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# INFORMATION SHEET

# DISCUSSION ON RACTOPAMINE IN CODEX AND IN THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

**(prepared by the Codex and JECFA Secretariats)**

## BACKGROUND

### What ractopamine is

Ractopamine is a synthetic substance that is used as a veterinary drug in animal feed to promote muscle growth in approved food animal species, namely pigs and cattle and, to a limited extent, heavy turkeys.. Ractopamine is not approved for use in humans for any medical purpose.

### How does ractopamine work

When used as a veterinary drug in animal feed ractopamine is readily absorbed, distributed and eliminated via urine and faeces. It is distributed to muscle tissues where it binds to specific receptors in the muscle cell membranes and initiates an increase in protein synthesis, resulting in increases in muscle fiber size. It also increases feed efficiency in food animals. It is intended only for use in mature (finishing) animals (e.g. pigs greater than 110 kg) prior to slaughter.

### Registered regulatory use of ractopamine

At country level regulatory approval processes for veterinary drugs require that a substance be safe and effective in the target animal and result in food products that are safe for human consumption. The safe concentrations for residues in foods of veterinary drugs have been published by the competent regulatory authorities in countries where the veterinary drug is registered for use. Ractopamine is currently allowed to be used as growth promoters to increase lean muscle mass in pigs and cattle in around 25 countries worldwide.

## DISCUSSION IN CODEX AND JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Codex does not address the authorisation of use of veterinary drugs in food producing animals but establishes Maximum Residue Levels (MRLs) for veterinary drugs in foods, as recommendation for national authorities. Codex has developed 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,* which provide governments with adequate criteria for the selection of drugs and their use in food producing animals and the subsequent determination of related residues in their products.

For its recommendations on residues of veterinary drugs in food, Codex relies on the scientific assessment of the FAO/WHO Expert Committee on Food Additives (JECFA) and the recommendations of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

### JECFA's Evaluation of Ractopamine

JECFA has reviewed the available data on ractopamine and performed comprehensive risk assessments considering its toxicology, residues in and intake from food animals in 1993, 2004, 2006 and in 2010.

JECFA considered ractopamine for the first time at its 40th meeting in 1993; however, the data submitted were inadequate to establish an ADI[1] (Acceptable Daily Intake). In 2004, the 62nd JECFA meeting established

[1] An estimate of the amount of a substance in food or drinking water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg). The ADI is listed in units of mg per kg of body weight (JECFA Glossary of terms).

an ADI and recommended MRLs for ractopamine in cattle and pig tissues (muscle, liver, kidney and fat) for consideration by the CCRVDF. The JECFA established the ADI based on an acute cardiac response from a human study, noting that there was a wide margin of safety. In 2006, the 66th JECFA meeting further considered ractopamine and reconfirmed the ADI and MRLs of its previous meeting.

In 2010, at the request of the Codex Alimentarius Commission, JECFA undertook a review of new data on residues of ractopamine in pig tissues including lung, heart, large and small intestines and considered whether these data would have any implication on the recommended MRLs. Based on the data provided, including information on dietary consumption, JECFA concluded that the recommended MRLs are compliant with the ADI for consumption of muscle, liver, kidney and fat.

The published JECFA risk assessments and reviews are available in the WHO Technical Report Series available on: http://www.who.int/foodsafety/chem/jecfa/publications/reports/en/index.html and in FAO Residue Monographs available on: http://www.fao.org/ag/agn/jecfa-vetdrugs/search.html.

## Codex Alimentarius Commission consideration of MRLs for Ractopamine

The CCRVDF included ractopamine in the priority list of substances to be evaluated by JECFA at its seventh and thirteenth sessions, in 1992 and 2003 respectively, and considered the recommendations of the 62nd and 66th JECFA meetings at its fifteenth, sixteenth and seventeenth sessions in 2004, 2005 and 2007, respectively.

At its seventeenth session (2007) the CCRVDF, noting that the justification for not supporting the advancement of the MRLs was not based on scientific arguments, agreed that the MRLs for ractopamine in cattle and pig tissues could be adopted by the Codex Alimentarius Commission and become Codex MRLs.

The Codex Alimentarius Commission has discussed the MRLs for ractopamine at its 31st, 32nd, 33rd and 34th sessions in 2008, 2009, 2010 and 2011, respectively. The discussion on the adoption of the MRLs for ractopamine is still ongoing in the Codex Alimentarius Commission, which is striving to find consensus among Codex Members supporting their adoption and those opposing.

Countries supporting the adoption of the MRLs noted that the MRLs for ractopamine were based on JECFA risk assessment and that the concern for residues in lung tissues was outside the scope of the MRLs under consideration. They also noted that JECFA had reviewed the MRLs three times and fulfilled its task by considering all available data. Countries opposing to the adoption of MRLs for ractopamine continued to be concerned with the safety of ractopamine, particularly with respect to the residues in lung tissue. These countries also noted that the use of veterinary drugs solely for growth promotion, without any therapeutic purposes is not allowed in many countries.

The Codex Alimentarius Commission, will continue its discussion on the MRLs for ractopamine, currently at Step 8, at its 35th session, which will be held at FAO Headquarters (Rome, Italy) on 2-7 July 2012.

Report of the meetings of the Codex Alimentarius Commission and CCRVDF are available on the Codex website: www.codexalimentarius.org.