



**Food and Agriculture  
Organization  
of the United Nations**



**World Health  
Organization**

***JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)***

**Veterinary Drug Residues in Food**

**REQUEST FOR DATA FOR EVALUATION OF RESIDUES OF RACTOPAMINE IN PIG TISSUES**

Issued 4 November 2009

With reference to the request of the Codex Alimentarius Commission at its thirty-second session (Rome, Italy 29 June – 4 July 2009, ALINORM 09/32/REP) to undertake a review of new data on residues of ractopamine in pig tissues, a summary of which was submitted to the eighteenth session of the Codex Committee on Residues of Veterinary Drugs in Food by China, the Secretariat of JECFA at FAO and WHO requests the submission of these data and any other pertinent information related to depletion of residues of ractopamine in pig tissues.

Ractopamine has been evaluated by JECFA at the fortieth, sixty-second and sixty-sixth meetings of the Committee. An ADI of 0 – 1.0 µg/ kg bodyweight was established at the sixty-second meeting and full MRLs were recommended for tissues of cattle and pigs. The MRL recommendations were confirmed by the sixty-sixth meeting of the Committee.

***Submission of data***

Governments, interested organizations, producers of these chemicals, and individuals are invited to submit data relating to residue depletion of ractopamine in pig tissues. The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference should be made to related published studies, where applicable. Summaries in the form of monographs are helpful, but they are not in themselves sufficient for evaluation.

Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA. Summaries of the studies will be published by FAO and WHO after the meetings in the form of specifications and toxicological monographs.

FAO and WHO have only limited data storage capacity. The submitted data can either be returned to submitters at their expense or destroyed after the evaluations have been completed. Please indicate the preferred procedure for data disposal at the time of submission. Key material can be stored up to five years and will then be destroyed. For substances that are being re-evaluated, the FAO and WHO Secretariats of JECFA encourage the sponsor to contact them before submission of data to determine whether documents and data reviewed at previous meetings of the Committee should be re-submitted.

The secretariats of JECFA at FAO and WHO encourage electronic submissions. Such data should be presented preferably using standard word processing or document formats, and should be submitted on CD-ROMs. To facilitate review, an effort should be made to provide a “Table of contents” on each CD-ROM using fully descriptive file names.

**Date for submission**

The submission of data is requested before

**15 December 2009.**

This deadline applies to all data to be submitted.

**Data that would be relevant to submit**

Studies on residues of ractopamine in pig tissues, including:

1. Chemical identity and properties of the drug;
2. Its use and dosage range;
3. Pharmacokinetic and metabolic studies;
4. Residue-depletion studies with radiolabelled drug in target animals from zero withdrawal time to periods extending beyond the recommended withdrawal time (these studies should provide information on total residues, including free and bound residues, and major residue components to permit selection of a marker residue and target tissue);
5. Residue-depletion studies with unlabelled drug for the analysis of marker residue in the target animals (these should include studies with appropriate formulations, routes of application, and species, at doses up to the maximum recommended), including all individual data;
6. A description of the analytical procedures used by the sponsor for the detection and determination of parent drug residues with information on validation and performance characteristics.

The data should be submitted to the address below:

Nutrition and Consumer Protection Division  
Attention: Dr. Annika Wennberg  
Food and Agriculture Organization of the United Nations  
Via delle Terme di Caracalla  
00153 Rome  
Italy  
Facsimile: (+39) 06 5705 4593  
Telephone: (+39) 06 5705 3283  
E-mail: [annika.wennberg@fao.org](mailto:annika.wennberg@fao.org)

**Presentation of data**

Please note that the above lists are not meant to be all-inclusive since it is recognized that other studies may, in some instances, assist in the evaluation.

All relevant data, both positive and negative, should be submitted. Data should be presented, summarized and referenced in a clear and concise manner, as described in the guidelines which are available at:

[http://www.fao.org/ag/agn/agns/jecfa\\_guidelines\\_1\\_en.asp](http://www.fao.org/ag/agn/agns/jecfa_guidelines_1_en.asp)

[http://www.who.int/ipcs/food/jecfa/en/guidelines\\_vet\\_drugs.pdf](http://www.who.int/ipcs/food/jecfa/en/guidelines_vet_drugs.pdf)

## **References**

1. Report of the thirty-second session of the Codex Alimentarius Commission, Rome, Italy, 29 June-4 July, 2009 (ALINORM 09/32/REP).
2. Report of the eighteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods, Natal, Brazil, 11-15 May 2009 (ALINORM 09/32/31).
3. Evaluation of certain veterinary drug residues in food (Fortieth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 832, 1993.
4. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper, No. 41/5, 1993.
5. Evaluation of certain veterinary drug residues in food (Sixty-second report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 925, 2004.
6. Toxicological evaluation of certain veterinary drug residues in food. WHO Food Additives Series, No. 53, 2005.
7. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper, No. 41/16, 2004.
8. Evaluation of certain veterinary drug residues in food (Sixty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 939, 2006.
9. Residue evaluation of certain veterinary drugs. Joint FAO/WHO Expert Committee on Food Additives, 66<sup>th</sup> meeting. FAO JECFA Monographs 2, 2006.