



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**  
**28<sup>th</sup> Session**  
**23-27 March 2026**

**Minneapolis, Minnesota, United States of America**

**REPORT OF THE WORKING GROUP ON THE PRIORITY LIST OF VETERINARY DRUGS  
REQUIRING EVALUATION OR RE-EVALUATION BY JECFA**

## Introduction

1. The physical working group (PWG) on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA was held on Sunday 22 March 2026 and chaired by James Deller (Australia). The PWG Chair reminded the PWG of the prioritization criteria and advised that document CX/RVDF 26/28/12 had been prepared for CCRVDF28 to communicate comments received in response to circular letter CL 2026/15-RVDF which was issued in January 2026.

## Update for compounds included on the Priority List for JECFA evaluation / re-evaluation at CCRVDF27

2. At CCRVDF27 in October 2024, six nominations and one concern form were included on the priority list. The delivery dates proposed for the dossier submission ranged from November 2024 to December 2026. JECFA has not met since October 2024 and updates on these previous nominations were sought to identify those which could be referred to JECFA for assessment at the next meeting. JECFA indicated that the data call in for the next JECFA meeting would likely be distributed soon after CCRVDF28 with a closing date in the Northern Hemisphere Summer (July 2026).
3. Umifoxolaner, a parasiticide compound, was included on the priority list as a parallel review (see Appendix 5). The request was for consideration of toxicology data and residue studies for cattle. It was nominated by Brazil and the date of dossier availability which was advised at CCRVDF27 was December 2024. The PWG was advised that the complete dossier will be available for submission by the next JECFA data call in, and that the nomination remains as a parallel review as the Brazilian registration process is ongoing.
4. Bromoform, an environmental inhibitor, was included on the priority list as a parallel review. The request was for consideration of toxicology data and residue studies for ruminants (cattle). It was nominated by New Zealand and the date of dossier availability which was advised at CCRVDF27 was July 2025. The PWG was advised that the complete dossier should be available for submission by Quarter 1 2027. The dossier for bromoform will therefore not be ready for the next JECFA data call and data availability should be confirmed at the next CCRVDF.
5. Amoxicillin, an antimicrobial compound, was included on the priority list for consideration of residue studies for chicken tissues (see Appendix 2). It was nominated by Chile and the date of dossier availability which was advised at CCRVDF27 was 31 March 2025. The PWG was advised that the complete dossier should be available by the next JECFA data call in.
6. Amoxicillin was also included on the priority list for consideration of residue studies for chicken eggs (see Appendix 3). It was nominated by the Republic of Korea and the date of dossier availability which was advised at CCRVDF27 was 30 September 2025. The PWG was advised that the complete dossier should be available by the next JECFA data call in.
7. Ethion, a parasiticide, was included on the priority list for consideration of additional data to support MRLs for cattle tissues. JECFA (85th meeting, 2018) previously had requested additional data/scientific argument to enable MR and MR:TR to be determined as well as analytical methodology. It was nominated by Argentina, Costa Rica and Uruguay and the date of dossier availability which was advised at CCRVDF27 was 31 December 2025. The PWG was advised by Uruguay that the completion of the studies had been further delayed and that

it was now expected that the dossier will be ready for submission in 2027. The dossier for ethion will therefore not be ready for the next JECFA data call and data availability should be confirmed at the next CCRVDF.

8. Fumagillin dicyclohexylamine (DCH), an antimicrobial compound, was included on the priority list for consideration of metabolism data and residue studies for DCH for trout tissues (see Appendix 4). It was nominated by the Republic of Korea and the date of dossier availability which was advised at CCRVDF27 was 31 December 2026. The PWG was advised that the complete dossier of additional studies for DCH in rainbow trout should be available by the next JECFA data call in and that monitoring data for rainbow trout and salmon would also be provided. The Republic of Korea later clarified to the PWG Chair that they have monitoring data for rainbow trout and eels, and not for salmon.
9. A concern form for Fumagillin dicyclohexylamine (DCH) was also included on the priority list at CCRVDF27. Canada and United States of America committed to submit a concern form by November 2024 to request JECFA reconsider the recommendations from JECFA98 for fish fillet and honey. The PWG was advised that the concerns raised in the concern form remain and that Canada has an additional study in honey to submit by the next JECFA data call in.

Recommendation 1: That umifoxolaner (cattle tissues) be included on Part IV of the priority list as the nomination is for parallel review and because data should be available for submission by the next JECFA data call in (see Appendix 1).

Recommendation 2: That bromoform (ruminant tissues and milk) remain on Part IV of the priority list with a note advising that data availability should be confirmed at the next CCRVDF, noting that the PWG was advised that data would likely be ready for submission in 2027, after the next JECFA call for data is expected to close (see Appendix 1).

Recommendation 3: That amoxicillin (chicken tissues and chicken eggs) and fumagillin (new study on rainbow trout and consideration of the concern form with a new honey study from Canada) be included on Part I of the priority list as data should be available for submission by the next JECFA data call in (see Appendix 1).

Recommendation 4: That ethion (cattle tissues) remain on Part I of the priority list with a note advising that data availability should be confirmed at the next CCRVDF, noting that the PWG was advised that data would likely be ready for submission in 2027, after the next JECFA call for data is expected to close (see Appendix 1).

#### **Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation**

10. Doramectin acute reference dose (ARfD): Doramectin has been assessed by JECFA in 1995, 1998, and 2002, resulting in the assignment of an ADI and MRLs for cattle and pig tissues. In response to CL 2026/15-RVDF, the United States nominated doramectin for consideration of an ARfD (see Appendix 6). The Sponsor has confirmed that a comprehensive toxicology dossier will be ready for submission by the next call for data. The PWG considered that this nomination met the nomination criteria.
11. Ketoprofen in cattle tissues: In response to CL 2026/15-RVDF, the United States nominated ketoprofen for consideration of an ADI, ARfD and MRLs for cattle tissues (muscle, fat, liver and kidney) (see Appendix 7). Ketoprofen has not been previously assessed by JECFA. GVP is established for ketoprofen which is available as a commercial injectable product in the United States. The Sponsor has confirmed that a comprehensive toxicology and residue dossier will be ready for submission by the next call for data. The PWG considered that this nomination met the nomination criteria.
12. Pradofloxacin in cattle and pig tissues: In response to CL 2026/15-RVDF, the United States nominated pradofloxacin for consideration of an ADI, ARfD and MRLs for cattle and pig tissues (muscle, fat, liver and kidney) (see Appendix 8). Pradofloxacin has not been previously assessed by JECFA. GVP is established for pradofloxacin which is available as commercial injectable products in the United States. The Sponsor has confirmed that a comprehensive toxicology, metabolism, residue and analytical methodology dossier will be ready for submission at the next call for data. The PWG considered that this nomination met the nomination criteria.

Recommendation 5: Approve the nominations for doramectin, ketoprofen and pradofloxacin for inclusion on the priority list as data should be available for submission by the next JECFA data call in.

13. Sulphonamides in honey: In response to CL 2026/15-RVDF, Egypt nominated the sulphonamide group (various compounds), for consideration of potential residues in honey. The PWG was advised that a new published analytical method was available, however additional metabolism and residue data was not available at this time. The PWG considered that this nomination did not meet the nomination criteria, however the PWG Chair encouraged members and observers to consider if data for sulphonamide compounds in honey could be made available to support a nomination at the next session of CCRVDF.

14. Nitrofurans in casings from offal: In response to CL 2026/15-RVDF, Egypt nominated nitrofurans including nitrofurantone, furazolidone, nitrofurazone and furaltadone, for consideration of potential residues in casings from offal matrix. JECFA has previously completed an evaluation for nitrofurans and Codex MRLs could not be established. CCRVDF has previously agreed to the risk management recommendation to communicate that significant health concerns were identified, and that semicarbazide is not a unique marker. The PWG was advised that a new published analytical method was available, however additional toxicology, metabolism, residue data was not available at this time. As there was no commitment at this session of the PWG on Priorities for submission of a complete dossier that may allow JECFA to complete a re-assessment of nitrofurans, the PWG considered that this nomination did not meet the nomination criteria.
15. Egypt expressed their view that the risk management advice recommendation for nitrofurans could be improved to clarify the scope of “food” to explicitly include food of animal origin, including edible offal. The PWG Chair advised that the discussion on the potential for amending agreed risk management recommendations for nitrofurans, was out of scope of the PWG on priorities.

#### Part V. Veterinary drug for extrapolation of MRLs to other species

16. In response to CL 2026/15-RVDF, New Zealand nominated 11 compounds for which cattle tissue and/or milk MRLs are established by Codex, for extrapolation to cover sheep and goat milk and sheep, goat and deer tissues.
17. The PWG Chair noted that extrapolated codex MRLs are currently presented on a different list to other MRLs in the Codex Database and that extrapolated MRLs are already established for three of the compounds which were nominated by New Zealand, specifically benzilpenicillins, tetracyclines and deltamethrin. No further consideration was required for these three compounds.
18. The PWG Chair presented a proposal for eight compounds nominated by New Zealand, specifically, abamectin, cypermethrin (alpha), dexamethasone, doramectin, eprinomectin, fenbendazole/oxfenbendazole, sulphadimidine and tylosin. The proposal was that extrapolation proposals be considered for Tissues or Tissues and milk of ‘All other ruminants’ based on the existing codex MRLs. For sulfadimidine, the PWG discussed if extrapolation to tissues was required as the current tissues MRLs are for ‘species not specified’ and it was recommended that tissues be included in scope for consideration in addition to milk.

Recommendation 6: Approve the below nominations Veterinary drug for extrapolation of MRLs to other species (see Appendix 1):

Compound	Current Codex MRLs	Extrapolation proposals
Abamectin	Cattle tissues	Tissues of ‘All other ruminants’
Cypermethrin (alpha)	Cattle and sheep tissues	Tissues of ‘All other ruminants’
Dexamethasone	Cattle, horse and pig tissues, cattle milk	Tissues and milk of ‘All other ruminants’
Doramectin	Cattle and pig tissues, cattle milk	Tissues and milk of ‘All other ruminants’
Eprinomectin	Cattle tissues, cattle milk	Tissues and milk of ‘All other ruminants’
Fenbendazole/oxfenbendazole	Cattle, goat, horse, pig and sheep tissues, cattle and sheep milk	Tissues and milk of ‘All other ruminants’
Sulfadimidine	Tissues (species not specified), cattle milk	Tissues and milk of ‘All other ruminants’
Tylosin	Cattle, chicken pig and sheep tissues, cattle milk	Tissues and milk of ‘All other ruminants’

#### Part VI. Establishment of Action Levels for veterinary drugs in food

19. No new nominations for the establishment of Action Levels for veterinary drugs in food were made.

**Priority list nomination templates**

20. Members and observers were invited to provide their views on whether there was a need to develop specific templates for the submission of nominations of compounds for MRL extrapolation and action levels, as well as for new compounds for JECFA evaluation under the “parallel review”, whether the current template could be amended or whether a template was needed at all. The current template is provided in Annex A to the *Risk analysis principles applied by CCRVDF*.

**Part 1 and Part IV template**

21. The PWG received general agreement that a template was required and the current questions within the template were appropriate for new nominations and parallel reviews. The PWG Chair proposed that two additional questions be included to help in considering the nominations. The two proposed ‘yes/no’ questions would be included under the administrative information section of the nomination form and were:
- Is this nomination for a parallel review?
  - Is this compound a dual use compound that can be applied to crops as a pesticide?
22. There was general support for the proposed additional questions for the nomination template for Part 1 and Part IV of the priority list. It was however raised that while this information could be useful, it should not impact the consideration of parallel assessments or hold up an assessment because another committee (e.g. CCPR) was about to start a consideration process of a dual use compound.

**Recommendation 7:** Approve the proposed additions to the Nomination template for new uses and parallel reviews (see Appendix 9).

**Part V template**

23. In response to the question about the need for a specific template for extrapolation nominations which was asked in CL 2026/15-RVDF, a Member made a proposal for a specific template in CX/RVDF 26/28/12 noting that the existing form for new uses and parallel reviews is unnecessarily detailed for extrapolation requests. The PWG supported the proposal with one modification: to make the request for the nominator to provide a brief analysis on if the extrapolation criteria would likely be met an optional requirement noting that the EWG on Extrapolation would perform the analysis against the extrapolation criteria.
24. The PWG agreed to take this proposal (see Appendix 10) for a specific template for nominations for Part V. Veterinary drug for extrapolation of MRLs to other species for to plenary for consideration.

**Recommendation 8:** Approve specific template for nominations for Part V. Veterinary drug for extrapolation of MRLs to other species (see Appendix 10).

25. The PWG considered the need for a template for the establishment of action levels for veterinary drugs in food but decided not to progress this at this session noting the ongoing work with regards to carry-over (Agenda Item 8.1 and 8.2).

**Other matters of relevance to the PWG on the priority list of veterinary drugs**

26. The PWG Chair informed the PWG that that CCPR established Codex MRLs for flumethrin in cattle meat and milk in 1999 with MRL for cattle meat (fat) at 0.2 mg/kg and milk at 0.05 mg/kg which were to accommodate external animal treatments. Codex MRLs established by CCPR are subject to periodic review requirements and that flumethrin was proposed for periodic review at CCPR56 in September 2025. In the absence of support or commitment of data from a member of sponsor, flumethrin was referred to an ‘unsupported compound’ electronic working group.
27. The PWG chair informed the PWG that unless there is a commitment for data, the Codex MRLs established for flumethrin may be revoked by CCPR.

## Appendix 1: Priority list of veterinary drugs for evaluation or re-evaluation by JECFA

Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
<b>PART I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation</b>					
Doramectin	Request for ARfD	GVP is established for doramectin which is available as a commercial injectable product in numerous countries, including the United States.	United States of America	Doramectin has been assessed by JECFA in 1995, 1998, and 2002, resulting in the assignment of an ADI and MRLs for cattle and pig tissues.	Toxicological data is expected to be available <b>July 2026</b>
Ketoprofen	Consideration of an ADI, ARfD and MRLs for cattle tissues (muscle, fat, liver and kidney)	GVP is established for ketoprofen which is available as a commercial injectable product in the United States	United States of America	-	Residue and toxicological data is expected to be available <b>July 2026</b>
Pradofloxacin	Consideration of an ADI, ARfD and MRLs for cattle and pig tissues (muscle, fat, liver and kidney).	GVP is established for pradofloxacin which is available as commercial injectable products in the United States.	United States of America	-	Residue and toxicological data is expected to be available <b>July 2026</b>
Amoxicillin	Request for MRLs for chicken muscle, skin/fat, liver and kidney.	Nominator noted that relevant registrations exist in the European Union, Canada and Chile.	Chile	ADI set by JECFA at 0-0.07 µg/kg bw (2011), ARfD 0.005 mg/kg bw (2017). Classified by WHO as a CIA and by the OIE as VCIA. This was included on the priority list at CCRVDF27.	Residue data is expected to be available <b>July 2026</b>
Amoxicillin	Request for MRL for chicken eggs	Nominator noted that relevant registrations exist in the Republic of Korea.	Republic of Korea	ADI set by JECFA at 0-0.07 µg/kg bw (2011), ARfD 0.005 mg/kg bw (2017). Classified by WHO as a CIA and by the OIE as VCIA.	Metabolism and residue depletion data is expected to be available <b>July 2026</b>

Fumagillin dicyclohexylamine (DCH)	Request for MRL for Rainbow trout (fillets)	Nominator noted that relevant registrations exist in the Republic of Korea	Republic of Korea	Compound considered by JECFA98 (2024)	Metabolism, residue depletion and analytical method studies for DCH in trout, and monitoring data for rainbow trout and eels, is expected to be available <b>July 2026</b>
Fumagillin dicyclohexylamine (DCH)	Request for MRL for fish fillet and honey	Nominator noted that relevant registrations exist in the Republic of Korea	Concern form from Canada and the USA	Concerns were raised about the JECFA98 (2024) assessment by Canada and the USA at CCRVDF27.	Canada committed additional residue data for honey, which is expected to be available <b>July 2026</b>
Ethion	Request ADI and MRL for cattle tissue	Nominator noted that relevant MRLs are established in a number of countries.	Argentina, Costa Rica and Uruguay	JECFA85 requested additional data/scientific argument to enable MR and MR:TR to be determined and analytical methodology. This was included on the priority list at CCRVDF27.	Metabolism studies to identify compounds of concern, validation of an analytical method and a radiolabel study to enable MR and MR:TR to be determined are expected to be completed in <b>2027</b> . <b>Data availability should be confirmed at the next CCRVDF.</b>
<b>Part II. Veterinary drugs for which data availability should be confirmed at the next CCRVDF</b>					
No compounds included in Part II					
<b>Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation</b>					
No compounds included in Part III					
<b>Part IV. Parallel review – Evaluation of a new compound</b>					
<b>Name of Compound</b>	<b>Information required by JECFA</b>	<b>Proposed by</b>	<b>Comments</b>	<b>When will data package be available</b>	

Umifoxolaner	Umifoxolaner has not been assessed by JECFA. A toxicological and residues dossier is required. The request is for an ADI to be established for umifoxolaner along with MRLs for cattle muscle, fat, liver and kidney.	Brazil	This was included on the priority list at CCRVDF27. At CCRVDF28, the nominator noted that the review of the risk assessment for food safety dossier is ongoing in Brazil. Approval is expected prior to the next JECFA meeting.	Residue and toxicological data is expected to be available <b>July 2026</b> .
Bromoform	Bromoform has not been assessed by JECFA. A toxicological and residues dossier is required.	New Zealand	This was included on the priority list at CCRVDF27. At CCRVDF28, the nominator noted that the review of the risk assessment in New Zealand had been delayed as additional data was required.	Toxicology, metabolism, pharmacokinetics, and residue depletion studies expected to be completed in <b>Q1 2027</b> . <b>Data availability should be confirmed at the next CCRVDF</b> .

**Part V. Veterinary drug for extrapolation of MRLs to other species**

Name of Compound(s)	Current Codex MRLs	Extrapolation proposal	Proposed by
Abamectin	Cattle tissues	Tissues of 'All other ruminants'	New Zealand
Cypermethrin (alpha)	Cattle and sheep tissues	Tissues of 'All other ruminants'	New Zealand
Dexamethasone	Cattle, horse and pig tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Doramectin	Cattle and pig tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Eprinomectin	Cattle tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Fenbendazole/ oxfenbendazole	Cattle, goat, horse, pig and sheep tissues, cattle and sheep milk	Tissues and milk of 'All other ruminants'	New Zealand
Sulfadimidine	Tissues (species not specified), cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Tylosin	Cattle, chicken pig and sheep tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand

**Part VI. Establishment of Action Levels for veterinary drugs in food**

No compounds included in Part VI

## Appendix 2: Nomination for amoxicillin in chicken tissues

The following information was provided in CX/RVDF 23/26/11:

### Administrative Information

1. Member(s) submitting the request for inclusion: Chile
2. Veterinary drug names: Amoxicillin 50%
3. Trade names: Primavet 50% (Centrovet) Vetrimonix 50% (Ceva Santé animale) Neumotona 50% (Veterquimica) Amoxyvet (Intermedicavet) Amoxy-50 (Zagro)
4. Chemical names and CAS registry number (2S,5R,6R)- 6-[[{(2R)-2-amino- 2-(4-hydroxyphenyl)-acetyl]amino}- 3,3-dimethyl- 7-oxo- 4-thia- 1-azabicyclo[3.2.0]heptane- 24-carboxylic acid
5. Names and addresses of basic producers Centrovet Ltda. Avda. Los Cerrillos 602, Cerrillos, Santiago, Chile [www.centrovet.com](http://www.centrovet.com) Veterquimica S.A. Camino a Lonquén 10387, Maipú, Santiago, Chile [www.veterquimica.com](http://www.veterquimica.com) Ceva Sante Animale Z.I. Tres Le Bois 22600, Loudéac, Francia

### Purpose, Scope and Rationale

6. Identification of the food safety issue (residue hazard): Amoxicillin is a broad-spectrum antibiotic widely used for treating both human and animal diseases, and it belongs to a group that are excreted unchanged within urine and faeces; therefore, it is possible to find traces of this drug or its degradation products in environmental water bodies. In water, it is rapidly degraded by biotic and abiotic factors, yielding different intermediate products; these are suspected of being more resistant to degradation, and potentially more toxic, than the parent compound. Amoxicillin may bioaccumulate in muscle tissues, with the possibility of the occurrence of these drugs in food, leading to a passive consumption of this antibiotic resulting in undesirable effects on consumer health such as immunoallergic responses. However, the main problem related with the presence of this antimicrobial compounds in tissues is the possibility of inducing bacterial resistance genes.

7. Assessment against the criteria for the inclusion on the priority list: Amoxicillin, has been assessment twice by JECFA, 75 (2011) and 85 (2017) meetings. It currently MRLs for cattle, sheep, pigs and fish has been established, however, there is no Codex MRL in broiler chicken tissues. Chile at CCRVDF24, after the discussion of "DATABASE OF COUNTRY MRL NEEDS (Agenda Item 11)", offered to develop dossiers to support the JECFA assessment for amoxicillin in poultry. Chile proposes a reevaluation of this drug. GVPs were established and there are three products registered in the country for use in broiler chickens. Verified maximum residue limits are necessary to ensure food safety for domestic use and protect the commercial destinations of edible broiler chicken tissues. Chile CX/RVDF 23/26/11 4

### Risk Profile Elements

8. Justification for use: For the treatment of Staphylococcosis and Avian Streptococcosis (Staphylococcus spp., Streptococcus spp.), Fowl Cholera (Pasteurella multocida), Infectious Coryza (Avibacterium paragallinarum), Avian Colibacillosis (Escherichia coli), Avian Salmonellosis and Paratyphosis (Salmonella spp.) and Clostridium perfringens.

9. Veterinary use pattern, including information on approved uses if available: Registered products are authorized for oral administration, dissolved in drinking water. Dosage of Amoxicillin 20 mg per kg bodyweight (bw) for day for 5 - 7 days.

10. Commodities for which Codex MRLs are required: Muscle, liver, kidney and skin and fat in natural proportions of broiler chickens.

### Available Information

12. Countries where the veterinary drugs are registered: European Union, Canada and Chile.

13. National/Regional MRLs or any other applicable tolerances

European Medicines Agency (EMA) Muscle 50 µg/kg Liver 50 µg/kg Skin and fat 50 µg/kg Kidney 50 µg/kg

14. List of data available (pharmacology, toxicology, metabolism, residue depletion, analytical methods):

A novel developed optimized and validated analytical methodologies for the detection of beta-lactams (amoxicillin) in edible (muscle, liver, kidney and fat) and feathers of broiler chickens.

An extraction method was developed for the detection and quantification of Amoxicillin residues in broiler chicken muscle and skin plus fat matrices. This was based on the publication of Benito-Peña et al., 2009 and Gajda et al.,

2019. The analysis will be performed by high-performance chromatography coupled to tandem mass spectrometry (API 5500, AB SCIEX®). The methodology will be validated for the parameters of linearity of the calibration curve, trueness, precision, decision limit (CC $\alpha$ ), matrix effect, specificity, stability and robustness, according to the recommendations of the European Union document: 2021/808/CE "Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC".

In parallel, a methodology for the analysis of amoxicillin in kidney and liver is being optimized. However, the extraction of this compound has been more complicated to implement due to the properties of the analyte, such as its stability, interaction with these matrices and its protein binding capacity, among others. A depletion study of amoxicillin in muscle, liver, kidney and skin and fat in natural proportion, of broiler chicken treated with isotopically labelled standards. In order to determine the amoxicillin depletion time in the study matrices, an in vivo assay was performed with broiler chickens. For this, the birds were treated with a 50% amoxicillin pharmaceutical formulation, therapeutically as indicated on the label. The study was based mainly on a trial with 40 broiler chickens of Ross 308 genetics, which were raised until 42 days of age, controlling temperature and relative humidity according to the physiological requirements of the birds, as well as drinking water and feed ad libitum, according to their nutritional requirements. These were kept from the first day of life in rearing batteries with a raised wire floor. The chicks were randomly divided from day 21 of life into a treatment group and a control group. The treatment group consisted of 30 birds treated with amoxicillin trihydrate 50% (authorized and described in the Register of Veterinary Medicines of the Agriculture and Livestock Service to be administered to broilers) at a therapeutic dose of 40 mg/kg/day for 7 days by orogastric tube, while the control or blank group consisted of 10 birds that did not receive treatment. After treatment, the matrices of interest were sampled on days 1, 2, 5, 9 and 18. For each sampling point, six samples of muscle, liver, kidney and fat plus skin were obtained. Once the solid-liquid extraction of amoxicillin residues from the study matrices has been performed, as indicated in the previous point, the samples are analyzed by HPLC-MS/MS in order to obtain the concentrations of these analytes, using the standards Amoxicillin (certified with purity greater than 95%) and Amoxicillin D4 (as internal standard).

The study has the Biosafety Certificate N°184 of the Biosafety Committee of the Faculty of Veterinary and Livestock Sciences of the University of Chile, and the certificate N° 23643 – VET – UCH of the Institutional Animal Care and Use Committee (CICUA), issued by the same faculty. The euthanasia method was guided according to the recommendations of "The AVMA Guidelines for the Euthanasia of Animals" (2013), and Regulation No. 1099/2009 associated with the protection of animals at the time of killing of the European Commission (2009). For the depletion study and the determination of the withdrawal period in the matrices, the guidelines of the document "Guideline on determination of withdrawal periods for edible tissues" of the European Medicines Agency (2018) will be followed.

#### **Timetable**

15. Date when data could be submitted to JECFA

A novel developed optimized and validated analytical methodologies for broiler muscle, and skin and fat: December 2023  
A novel developed optimized and validated analytical methodologies for broiler liver and kidney: July 2024

A depletion study of amoxicillin in muscle, and skin and fat in natural proportions, of broiler chicken: July 2024

A depletion study of amoxicillin in liver and kidney, of broiler chicken: July 2024  
It is important to consider that we are currently working on the extraction method for broiler chicken liver and kidney matrices, so the dates of the validation and depletion study are subject to the achievement of the development of the method.

*At the PWG prior to CCRVDF28, Chile provided the update that the data should be available by July 2026*

**Appendix 3: Nomination for amoxicillin in eggs**

The following information was provided in CRD10 for CCRVDF27:

**Administrative Information**

1. Member submitting the request for inclusion: Republic of Korea
2. Veterinary drug name: Amoxicillin, Amoxicillin trihydrate
3. Trade names: Amoxicillin
4. Chemical names and CAS registry number:  
Amoxicillin: 26787-78-0, Amoxicillin trihydrate: 61336-70-7F
5. Names and addresses of basic produces: Woogene B&G, 230, Jeongmunsongsan-ro, Yanggam-myeon, Hwaseong-si, Gyeonggi-do, Korea

**Purpose, Scope and Rationale**

6. Identification of the food safety issue (residue hazard)
  - Residues (including any potential metabolites) of amoxicillin in eggs of laying hens after oral administration of amoxicillin
7. Assessment against the criteria for the inclusion on the priority list:
  - The eighty-fifth JECFA assessed Amoxicillin (See WHO Technical Report Series 1008)
  - The Committee did not assess residues (including any potential metabolites) of amoxicillin in eggs after oral administration of amoxicillin via feed admixture or drinking water for lack of data.

**Risk Profile Elements**

8. Justification for use: Treatment or control of bacterial infections in animals (including pigs, cattles, milking cows, goats, sheep, chicken, laying hens and etc) and human
9. Veterinary use pattern, including information on approved uses if available:
  - Laying hens: Incorporate it in feeds or drinking water and provide it at 100 mg per kg body weight twice per day for 5 days
10. Commodities for which Codex MRLs are required: Eggs

**Risk Assessment Needs and Questions for the Risk Assessors**

11. Specific request to risk assessors:
  - Residues of amoxicillin (including any potential metabolites) in eggs are required to be monitored when amoxicillin preparations are used in laying hens

**Available Information**

12. Countries where the veterinary drugs are registered: Republic of Korea
13. National/Regional MRLs or any other applicable tolerances:
  - In poultry muscle, liver, kidney and fat 0.05 mg/kg for the MR amoxicillin as Korea's national MRL
  - In egg of 0.01 mg/kg for the MR amoxicillin as Korea's national MRL
14. List of data available:
  - Metabolism study of amoxicillin to determine the quantity and identify the nature of amoxicillin in eggs of laying hens after oral administration of amoxicillin hydrate.
  - Residue depletion data of amoxicillin in eggs of laying hens after oral administration of amoxicillin hydrate via feed admixture or drinking water

**Timetable**

15. date when data could be submitted to JECFA: September 30 2025

*At the PWG prior to CCRVDF28, Rep. Korea provided the update that the data should be available by July 2026*

#### Appendix 4: Nomination for fumagillin DCH

The following information was provided in CRD10 for CCRVDF27:

##### Administrative Information

1. Member submitting the request for inclusion: Republic of Korea
2. Veterinary drug name: Fumagillin dicyclohexylamine
3. Trade names: Fumidil-B
4. Chemical names and CAS registry number: Fumagillin, 23110-15-8
5. Names and addresses of basic produces: KBNP, 415 Heungandae-ro, Dongan-gu, Anyang-si, Gyeonggi Province

##### Purpose, Scope and Rationale

6. Identification of the food safety issue (residue hazard)
  - Residues (including any potential metabolites) of dicyclohexylamine in fillet of rainbow trout after oral administration of Fumagillin dicyclohexylamine.
7. Assessment against the criteria for the inclusion on the priority list:
  - The ninety-eight JECFA assessed Fumagillin DCH (See WHO Technical Report Series 1055)
  - The Committee could not assess residues (including any potential metabolites) of dicyclohexylamine in trout fillet after oral administration of Fumagillin dicyclohexylamine for lack of data and without suitable analytical method for DCH in fish fillet.

##### Risk Profile Elements

8. Justification for use: Treatment for Sphaerospora sp or Myxobolus cerebralis in rainbow trouts
9. Veterinary use pattern, including information on approved uses if available:
  - Fish: Incorporate it in feeds at 300g~1kg/day/ton of fish weight or 1.2kg/ton of water weight for 5 days
10. Commodities for which Codex MRLs are required: Fish fillet

##### Risk Assessment Needs and Questions for the Risk Assessors

11. Specific request to risk assessors:
  - Residues of DCH (including any potential metabolites) are required to be monitored when fumagillin DCH preparations are used in fish to ensure that the concentration is < 1000 µg/kg, a target level compatible with the upper bound of the ADI of DCH (0-0.02 mg/kg bw).
  - A suitable analytical method for determination of DCH in fish fillet is need to be developed.

##### Available Information

12. Countries where the veterinary drugs are registered: Republic of Korea
13. National/Regional MRLs or any other applicable tolerances:
  - In fish fillet of 0.01 mg/kg for the MR fumagillin as Korea's national provisional MRL
14. List of data available:
  - Metabolism study of DCH to determine the quantity and identify the nature of DCH in rainbow trout after oral administration of Fumagillin DCH.
  - Residue depletion data of DCH in fillet of rainbow trout after oral administration of Fumagillin DCH via feed admixture
  - Residue analytical method for determination of DCH in fish fillet

##### Timetable

15. date when data could be submitted to JECFA: Until December 31 2026

*At the PWG prior to CCRVDF28, Rep Korea provided the update that the data should be available by July 2026*

**Appendix 5: Nomination for umifoxolaner in beef tissues**

The following information was provided in CX/RVDF 24/27/10:

**ADMINISTRATIVE INFORMATION**

1. Member(s) submitting the request for inclusion: BRAZIL
2. Veterinary drug names: UMIFOXOLANER (INN)
3. Trade names: SOLECTUS®
4. Chemical names and CAS registry number:  
IUPAC (International Union of Pure and Applied Chemistry) Nomenclature: 4-[(5S)-5-[3-chloro-4-fluoro-5-(trifluoro-methyl)phenyl]-4,5-dihydro-5-(trifluoro-methyl)-3-isoxazolyl]-N-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl]-1-naphthalene-carboxamide  
Synonyms: ML-3,032,878, ML-878 and MR-026, CLM2317  
CAS number: 2021230-37-3  
International Non-proprietary Name (INN): umifoxolaner
5. Names and addresses of basic producers: BOEHRINGER INGELHEIM ANIMAL HEALTH DO BRASIL LTDA, Avenida Doutor Roberto Moreira, n° 5005, Recanto dos Pássaros, CEP 13148-914, Paulínia/SP – Brazil

**PURPOSE, SCOPE, AND RATIONALE**

6. Identification of the food safety issue (residue hazard):  
The food safety issue concerns the potential for residues of umifoxolaner to be remained in food products (cattle tissues) consumed by humans. Residues could pose health risks and therefore it is necessary to establish ADI (Acute Daily Intake), ARfD (Acute Reference Dose) and Maximum Residue Limits (MRLs) to ensure that any residue present in food are within safe levels for human consumption.  
Umifoxolaner is a novel veterinary drug that has not yet been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for use in veterinary medicine, and there is currently no established ADI, ARfD and MRLs for its residues in cattle tissues.
7. Assessment against the criteria for the inclusion on the priority list:  
The MAPA registration procedure will be performed in parallel to the JECFA/CCRVDf review. Currently the risk assessment for food safety dossier is under review at ANVISA.  
Umifoxolaner is intended to be registered in Brazil, Argentina, Colombia, Uruguay, Bolivia, Paraguay, Mexico, Australia, New Zealand, South Africa, Botswana, Namibia, Zimbabwe, Kenya, Tanzania, Uganda, Ethiopia, Nigeria, Egypt, Algeria and Morocco member states for use in cattle. Relevant data are available on toxicology, metabolism, pharmacokinetics, and residue depletion studies conducted with both radiolabeled and non-radiolabeled forms of the drug in the target species. A comprehensive dossier will be provided for the risk assessment.

**RISK PROFILE ELEMENTS**

8. Justification for use:  
Treatment and control of infestations caused by single-host ticks *Rhipicephalus (Boophilus) microplus*.  
Treatment and control of infestations caused by larvae of *Dermatobia hominis*.  
Prevention of infestations caused by *Cochliomyia hominivorax* larvae (screwworm myiasis), including prevention of postoperative wound myiasis and prevention of umbilical myiasis of newborn calves.  
Treatment and control of infestations caused by chewing lice (*Bovicola bovis*).
9. Veterinary use pattern, including information on approved uses if available (*this should include product labels or other evidence of official use authorization*):  
It is recommended to administer Solectus® in cattle, in a subcutaneous injection of 0.6 mg of umifoxolaner per kg of body weight (BW), equivalent to 1 mL of product per 100 kg of body weight (BW).  
Solectus® is indicated for beef cattle and can be given to all ages of animals including one-day-old calves.  
The recommended withdrawal period is 105 days.  
Do not use the product on dairy cows producing milk for human consumption (Milk depletion studies are currently in progress).
10. Commodities for which Codex MRLs are required: Cattle Liver, kidney, fat, muscle.

**Specific request to risk assessors**

11. Request for establishment of ADI, ARfD and MRLs for umifoxolaner for cattle muscle, liver, kidney and fat using the parallel review process.

**AVAILABLE INFORMATION**

12. Countries where the veterinary drugs are registered: Under review by Naonal Authorities in Brazil, Argentina and Uruguay.
13. National/Regional MRLs or any other applicable tolerances:  
Review of the risk assessment for food safety dossier ongoing in Brazil (by ANVISA) and in Australia (APVMA Technical Assessment).
14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles and whether the compound is also registered as pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re- evaluation by JMPR*):  
The compound is not registered as pesticide and has not been evaluated or scheduled for evaluation by JMPR.  
The list of data is as follows:

**TOXICOLOGY****Genotoxicity Studies**

- Bacterial Reverse Mutation Assay.
- In Vitro Mammalian Cell Micronucleus Assay in TK6 Cells.
- In Vivo Mammalian Erythrocyte Micronucleus Assay in Mice.
- Position paper on carcinogenicity study.

**Acute Toxicity studies**

- Acute Oral Toxicity in Sprague Dawley Rats.
- A Single-Dose Oral Gavage Maximum Tolerated Dose (MTD) Study in Sprague Dawley Rats.
- Acute Dermal Toxicity Study in Albino Rats.
- Acute Dermal Irritation Study in Albino Rabbits.
- Acute Ocular Irritation Study in Albino Rabbits.

**Subacute Toxicity**

- 7-Day Oral Gavage Toxicity Study in Sprague Dawley Rats.
- Escalating-Dose Phase and 7-Day Repeated-Dose Phase Study by Oral Capsule in Beagle Dogs.
- 28-Day Oral (Dietary) Toxicity Study in Sprague Dawley Rats.
- 28 Day Repeated-Dose Study by Oral Capsule in Beagle Dogs.
- 90 Day Oral Dietary Toxicity Study in Sprague Dawley Rats.
- 90-day oral toxicity study in Beagle Dogs.

**Chronic Toxicity Studies**

- A 52-Week Oral Dietary Toxicity Study in Sprague Dawley Rats.

**Toxicity Studies on Reproduction and Development**

- Oral (Gavage) Prenatal Developmental Toxicity Study in Sprague Dawley Rats.
- Oral (Gavage) Prenatal Developmental Toxicity Study in New Zealand White Rabbits.
- Oral (Gavage) Two-Generation Reproductive Toxicity Study in Sprague Dawley Rats.

**Additional studies**

- MIC study on Human Gastrointestinal Tract Microbiota (to be ready in October 2024).

**PHARMACOLOGY, METABOLISM and RESIDUES**

- Comparative Metabolism Study following Repeated Oral (Gavage) Administration to Rats.
- Comparative Metabolism Study following Repeated Oral (Gavage) Administration to Dogs.
- 28-Day Pharmacokinetic Study of ML-3,032,878 by Intravenous Injection and Oral Gavage in Sprague Dawley Rats.
- Study to Determine the Pharmacokinetic Profiles in Plasma of Cattle Administered a Single Intravenous Dose at 0.6 mg/kg body weight or a Single Subcutaneous Dose at 0.3, 0.6 or 1.2 mg/kg body weight.
- Pivotal Radio-Residue Metabolism and Depletion Study in Beef Cattle Following a Single Subcutaneous Injection at 0.6 mg/kg Body Weight.
- In Vitro Metabolite Profiling in HuREL Rat, Mouse, Dog, Cattle and Sheep Hepatocytes Co-cultures.
- Plasma Protein Binding in Cattle, Sheep, Dog, Rat and Mouse Plasma.
- Marker Residue Depletion Studies in Bovine Edible Tissues aÖer a Single Subcutaneous Dose.

**ANALYICAL METHOD**

- Validation of an LC-MS/MS Method for the Quantification of ML-3,032,878 in Bovine Plasma.
- Validation of an LC-MS/MS Method for the Quantitation of ML-3,032,878 in bovine edible tissues.
- Long-Term stability of Umifoxolaner in bovine edible tissues During Storage in Freezer set at -20oC.

**TIMETABLE**

15. Date when data could be submitted to JECFA: December 2024

*At the PWG prior to CCRVDF28, Brazil provided the update that the data should be available by July 2026*

**Appendix 6: Nomination for doramectin**

The following information was provided in CX/RVDF 26/28/12:

**Nomination Form to add DORAMECTIN to the Priority List.**

**ADMINISTRATIVE INFORMATION**

1. **Member(s) submitting the request for inclusion**

United States of America

2. **Veterinary drug names**

Doramectin

3. **Trade names**

Dectomax® Injectable Solution for Cattle and Swine; Dectomax® Pour on Solution for Cattle; DECTOMAX® CA1

4. **Chemical names and CAS registry number**

(1'R,2R,3S,4'S,6S,8'R,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-2-cyclohexyl-21',24'-dihydroxy-12'-[(2R,4S,5S,6S)-5-[(2S,4S,5S,6S)-5-hydroxy-4-methoxy-6-methyloxan-2-yl]oxy-4-methoxy-6-methyloxan-2-yl]oxy-3,11',13',22'-tetramethylspiro[2,3-dihydropyran-6,6'-3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene]-2'-one  
117704-25-3

5. **Names and addresses of basic producers**

Zoetis, Inc.  
333 Portage Street  
Kalamazoo, Michigan, United States of America 49007  
PURPOSE, SCOPE, AND RATIONALE

6. **Identification of the food safety issue (residue hazard)**

Residues of doramectin are present in edible swine and cattle tissues when the product is used in accordance with Good Veterinary Practice (GVP). When GVPs are followed, including applicable withdrawal periods, residues of doramectin are safe for human consumption. Doramectin has previously undergone review in 1995, 1998, and 2002, resulting in the assignment of maximum residue limits (MRLs) for cattle and swine. As noted by JECFA, concentrations of doramectin are elevated at the injection site in cattle and swine. In light of this, the United States of America respectfully requests to add doramectin to the priority list with a view towards a JECFA evaluation that establishes an acute reference dose (ARfD). A JECFA-established ARfD can be used by risk managers to evaluate the occasional elevated residue at the injection site. This would help minimize the risk of rejecting good, quality food products during international trade, thereby supporting global food safety and security.

In addition, there has been a recent global rise in the use of doramectin for the control of New World screwworm. To that end, adding doramectin to the priority list is in line with a One Health Approach to addressing an ongoing and emerging global issue.

7. **Assessment against the criteria for inclusion on the priority list**

Doramectin meets the criteria for inclusion on the priority list as specified in the Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

- Doramectin is approved/registered for use in the United States of America and several other Member countries, and GVPs have been established as part of those approvals/registrations.
- When GVPs are followed, including applicable withdrawal periods, residues of doramectin are safe for human consumption. Occasionally, residues at the injection site can be high. Therefore, a JECFA established ARfD can be used by risk managers to evaluate the occasional elevated residue at the injection site.
- Doramectin is available as a commercial product.
- The sponsoring company is committed to provide a dossier to JECFA.

**RISK PROFILE ELEMENTS**

8. **Justification for use**

Dectomax® Injectable Solution for Cattle and Swine is indicated as follows:

- Cattle: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites.
- Cattle: To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

- Swine: For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.  
Dectomax® Pour on Solution for Cattle is indicated as follows:
  - For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and fourth-stage larvae), *Ostertagia ostertagi* (inhibited fourth-stage larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and fourth-stage larvae), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults and fourth-stage larvae), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia pectinata* (adults), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, and *Solenopotes capillatus*; biting lice: *Bovicola* (*Damalinia*) *bovis*; mange mites: *Chorioptes bovis* and *Sarcoptes scabiei*; horn flies: *Haematobia irritans*.
  - To control infections and to protect from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, and *Oesophagostomum radiatum* for 28 days; and with *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment
  - To control infestations and to protect from reinfestation with *Linognathus vituli* for 42 days and with *Bovicola* (*Damalinia*) *bovis* for 77 days after treatment.  
DECTOMAX® CA1 is indicated for prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle.
9. **Veterinary use pattern, including information on approved uses if available**  
Dectomax® Injectable Solution for Cattle and Swine is administered to cattle as a subcutaneous or intramuscular injection at a dose of 0.2 mg/kg body weight and to swine as an intramuscular injection at a dose of 0.3 mg/kg body weight. The withdrawal periods for cattle and swine are 35 days and 24 days, respectively, in the United States of America. Dectomax® Pour on Solution for Cattle is administered topically at a dose of 0.5 mg doramectin/kg body weight. The withdrawal period is 45 days in the United States of America.  
DECTOMAX® CA1 is administered to cattle as a subcutaneous or intramuscular injection at a dose of 0.2 mg/kg body weight. The withdrawal period is 35 days in the United States of America.
10. **Commodities for which Codex MRLs are required**  
Codex MRLs have been established previously for doramectin. The United States is requesting a JECFA evaluation that establishes an ARfD.
- RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS**
11. **Specific request to risk assessors**  
To conduct a JECFA evaluation that establishes an ARfD that can be used by risk managers to evaluate the occasional elevated residue at the injection site.
- AVAILABLE INFORMATION**
12. **Countries where the veterinary drugs are registered**  
Dectomax® Injectable Solution for Cattle and Swine: United States of America, European Union, United Arab Emirates, Argentina, Australia, Brazil, Chile, China, Colombian, Costa Rica, Egypt, United Kingdom, Canada, Thailand.  
Dectomax® Pour on Solution for Cattle: United States of America, Austria, France, Norway, Portugal, Sweden, Slovenia, Australia, and New Zealand.  
DECTOMAX® CA1: United States of America  
Dectomax Drench®- Australia, New Zealand
13. **National/Regional MRLs or any other applicable tolerances**  
The United States of America has established the following tolerances (US equivalent to MRLs) for parent doramectin (marker residue):
- 300 µg/kg in cattle liver (target tissue)
  - 30 µg/kg in cattle muscle
  - 160 µg/kg in swine liver (target tissue)
- Australia has established the following MRLs for parent doramectin (marker residue):

- 100 µg/kg in cattle liver
  - 100 µg/kg in cattle kidney
  - 10 µg/kg in cattle muscle
  - 100 µg/kg in cattle fat
- 100 µg/kg in swine liver
- 100 µg/kg in swine kidney
- 10 µg/kg in swine muscle
- 100 µg/kg in swine fat
- 50 µg/kg in ovine liver
- 50 µg/kg in ovine kidney
- 20 µg/kg in ovine muscle
- 100 µg/kg in ovine fat

The European Union has established the following MRLs for parent doramectin (marker residue):

- 100 µg/kg in liver of all mammalian food producing species (excludes lactating animals)
  - 60 µg/kg in cattle kidney of all mammalian food producing species
  - 40 µg/kg in cattle muscle of all mammalian food producing species
  - 150 µg/kg in cattle fat of all mammalian food producing species

In addition, Codex has adopted the following MRLs:

- 10 µg/kg in cattle muscle
  - 100 µg/kg in cattle liver
  - 30 µg/kg in cattle kidney
  - 150 µg/kg in cattle fat
  - 15 µg/kg in cow's milk
  - 5 µg/kg in swine muscle
  - 100 µg/kg in swine liver
  - 30 µg/kg in swine kidney
  - 150 µg/kg in swine fat

14. **List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available**

A full, comprehensive toxicology dossier will be submitted to JECFA to enable the establishment of an ARfD. Studies adhere to GLPs and VICH Guidelines as appropriate.

**TIMETABLE**

15. **Date when data could be submitted to JECFA**

The dossier will be available for submission upon the next JECFA call for data.

**ADDITIONAL INFORMATION**

Approval information in the United States can be accessed as follows:

<https://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/141-061>

<https://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/141-095>

<https://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/141-616>

**Appendix 7: Nomination for ketoprofen**

The following information was provided in CX/RVDF 26/28/12:

**Nomination Form to add KETOPROFEN to the Priority List****ADMINISTRATIVE INFORMATION****1. Member(s) submitting the request for inclusion**

United States of America

**2. Veterinary drug names**

Ketoprofen

**3. Trade names**

KETOFEN® Injectable Solution

**4. Chemical names and CAS registry number**

2-(3-benzoylphenyl)propanoic acid

22071-15-4

**5. Names and addresses of basic producers**

Zoetis, Inc.

333 Portage Street

Kalamazoo, Michigan, United States of America 49007

**PURPOSE, SCOPE, AND RATIONALE****6. Identification of the food safety issue (residue hazard)**

Residues of ketoprofen are present in edible cattle tissues when the product is used in accordance with Good Veterinary Practice (GVP). When GVPs are followed, including an applicable withdrawal period, residues of ketoprofen are safe for human consumption. Ketoprofen has not been evaluated by JECFA. The United States of America respectfully requests to add ketoprofen to the priority list with a view towards a JECFA evaluation that establishes an acceptable daily intake (ADI) and acute reference dose (ARfD) and recommends maximum residue limits (MRLs) for cattle muscle, liver, fat and kidney. These MRLs can be used by risk managers to evaluate the residues in edible cattle tissues and would help ensure the safety of the consumer and facilitate fair trade of commodities from cattle treated with ketoprofen.

**7. Assessment against the criteria for inclusion on the priority list**

Ketoprofen meets the criteria for inclusion on the priority list as specified in the Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

- Ketoprofen is approved/registered for use in the United States of America and several other Member countries, and GVPs have been established as part of those approvals/registrations.
- When GVPs are followed, including an applicable withdrawal period, residues of ketoprofen are safe for human consumption. Codex MRLs can be used by risk managers to evaluate the residues in the edible cattle tissues.
- Ketoprofen is available as a commercial product.
- The sponsoring company is committed to provide a dossier to JECFA.

**RISK PROFILE ELEMENTS****8. Justification for use**

KETOFEN® Injectable Solution is indicated for the control of pyrexia associated with Bovine Respiratory Disease.

**9. Veterinary use pattern, including information on approved uses if available**

KETOFEN® Injectable Solution is administered to cattle by subcutaneous injection at 3 mg/kg body weight once daily and may be repeated for up to three days if pyrexia persists. The withdrawal period is 48 hours in the United States of America.

**10. Commodities for which Codex MRLs are required**

The United States is requesting a JECFA evaluation that establishes an ADI and ARfD and recommends MRLs for cattle muscle, liver, fat and kidney.

**RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS****11. Specific request to risk assessors**

To conduct a JECFA evaluation that establishes an ADI and ARfD and recommends MRLs for cattle muscle, liver, fat and kidney that can be used by risk managers to evaluate residues in edible cattle tissues.

**AVAILABLE INFORMATION**

**12. Countries where the veterinary drugs are registered**

KETOFEN® Injectable Solution: United States of America

**13. National/Regional MRLs or any other applicable tolerances**

The United States of America has established the following tolerances (US equivalent to MRLs) for parent ketoprofen (marker residue):

- 360 µg/kg in cattle kidney (target tissue)

The European Union has established the following MRLs for ketoprofen (marker residue):

- Liver 20 µg/kg
- Kidney 50 µg/kg
- Muscle 50 µg/kg
- Fat 20 µg/kg

**14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available**

A full, comprehensive toxicology and residue dossier will be submitted to JECFA to enable the establishment of an ADI and ARfD and recommendation of MRLs for cattle muscle, liver, fat, and kidney. Studies adhere to GLPs and VICH Guidelines as appropriate.

**TIMETABLE**

15. Date when data could be submitted to JECFA.

The dossier will be available for submission upon the next JECFA call for data.

**ADDITIONAL INFORMATION**

Approval information in the United States can be accessed as follows:

<https://animaldrugstfda.fda.gov/adafda/views/#/home/previewsearch/140-269>

**Appendix 8: Nomination for pradofloxacin**

The following information was provided in CX/RVDF 26/28/12:

**Nomination Form to Add PRADOFLOXACIN to the Priority List****ADMINISTRATIVE INFORMATION****1. Member(s) submitting the request for inclusion**

United States of America

**2. Veterinary drug names**

Pradofloxacin

**3. Trade names**

Pradalex™

**4. Chemical names and CAS registry number**

8-Cyano-1-cyclopropyl-7-(1S, 6S)-2,8-diazabicyclo-(4.3.0)nonan-8-yl)-6-fluoro-4-oxo-3-quinoline carboxylic acid

195532-12-8

**5. Names and addresses of basic producers**

Elanco Animal Health

450 Elanco Circle

Indianapolis, IN 46221 USA

(contact: Jesse Sevcik, [jesse.sevcik@elancoah.com](mailto:jesse.sevcik@elancoah.com))

**PURPOSE, SCOPE, AND RATIONALE****6. Identification of the food safety issue (residue hazard)**

Residues of pradofloxacin are present in edible tissues of cattle and swine when the product is used in accordance with Good Veterinary Practice (GVP). When GVPs are followed, including applicable withdrawal periods, residues of pradofloxacin are safe for human consumption. National authorities have established tolerances and withdrawal periods to ensure that residues in edible tissues are within safe limits. At present, no Codex maximum residue limits (MRLs) have been established for pradofloxacin in food-producing species. To that end, global MRLs are needed to ensure the safety of the consumer and facilitate fair trade of commodities from cattle and swine treated with pradofloxacin.

**7. Assessment against the criteria for inclusion on the priority list**

- Pradofloxacin is approved for use in the United States of America, and GVPs have been established as part of that approval. Pradofloxacin is approved as a prescription drug with a defined dose, administration route, and withdrawal period for specific indications in cattle and swine.
- When GVPs are followed, including applicable withdrawal periods, residues of pradofloxacin are safe for human consumption. Therefore, global MRLs are needed to ensure the safety of the consumer and facilitate fair trade of commodities from cattle and swine treated with pradofloxacin.
- Pradofloxacin is available as a commercial product.
- The sponsoring company is committed to provide a dossier to JECFA.

**RISK PROFILE ELEMENTS****8. Justification for use**

Pradalex™ is a prescription antimicrobial drug that is administered as a single injection (subcutaneous in cattle and intramuscular in swine). Pradalex is approved in cattle for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*; and in swine for the treatment of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica*, *Glaesserella (Haemophilus) parasuis*, *Pasteurella multocida*, *Streptococcus suis*, and *Mycoplasma hyopneumoniae*.

**9. Veterinary use pattern, including information on approved uses if available**

Cattle: Pradofloxacin is administered as a single subcutaneous injection at a dose of 10 mg/kg body weight. No more than 15 mL may be injected into a single site. The withdrawal period is 4 days in the United States of America.

Swine: Pradofloxacin is administered as a single intramuscular injection in the neck at a dose of 7.5 mg/kg body weight. No more than 5 mL may be injected into a single site. The withdrawal period

is 2 days in the United States of America.

10. **Commodities for which Codex MRLs are required**

Cattle muscle, liver, fat and kidney

Swine muscle, liver, fat and kidney

**RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS**

11. **Specific request to risk assessors**

To evaluate the toxicological and residue data for pradofloxacin to establish an Acceptable Daily Intake (ADI) and recommend Maximum Residue Limits (MRLs) for edible tissues of cattle and swine (muscle, liver, kidney, fat).

**AVAILABLE INFORMATION**

12. **Countries where the veterinary drugs are registered**

United States of America

13. **National/Regional MRLs or any other applicable tolerances**

The United States of America has established the following tolerances (US equivalent to MRLs) for parent pradofloxacin (marker residue):

- Cattle kidney: 30 µg/kg
- Swine kidney: 1000 µg/kg

14. **List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available**

A full and comprehensive human food safety dossier will be submitted to JECFA. This includes complete studies on pharmacology, toxicology, metabolism, residue depletion, and analytical methods that adhere to GLPs and VICH Guidelines as appropriate.

**TIMETABLE**

15. **Date when data could be submitted to JECFA**

The dossier will be available for submission upon the next JECFA call for data.

**ADDITIONAL INFORMATION**

Approval information in the United States can be accessed at

<https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/18030>.

**Appendix 9: Nomination template for new uses and parallel reviews:**

New proposals highlighted in yellow

**TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF  
(To be completed by Codex members in relation to Parts I and IV of the Priority List)**

**ADMINISTRATIVE INFORMATION**

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names and CAS registry number
5. Names and addresses of basic producers
6. Is this nomination for a parallel review (Yes/No)
7. Is this compound a dual use compound that can be applied to crops as a pesticide (Yes/No)

**PURPOSE, SCOPE, AND RATIONALE**

8. Identification of the food safety issue (residue hazard)
9. Assessment against the criteria for inclusion on the priority list

**RISK PROFILE ELEMENTS**

10. Justification for use
11. Veterinary use pattern, including information on approved uses if available (*this should include product labels or other evidence of official use authorization*)
12. Commodities for which Codex MRLs are required

**RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS**

13. Specific request to risk assessors

**AVAILABLE INFORMATION<sup>1</sup>**

14. Countries where the veterinary drugs are registered
15. National/Regional MRLs or any other applicable tolerances
16. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles and whether the compound is also registered as a pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re-evaluation by JMPR*)

**TIMETABLE**

17. Date when data could be submitted to JECFA.

**ADDITIONAL INFORMATION**

18. Please provide additional information as appropriate by:
  - Including links under this section and/or
  - Sending attachments to the following addresses: [CCRVDF-USSEC@usda.gov](mailto:CCRVDF-USSEC@usda.gov) with a copy to [codex@fao.org](mailto:codex@fao.org).

**Note 1:** Codex members interested in proposing MRLs for compounds listed in the database on countries' needs for MRLs for veterinary drugs can download the list of compounds/tissues from: [https://www.fao.org/fileadmin/user\\_upload/codexalimentarius/doc/CCRVDF27DBcountryneedsMRLsVetDrugs\\_e\\_CC\\_RVDF28\\_2026.xlsx](https://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/CCRVDF27DBcountryneedsMRLsVetDrugs_e_CC_RVDF28_2026.xlsx)

<sup>1</sup> When preparing a preliminary risk profile, Member(s) should consider the updated data requirement to enable evaluation of a veterinary drug to establish an ADI and MRLs published by JECFA.

**Note 2:** Points 12 and 13 may not be applicable for new compounds prioritized for JECFA evaluation under the “parallel review”

**Note 3:** The template does not apply to the nomination of compounds for MRL extrapolation or Action Levels. Data/information submitted for these requests should be provided in accordance with the *Risk analysis principles applied by CCRVDF*, as set out in Annexes C and D (see paragraphs 18 and 20 of CL 2026/15-RVDF).

**Appendix 10: Proposed new template for nominations for Part V. Veterinary drug for extrapolation of MRLs to other species**

Information to be provided should include:

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Species in which MRLs have been established on the basis of a JECFA evaluation
4. Species to which extrapolation is proposed
5. Additional information (optional), such as an initial assessment of if the nomination is likely to meet the agreed approach for extrapolation of MRLs of veterinary drugs to one or more species