



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES**  
***Eighty-fifth meeting***

**Veterinary Drug Residues in Food**  
**Geneva – Switzerland, 24 October to 2 November 2017**  
Published 14 November 2016

**LIST OF SUBSTANCES SCHEDULED FOR EVALUATION  
AND REQUEST FOR DATA**

Attached is the list of substances (Annex 1) scheduled for evaluation or re-evaluation at the Eighty-fifth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This list has been prepared by the Joint FAO/WHO Secretariat of the Committee and is based on recommendations of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) and previous provisional decisions of JECFA.

***Submission of data***

Annex 1 lists the veterinary drugs to be considered at the meeting. Governments, interested organizations, producers, and individuals are invited to submit data relating to the listed compounds. The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. References to relevant published studies should also be provided, 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Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA.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 residues 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 **preferably on USB-sticks**. To facilitate review, an effort should be made to provide a “Table of contents” on each drive using fully descriptive file names.

**Date for submission**

The submission of data on those compounds listed in Annex 1 is requested before

**31<sup>st</sup> March 2017**

This deadline applies to all data to be submitted.

**Toxicological data**

Data relevant to the toxicological evaluations of the substances on the agenda include the results of studies on:

1. Biochemical data: pharmacokinetic, metabolic, and pharmacodynamic studies in experimental and food-producing animals, and in humans when available, effects on enzymes and other biochemical parameters;
2. Toxicological studies: acute toxicity, short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity and developmental toxicity studies in experimental animals and genotoxicity studies;
3. Studies providing relevant data on the exposure to the compound by humans, including studies of effects observed after occupational exposure and epidemiological data following use in humans;
4. Special studies designed to investigate specific effects of the compound, such as neurotoxicity, immune responses, mechanism of toxicity, or macromolecular binding.
5. Data, studies or reasoned argument to determine the toxicological relevance of metabolites and degradates<sup>a</sup>.
6. For compounds with antimicrobial activity, studies designed to evaluate the possibility that residues of the compound might have an adverse effect on the microbial ecology of the human intestinal tract;
7. Information on registration status and existing assessments of the compound.

Three copies of the data are required, one for submission to the address below, one for submission directly to the WHO Expert who will be reviewing the data (if requested a paper copy should also be provided), and one for the Member assigned to peer review the working paper. Please contact the WHO Joint Secretary prior to submission of the data for information on where to send the copies.

Attention: Dr Philippe Verger  
Department of Food Safety and Zoonoses  
World Health Organization  
Avenue Appia  
1211 Geneva 27  
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Facsimile: +41 (0) 22 791 4807  
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<sup>a</sup> This should include within the toxicological dossier a summary table for the occurrence of parent compounds, metabolites and degradates in various crops and animals. Where metabolites may be formed by alternate pathways in test species, evidence should be provided for the extent of exposure to intermediate metabolite(s), if these could be toxicologically relevant.

**Data relevant to recommending MRLs**

Data relevant to the evaluation of residues in food products of animal origin, including:

1. Chemical identity and properties of the drug;
2. Drug use and dosage range;
3. Pharmacokinetic and metabolic studies in experimental animals, target animals, and humans if available (information required by both FAO and WHO);
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 marker residue and target tissues);
5. Residue-depletion studies with unlabelled drug for the analysis of marker residue in target animals and in eggs, milk, and honey (these should include studies with appropriate formulations, routes of application, and species, at doses up to the maximum recommended);
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;
7. A review of routine analytical methods that may be used by regulatory authorities for the detection of residues in target tissue, including information on quality assurance systems and sampling procedures recommended; and
8. Information on registration status of veterinary drugs and on approved conditions of use

Three copies of the data are required, one for submission to the address below, and two for submission directly to the FAO experts who will be reviewing the data. Please contact the FAO Joint Secretariat prior to submission of the data for information on where to send the copies.

Attention: Dr Markus Lipp  
Food Safety and Quality Unit - Room C- 278  
Agriculture and Consumer Protection Department (AG)  
Food and Agriculture Organization of the United Nations  
Viale delle Terme di Caracalla  
00153 Rome  
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Facsimile: +39 06 5705 4593  
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E-mail: [jecfa@fao.org](mailto:jecfa@fao.org)

**Presentation of data**

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

Procedures for the evaluation of chemicals in food were updated and published by FAO and WHO as *Methods and Principles for the Safety Assessment of Food Additives and Contaminants in Food* – Environmental Health Criteria No. 240, available at <http://www.who.int/foodsafety/publications/chemical-food/en/>

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/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/>  
<http://www.who.int/foodsafety/chem/jecfa/guidelines/en/index.html>

**Annex 1****Joint FAO/WHO Expert Committee on Food Additives (JECFA)  
Geneva – Switzerland, 24 October to 2 November 2017****List of substances scheduled for evaluation or re-evaluation**

General information: Links to available electronic versions of the reports published in the WHO Technical Report Series, toxicological monographs published in the WHO Food Additives Series and residue monographs published in the FAO JECFA Monograph series and the FAO Food and Nutrition Paper 41 series that are referenced below are available at the JECFA web-pages of FAO and WHO. FAO and WHO procedural guidelines and guidelines for the preparation of toxicological working papers and guidelines for the preparation of working papers on the residue evaluation are available from the JECFA Secretariats or at <http://www.who.int/foodsafety/chem/jecfa/guidelines/en/> and <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/guidelines0/en/>.

**Note: It is necessary to consult the requirements and background, including previous evaluations, as contained in previous reports and monographs of the Committee before submitting data.**

<b>Substance</b>	<b>References</b>	<b>Data required</b>
<b>New evaluations/ re-evaluations</b>		
Amoxicillin	Appendix VI of the report of the twenty-third session of CCRVDF <sup>(1)</sup> . An ADI of 0-0.07 mg/kg bw was established by JECFA in 2011 <sup>(5)</sup> . MRLs were established for meat and milk.	All data necessary to assess the risk, establish relevant Health Based Guidance Values and recommend MRLs in fin fish muscle and skin in natural proportions.
Ampicillin	Appendix VI of the report of the twenty-third session of CCRVDF <sup>(1)</sup> .	All data necessary to assess the risk, establish relevant Health Based Guidance Values and recommend MRLs in fin fish muscle and skin in natural proportions.
Bismuth sub-nitrate	Appendix VI of the report of the twenty-third session of CCRVDF <sup>(1)</sup> .	All data necessary to assess the risk, establish relevant Health Based Guidance Values and recommend MRLs in cattle milk.
Ethion <sup>a</sup>	<u>Decision of the CCRVDF to include in the priority list in the absence of commitment from sponsor (see para.134-138 of the report of the twenty-third session of CCRVDF<sup>(1)</sup>)</u> Evaluated by JMPR <sup>(2)</sup> in 1990, ADI established at 0-0.002 mg/kg bw (1990). Not supported by original sponsor, not scheduled for periodic re-evaluation by JMPR.	All data necessary to assess the risk, establish relevant Health Based Guidance Values and recommend MRLs in cattle tissues.

<sup>a</sup> Recognizing the possibility of limited proprietary data for the evaluation of ethion, data resulting from a comprehensive search of the available published literature are particularly requested, and should be submitted to JECFA.

Flumethrin	Appendix VI of the report of the twenty-third session of CCRVDF <sup>(1)</sup> . ADI set by JMPR <sup>(3)</sup> at 0-0.004 mg/kg bw (1996). Scheduled for periodic re-evaluation by JMPR in 2018.	All data necessary to assess the risk and establish relevant Health Based Guidance Values for this compound - prioritized both by CCRVDF and CCPR (periodic re-evaluation in 2018) - and recommend MRLs in honey.
Halquinol	Appendix VI of the report of the twenty-third session of CCRVDF <sup>(1)</sup> .	All data necessary to assess the risk, establish relevant Health Based Guidance Values and recommend MRLs in swine tissues
Lufenuron	Appendix VI of the report of the twenty-third session of CCRVDF <sup>(1)</sup> . Evaluated by JMPR <sup>(4)</sup> in 2015, ADI established at 0-0.02 mg/kg bw. ARfD not necessary.	All data necessary to assess the risk, establish relevant Health Based Guidance Values and recommend MRLs in fin fish (salmon/trout) muscle and skin in natural proportions
Monepantel	An ADI of 0-0.02 mg/kg bw was established by JECFA in 2013 <sup>(6)</sup> . MRLs were established for sheep tissues.	All data necessary to recommend MRL in cattle tissues

Substance	References	Data required
<b>Follow-up evaluations to JECFA 81</b>		
Diflubenzuron	Evaluated by JECFA in 2015 <sup>(7)</sup> . No ADI was established and no MRLs were recommended.	Toxicity and/or occurrence data for 4-chloroaniline (PCA) in fish to allow establishing an ADI and recommend MRLs in fish
Sisapronil	Evaluated by JECFA in 2015 <sup>(7)</sup> . No ADI was established and no MRLs were recommended.	Additional data on long term toxicity to enable establishing an ADI and recommend MRLs.
Zilpaterol	Evaluated by JECFA in 2013 and 2015 <sup>(6, 7, 8)</sup> . An ADI of 0-0.00004 mg/kg bw and an ARfD of 0.00004 mg/kg bw were established by JECFA in 2015 <sup>(7,8)</sup> , and MRLs were established for cattle tissues.	Data on relative bioavailability.

### References

1. Report of the twenty-third session of the Codex Committee on Residues of Veterinary Drugs in Foods. Houston (TX), United States of America, 16 – 20 October 2016. [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-730-23%252FReport%252FFinal%252FREP17\\_RVDF.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-730-23%252FReport%252FFinal%252FREP17_RVDF.pdf)
2. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group, FAO Plant Production and Protection Paper, 102, (1990). <http://apps.who.int/pesticide-residues-jmpr-database/pesticide?name=ETHION>
3. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group, FAO Plant Production and Protection Paper, 140, (1996). <http://apps.who.int/pesticide-residues-jmpr-database/pesticide?name=FLUMETHRIN>

4. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group, FAO Plant Production and Protection Paper, 223, (2015). <http://apps.who.int/pesticide-residues-jmpr-database/pesticide?name=Lufenuron>
5. Evaluation of certain veterinary drug residues in food (Seventy-fifth meeting of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 969, 2011 [http://whqlibdoc.who.int/publications/2012/9789241209694\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241209694_eng.pdf)
6. Evaluation of certain veterinary drug residues in food (Seventy-eight meeting of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 988, 2013 [http://apps.who.int/iris/bitstream/10665/127845/1/9789241209885\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/127845/1/9789241209885_eng.pdf)
7. Evaluation of certain veterinary drug residues in food (Eighty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 997, 2015 [http://apps.who.int/iris/bitstream/10665/204670/1/9789240695504\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/204670/1/9789240695504_eng.pdf)
8. Residue Evaluation of Certain Veterinary Drugs, eighty-first meeting. FAO JECFA Monographs 18, 2015. <http://www.fao.org/documents/card/en/c/1cc884f7-c40c-4a9d-a8ec-48533c709656/>

**Annex 2****JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES****BACKGROUND**

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) was established in the mid-1950s by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to assess chemical additives in food on an international basis. The first meeting was held in 1956 in response to recommendations made at an FAO/WHO Conference on Food Additives that met in Geneva in 1955.

In the early 1960s the Codex Alimentarius Commission (CAC), which is an international intergovernmental body, was established. The primary aims of the CAC are to protect the health of the consumer and facilitate international trade in food. At the time that the CAC was formed it was decided that JECFA would provide expert advice to Codex on matters relating to food additives. A system was established whereby the Codex Committee on Food Additives, a general subject committee, identified food additives that should receive priority attention, which were then referred to JECFA for assessment before being considered for inclusion in Codex Food Standards.

This system is still in place, but it has been expanded to include food contaminants and residues of veterinary drugs in food to provide advice to the presently-existing Codex Committee on Food Additives (CCFA), Codex Committee on Contaminants in Food (CCCF) and Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). JECFA also provides scientific advice directly to FAO and WHO Member States, and requests for assessment may come directly from them. JECFA is not a component of the CAC.

Specialists invited to serve as Members of JECFA are independent scientists who serve in their individual capacities as experts, and not as representatives of their governments or employers. The goal is to establish safe levels of intake and to develop specifications for identity and purity (food additives) or maximum residue limits when veterinary drugs are used in accordance with good practice in the use of veterinary drugs.

Through 2016, a total of eighty-three meetings of JECFA have been held. The reports are published in the WHO Technical Report Series (<http://www.who.int/foodsafety/publications/jecfa-reports/en/>). The toxicological evaluations, that summarize the data that serve as the basis for the safety assessments, are published in the WHO Food Additives Series <http://www.who.int/foodsafety/publications/monographs/en/>). The specifications and veterinary drug residue evaluations are published in the FAO JECFA Monographs and are available at <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/>. The Combined Compendium of Food Additive Specifications of all current JECFA specifications is available on-line <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. The updated database on specifications for flavouring agents is available at <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>. The updated database on residues of veterinary drugs in food is available at <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-vetdrugs/en/>

A *Summary of Evaluations* performed by the Joint FAO/WHO Expert Committee on Food Additives, a comprehensive searchable database that summarizes all JECFA evaluations from the first through recent meetings, is available at <http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx>