28 April 2009

Codex Committee on Residues of Veterinary Drugs in Foods (18th Session) Natal, Brazil, 11-15 May 2009

European Community comments on the MRLs for Ractopamine

Agenda item 2, CX/RVDF 09/18/2

European Community competence
European Community vote

The 31st Codex Alimentarius Commission (CAC) agreed to hold the maximum residue limits (MRL) for ractopamine at Step 8 for further discussion at its next session in June-July 2009. It requested Members to submit information on the availability of scientific data to CCRVDF thus allowing for a possible decision by the 18th session of CCRVDF regarding the inclusion of ractopamine in the priority list of substances for re-evaluation by JECFA.

In order to respond to the request of CAC, the European Commission asked the European Food Safety Authority (EFSA) to review the JECFA risk assessment and other scientific information regarding the safety of ractopamine. EFSA also considered other relevant issues, particularly safety for the target species and product quality.

EFSA adopted the opinion on ractopamine on 2 April 2009. The full report is attached. It is also available on the EFSA website:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902436747.htm

The EFSA opinion points out a number of uncertainties and weaknesses in the data underlying the JECFA assessment which would undermine any proposal for MRLs for ractopamine. Most notably, it was found that the study on cardiovascular effects in humans cannot be taken as a basis to derive an Acceptable Daily Intake (ADI) of 0-1 µg/kg of body weight per day as proposed by JECFA. It was also considered that the human study presents a series of weaknesses and uncertainties (e.g. small sample size which does not allow detecting clinical relevant responses, lack of endpoints measuring extra cardiac effects) and that the safety factor applied by JECFA to derive the ADI did not sufficiently take into account population subsets at higher risk.

EFSA consulted the European Medicines Agency (EMEA) and included the results of this process in its final opinion. The Committee for Medicinal Products for Veterinary Use of the EMEA fully supported the EFSA safety evaluation of ractopamine.

The above facts clearly call for a re-evaluation of ractopamine by JECFA. Therefore, the EC requests CCRVDF to recommend the inclusion of ractopamine in the priority list of substances for re-evaluation by JECFA.