such a vote, as required by the Rule XII.2 of the Rules of the Procedure of the Codex Alimentarius Commission.

108. The discussion which followed showed that delegations were divided among (i) delegations which considered that all efforts had been made to achieve consensus, that Codex was based on science and it was necessary to take a decision at the present session and, therefore, supported proceeding with a vote; (ii) delegations which opposed the adoption of the draft MRLs and proposed discontinuation of work; and (iii) delegations which were prepared to adopt the draft MRLs in substance but did not agree with proceeding with a vote considering that not every effort had been made to reach consensus and that a vote would undermine the credibility of Codex and the MRLs under discussion.

109. The Chairperson said that her observation was that more delegations felt that there were still possibilities to find consensus. In this context, the FAO Legal Counsel clarified that the determination whether or not the requirements of Rule XII.2 had been met rests with the Chairperson. He specified, however, that the Commission could overrule the Chairperson.

110. Following some further debate and in the apparent absence of consensus on whether the requirements of Rule XII.2 had been met, the Chairperson proposed to vote on the following question: *Do you want to proceed with a vote on adoption of the MRLs for ractopamine at this session of the Commission?* (Vote 1). The FAO Legal Counsel clarified

that voting would be conducted either by a show of hands, a roll-call vote, if requested by a Member, or a secret ballot, if so determined by the Commission.

111. A number of delegations wished that the vote be conducted by secret ballot. However, in the absence of consensus on the manner of voting, he Commission carried out a roll-call vote to decide on how to conduct Vote 1.

112. It was noted that, as the European Union was competent to vote on this matter on behalf of its Member States (see CRD1), the European Union cast 27 votes, one for each of the European Union Member States present at the session (at the starting of the voting the presence of the 27 European Union Member States was confirmed by the Secretariat).

Votes in favour: Angola, Argentina, Australia, Barbados, Benin, Botswana, Brazil, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Central African Republic, Chile, Colombia, Costa Rica, Cuba, Democratic Republic of Congo, Djibouti, Dominican Republic, Ecuador, El Salvador, Fiji, Gambia, Ghana, Guatemala, Guinea Bissau, Honduras, Indonesia, Jamaica, Lesotho, Madagascar, Mexico, Nepal, New Zealand, Nigeria, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Republic of Korea, Rwanda, Samoa, Senegal, Singapore, Solomon Islands, South Africa, Sri Lanka, Sudan, Suriname, Swaziland, Thailand, Togo, Tonga, Turkey, Uganda, United Republic of Tanzania, United States of America, Vanuatu, Venezuela, Viet Nam, Zambia.

Votes against: Albania, Armenia, Belarus, Bhutan, China, Cote d'Ivoire, Croatia, Egypt, Georgia, Guinea, India, Iran (Islamic Republic of), Iraq, Japan, Kazakhstan, Kenya, Kyrgyzstan, Lebanon, Mali, Morocco, Norway, Russian Federation, Switzerland, Tajikistan, The Former Yugoslav Republic of Macedonia, Tunisia, Zimbabwe, European Union (27 votes).

Abstaining: Ethiopia, Gabon, Jordan, Malaysia, Namibia, Uruguay.

Tally: 117 votes cast, 63 in favour, 54 against, 6 abstentions (majority required 59).

Result: Vote 1 should be conducted by secret ballot.

113. In view of the above result, the Commission proceeded with Vote 1 by secret ballot. The presence of the 27 European Union Member States was verified again by the Secretariat.

114. The result of the secret ballot was:

Ballots:	136
Returned ballots	136
Defective ballots:	0
Valid ballots:	136
Abstentions:	9
Votes cast:	127
Simple majority:	64
Votes in favour:	59
Votes against:	68

Result: The Commission would not proceed with a vote on the adoption of the draft MRLs for ractopamine at the present session.

Conclusions

115. Following the result of the vote, the draft MRLs for ractopamine in bovine and pig tissues were retained at Step 8.