CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/CAC 11/34/3-Add.2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

34th Session

Geneva, Switzerland, 4-9 July 2011

DRAFT STANDARDS AND RELATED TEXTS AT STEP 8 OF THE PROCEDURE

Standards and related texts held at Step 8 by the Commission

Draft MRLs for Ractopamine

Summary of Friends of the Chair – Ractopamine

The 33rd Session of the Codex Alimentarius Commission agreed to establish a Friends of the Chair (FOTC) working group charged with the mandate to carry out informal discussions on possible solutions for ractopamine MRLs that would focus on risk management questions and would not re-evaluate the science. FOTC discussions took place over the course of six months and were hosted by three separate FOTC participants: Mexico, the European Union, and China. This report offers a brief summary of those sessions.

FOTC 1: Mexico City, Mexico

The first FOTC session was held December 9-10, 2010 in Mexico City, Mexico. The meetings were attended by Brazil, Canada, China, the European Union (EU), Ghana, Japan, Mexico, Norway, the United States (U.S.), the International Federation for Animal Health (IFAH), and Consumers International (CI). During the first session, participants outlined their individual positions on the issue of ractopamine MRLs and highlighted the critical elements behind those stances. Following this, FOTC members participated in an exercise that required them to specify the circumstances under which they could consider revising their positions. As the session concluded, FOTC participants expressed a clarified understanding of the important issues standing between them and their colleagues who maintained opposing positions.

FOTC 2: Brussels, Belgium

The second FOTC was held February 10-11 in Brussels, Belgium. The meetings were attended by Brazil, Canada, China, EU, Ghana, Japan, Mexico, Norway, South Africa, the U.S., IFAH, and CI. Following an open discussion to summarize individual national positions around the room, the meeting facilitators created two separate working groups. They charged one group with developing a compromise concept that operated on the premise of adoption, while the other team drafted a process built upon the notion of non-adoption. After the breakout groups crafted their individual concepts, the full FOTC reconvened to discuss them and assess their commonalities. Following the Brussels FOTC meetings, those concepts were circulated to the FOTC membership for further consideration and refinement.

FOTC 3: Beijing, China

The third FOTC was held April 26-27 in Beijing, China. The meetings were attended by Brazil, Canada, China, the EU, Ghana, Japan, Mexico, Norway, U.S., IFAH, and CI. The meeting began with another round of discussion regarding individual positions. A series of caucuses by the pro-adoption and non-adoption groups ensued, and those intertwined with full FOTC discussions. Ultimately, two proposals emerged at the conclusion of the Beijing FOTC meetings: one proposal focuses on the premise of adopting the JECFA-recommended MRLs; the other operates on the notion of non-adoption. FOTC agreed to remain in communications until the beginning of the 34th Session of the Codex Alimentarius Commission, and it will re-convene for a final FOTC meeting immediately prior to CAC.

Solution: Adoption of the Ractopamine MRLs for muscle, fat, liver and kidney tissues from cattle and pig

Based on the conclusive JECFA evaluation, including the consideration of the most recently submitted data (as a result of the 2009 call for data), it is recommended that CAC follows the recommendation of CCRVDF in adopting the Ractopamine MRLs for muscle, fat, liver and kidney tissues from cattle and pig. This decision is aligned with the CAC mandate to protect consumers' health and ensure fair practices in the food trade.

Possible compromise:

Adopt the Ractopamine MRLs for muscle, fat, liver and kidney tissues from cattle and pig and commit to undertake additional work associated with Ractopamine MRLs for other tissues of interest (e.g. MRLs for lung tissues), as a matter of priority and under the close monitoring for progress by CAC.

1) Description and Rationale of the option:

- The proposal to adopt the Ractopamine standards held at step 8 at the Codex Alimentarius Commission is based upon scientific advice from the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the recommendation of the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF), and the current Codex step process. It acknowledges the validity of JECFA's risk assessments undertaken in 2004, 2006 and 2010 and their recommended MRLs for Ractopamine (Ractopamine hydrochloride) in the target tissues (muscle, fat, liver and kidney) for cattle and pigs, as advanced through the Codex step process.
- This option supports the safe use of Ractopamine according to Codex guidelines relevant to good animal husbandry and good veterinary practices, as described in the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) and the *Codex Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).
- This proposal would also explicitly exclude pig lung tissue from the scope of the MRLs proposed for adoption, by the addition of a footnote to the standard as described below.
- The proposal takes note of the decision by CCRVDF in September 2010, to include Ractopamine in the "Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA" with a request for a recommended MRL for pig lung. The JECFA Secretariat has already issued a call for data as it recognizes that JECFA must establish a consumption factor for lung prior to establishing an MRL for pig lung tissue.
- The proposal also recognizes the priority given by CCRVDF to review the current food basket by requesting FAO/WHO to convene an expert consultation on dietary exposure assessment as it relates to veterinary drug residues in food, which would also consider enlarging the scope of the current food basket to include other tissues. The progress on these two commitments would be subject to close monitoring by the CAC

2) Proposed text for the Report of the 34th CAC

"The Commission decided to adopt the MRLs for Ractopamine (Ractopamine Hydrochloride) in the target tissues (muscle, fat, liver and kidney) for cattle and pig. This decision is based upon JECFAs' conclusive scientific risk assessments and CCRVDFs' recommendations. The Commission agreed to add a footnote to the standard, to explicitly exclude pig lung tissue from these MRLs. It was noted by the Commission that these MRLs are to be used in accordance with Codex guidelines such as *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) and the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004). Members were also encouraged to exchange information on best practices that support the safe use of Ractopamine.

The Commission noted the reservations expressed by the delegations of XXXXX (add countries with reservations), but also noted that these reservations were based upon concerns beyond the CAC mandate i.e. not relevant to the protection of consumers' health and ensuring fair practices in the food trade. The commission noted the commitment of new work to be conducted as a matter of priority, related to Ractopamine standards. In particular, it was noted that the CCRVDF has, in its 19th Session of 2010, given priority to establish a specific MRL for Ractopamine in pig lung tissue. This will help address concerns of some members due to their specific food consumption patterns. CCRVDF has also proposed revision of the current food basket and requested FAO/WHO to convene an expert consultation on dietary exposure assessment as it relates to veterinary drug residues in food. The Commission supported CCRVDF's recommendation that this work be conducted with the utmost level of priority. Progress will be monitored by the CCEXEC and CAC at their upcoming sessions"

3) Proposed listing of the adopted standard:

Ractopamine (Ractopamine Hydrochloride)				
Acceptable Daily Intake (ADI) 0-1 µg/kg of body weight				
1 µg/kg equals 1 part per billion				
Maximum Residue Limits (MRLs)				
Species	**Muscle (µg/kg)**	**Fat (µg/kg)**	**Liver (µg/kg)**	**Kidney (µg/kg)**
Cattle	10	10	40	90
Pigs	10	10	40	90

Footnote: These MRLs do not apply to pig lung tissue.

4) Work to be undertaken as a matter of priority, and to be monitored by the CAC in upcoming sessions

- Establishment of pig lung MRL for Ractopamine
- Review of CCRVDFs' current food basket

1) SOLUTION: DISCONTINUATION OF WORK

Based on the clear absence of consensus after discussion at CAC level in three consecutive sessions.

It should be noted that there are other examples where Codex has discontinued work on certain standards and guidelines because consensus was not achievable (e.g. Parmesan cheese).

2) POSSIBLE COMPROMISE: STANDARD PUT IN ABEYANCE UNTIL UNRESOLVED ISSUES ARE BEING ADDRESSED

2.1 Objectives of the proposal:

- Put the standard in abeyance until all unresolved issues have been addressed, as consensus is not yet reached;

- Recognize that some Codex members still have safety concerns especially vis-à-vis ADI for ractopamine, residues in lungs and other offal tissues (food basket, different risk assessments).

- In order to address the concerns voiced by several Codex members requesting an international scientific reference upon which national measures would be set, it is recalled that JECFA can directly provide advice to governments (CAC Procedural Manual 19th EN edition, paragraph 6 page 101); some specific text could already be included in the report of next CAC to encourage countries wishing to implement national MRLs for ractopamine to use the JECFA risk assessment and the draft MRLs already adopted by Codex. Proposed text e.g.:***"While no consensus could emerge on the final adoption of the proposals of MRLs for ractopamine due in particular to the fact that some members still had concerns about the adequacy of the JECFA risk assessment, the Commission recalled that the risk assessment process had been completed for fat, kidney, liver and muscle in cattle and pig by JECFA and that draft MRLs for ractopamine had been adopted at Step 5 at the 29th session of the CAC[1]. Consequently the Commission encouraged members willing to develop national sanitary measures on this matter to take the draft MRLs for Ractopamine as a basis."***

2.2 What needs to be achieved:

1. **MRLs for lungs**– A radiolabeled residue study shall be conducted and the data provided to JECFA for the purpose of deriving a porcine and a bovine lung MRL. The development of MRLs for lungs of other species could be considered in the future.

2. **Ractopamine Risk Assessment Summit**: The summit will bring together risk assessors who have contributed to risk assessments of ractopamine or have raised issues concerning the JECFA risk assessment of ractopamine, and should include risk assessors from JECFA, EFSA, China, US FDA, and other relevant scientists and risk assessors. The goal of the summit will be to (1) resolve any remaining methodological or other concerns between the findings of the various scientific bodies; (2) put the Chinese data on muscle, fat, kidney, and liver into context of the JECFA report.

3. **Re-evaluation of the components of the JECFA Food Basket** (on going) – JECFA issued a call for data, with the deadline for data submission on 31 January 2011. JECFA shall convene an expert panel to re-evaluate the current components of the food basket, and shall issue a final monograph. The JECFA secretariat will be working to prepare for and arrange the expert consultation on dietary exposure assessment, this should be advanced promptly for inclusion in future JECFA assessments.

4. **Consideration of other legitimate factors**, including consumer preferences and consumer acceptance of animal derived foods production aids (including non therapeutic use of veterinary drugs), environmental sustainability, animal welfare, food security etc…

5. **Information sharing mechanism with the view to bring clarity to the discussion on ractopamine**: This is to ensure that all delegations are apprised with information on the issues(e.g. listing of documents on Ractopamine, from sources (CODEX, JEFCA, EFSA, US-FDA) and sharing them through the codex website..

[1] ALINORM 06/29/41 Appendix V