

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 10

CX/RVDF 26/28/12

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

28th Session

23-27 March 2026

Minneapolis, Minnesota, United States of America

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA

Comments in reply to CL 2026/15-RVDF

Comments by Ecuador, Egypt, European Union (EU), Indonesia, Malaysia, New Zealand, Panama, Saudi Arabia, Senegal, the United Arab Emirates (UAE), and the United States of America (USA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2026/15-RVDF¹ issued in December 2025. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

¹ <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

ANNEX

COMMENT	MEMBER/OBSERVER
General comments Ecuador thanks the Codex Alimentarius Commission, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) for issuing the Circular Letter CL 2026/15-RVDF, and recognizes the strategic relevance of the priority list as a technical instrument for the international harmonization of maximum residue limits (MRL), protecting public health, and facilitating trade. Ecuador has many of the active substances mentioned in the list, which have been registered for use on animals for food production under regulation by the Phytosanitary and Animal Health Regulation and Control Agency, and for that reason, this circular letter is of great national importance. In general terms, Ecuador believes that in the sections mentioned below, the priority list presented is consistent with international risk management needs, and contributes to strengthening national systems for official control, and reiterates its support for advancing with work in line with the Principles for Risk Analysis applied by CCRVDF. Specific comments Part I: Assessment or reassessment by JECFA Ecuador supports the prioritization of amoxicillin in chicken tissues and eggs, as well as ethion in cattle tissue, considering that both active substances are linked to relevant production systems in Ecuador, particularly in the poultry and cattle sectors, and their updated scientific assessment contributes to strengthening national residue monitoring programs, ensuring international regulatory consistency, and preventing potential impacts on foreign trade caused by MRL discrepancies. Part IV: Parallel review Ecuador supports the prioritization of umifoxolaner for cattle and bromoform as an environmental inhibitor in ruminants within the framework of parallel review, given that this mechanism promotes regulatory efficiency and permits timely international scientific assessments that may serve as a reference for any future national registration requests, ensuring that any technological innovation is accompanied by a rigorous consumer safety assessment.	Ecuador

COMMENT	MEMBER/OBSERVER
Inclusion of Nitrofurans in the priority list for subsequent recommendation to JECFA for evaluation Egypt proposes the inclusion of the veterinary drug Nitrofurans in the priority list for subsequent recommendation to JECFA for evaluation. The information recommended for consideration in the priority list by CCRVDF has been completed and is attached. Relevant data are anticipated to be available on toxicology, metabolism, pharmacokinetics, and residue depletion studies conducted on the drug in the target species in food, including (Casing matrix from offal). In view of no safe level of residues of Nitrofurans or their metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, Egypt suggests preventing residues of Nitrofurans in food, including (Casing matrix from offal). ADMINISTRATIVE INFORMATION 1. Member(s) Submitting the Request: ○ Egypt 2. Veterinary Drug Names: ○ Nitrofurantoin ○ Nitrofurazone ○ Nitrofurantoin-mono 3. Trade Names: ○ Furadantin (Nitrofurantoin) ○ Furacin (Nitrofurazone) 4. Chemical Names and CAS Registry Number: ○ Nitrofurantoin: 67-20-9 ○ Nitrofurazone: 59-87-0 5. Names and Addresses of Basic Producers: 5.1 Production Regions: Nitrofurantoin and related nitrofurans are synthesized in China, India, Italy, the Netherlands, and Spain. 5.2 Key Manufacturers/Suppliers (Generic/API): 5.2.1 China: Various chemical manufacturers in China have historically been the main source of nitrofuran Active Pharmaceutical Ingredients (APIs). 5.2.2 India: Various API manufacturers, including suppliers listed in databases like Chemical Information Services. 5.2.3 Pharm affiliates Analytics & Synthetics (India): Supplier of Nitrofurantoin API (Catalogue number: PA 14 34000). 5.2.4 Sigma-Aldrich (now Merck): Supplier of analytical standards for nitrofurans (e.g., 2-nitrobenzaldehyde and SEM hydrochloride).	Egypt

PURPOSE, SCOPE, AND RATIONALE 6. Identification of the Food Safety Issue (Residue Hazard): - o Potential for residues in (<u>Casing matrix from offal</u>) leading to health risks in humans. 7. Assessment Against the Criteria for Inclusion on the Priority List: - o Evaluation based on usage patterns, resistance development, and presence in (<u>Casing matrix from offal</u>) RISK PROFILE ELEMENTS 8. Justification for Use: - o Effective against bacterial infections in veterinary medicine. - o Utilized in the treatment of various infections in livestock. 9. Veterinary Use Pattern - o Approved uses include treatment of urinary tract infections in animals. - o [Include product labels or official use authorization documentation] 10. Commodities for Which Codex MRLs Are Required - o Meat (beef, poultry) - o Dairy products - o Fish - o (<u>Casing matrix from offal</u>) 11. Specific Request to Risk Assessors • Assessment of Residue Risks: - o Evaluate potential risks associated with Nitrofurans residues in (<u>Casing matrix from offal</u>). • Health Impact Analysis: - o Assess the short-term and long-term health impacts of exposure to Nitrofurans residues. • Comparative Efficacy: - o Analyse the effectiveness of Nitrofurans compared to alternative veterinary drugs. AVAILABLE INFORMATION 12. Countries Where the Veterinary Drugs Are Registered Indonesia (44 substances), China (28 substances), India (28 substances), US (27 substances), and Australia (23 substances). China	
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13. National/Regional MRLs or Any Other Applicable Tolerances

No safe level of residues of Nitrofurans or their metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, Egypt prevents residues of Nitrofurans in food.

14. List of Data Available

Sub group	Compound	Main analysis technique	Limit of quantification, LOQ [$\mu\text{g/Kg}$]	Accredited (Y/N)	Sub group
A2b	Nitrofurans	Nitrofurantoin (AHD)	LC-MS/MS	0.5	Y
		Furazolidone (AOZ)	LC-MS/MS	0.5	Y
		Nitrofurazone (SEM)	LC-MS/MS	0.5	Y
		Furaltadone (AMAZ)	LC-MS/MS	0.5	Y

Inclusion of Sulfadimidines in the priority list for subsequent recommendation to JECFA for evaluation

Egypt proposes the inclusion of the veterinary drug Sulfadimidines in the priority list for subsequent recommendation to JECFA for evaluation. The information recommended for consideration in the priority list by CCRVDF has been completed and is attached. Relevant data are anticipated to be available on toxicology, metabolism, pharmacokinetics, and residue-depletion studies conducted on the drug in honey. In view of no safe level of residues of Sulphonamides or their metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, Egypt suggests preventing residues of Sulfadimidines in honey.

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

- Egypt

Egypt

2. Veterinary drug names • Common Sulfonamides: Sulfadiazine, Sulfadimethoxine, Sulfamethazine (Sulfadimidine), Sulfamerazine, Sulfachlorpyridazine, Sulfaquinoxaline, Sulfathiazole, Sulfamethoxazole, Sulfamonomethoxine, Sulfisoxazole. • Potentiated Combinations: Trimethoprim-sulfadiazine (co-trimazine), Trimethoprim-sulfamethoxazole (co-trimoxazole), Ormetoprim-sulfadimethoxine. 3. Trade names • Albon (Sulfadimethoxine) • Sulmet, Sulfabrom (Sulfamethazine) • Tribrissen, Equisul-SDT (Sulfadiazine/Trimethoprim) • Di-Methox (Sulfadimethoxine) • Others: Intradine, Calfspan, Mediprim, Bimadine, Sulfazine 4. Chemical names and CAS registry number • Sulfachlorpyridazine: (6-Chloro-3-pyridazinyl)sulfanilamide • Sulfadimethoxine: 4-Amino- -(2,6-dimethoxy-4-pyrimidinyl)benzenesulfonamide • Sulfamethazine (Sulfadimidine): 4-Amino- -(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide • Sulfaquinoxaline: -2-Quinoxalinylsulfanilamide • Sulfathiazole: 4-Amino- -2-thiazolybenzenesulfonamide 5. Names and addresses of basic producers • <i>Key producers mentioned in literature include:</i> Huvepharma (USA), Zoetis (USA), Bimeda Animal Health (Ireland), Virbac (Italy/South Africa), Norbrook Laboratories (Ireland/UK), Ceva (Italy).	
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PURPOSE, SCOPE, AND RATIONALE 6. Identification of the food safety issue (residue hazard) • Residue Hazards: Sulfonamide residues in honey can cause hypersensitivity reactions (allergies), toxicity (crystal urine, hematuria), and potential cancer risks in consumers. • Antimicrobial Resistance (AMR): Their misuse contributes to the development of resistant bacteria, identified as a top 10 public health threat by the WHO. • Stability: Sulfonamides demonstrate high thermal stability, meaning they persist even after cooking or processing. 7. Assessment against the criteria for inclusion on the priority list • Widespread Use: They are widely used for prophylaxis and treatment of bacterial infections in bees. • High Occurrence in Food: Residues are frequently detected in honey RISK PROFILE ELEMENTS 8. Justification for use • Antibacterial Action: Used for treatment and prevention of bacterial diseases, including respiratory, enteric, and urinary tract infections. • Coccidiostat: Used for controlling coccidiosis in bees. 9. Veterinary use pattern • Target Species: bee • Administration: Oral (feed/water), injection, and boluses. • Withdrawal Periods: Strict adherence to withdrawal times is necessary to avoid residues in edible tissues. In the US, extra-label use in lactating dairy cattle is prohibited. • Common Use in Combination: Often used with diaminopyrimidines (e.g., trimethoprim) to increase efficacy. 10. Commodities for which Codex MRLs are required • Honey: Specifically mentioned for bee products. 11. Specific Request to Risk Assessors • Safety Evaluation of Older Compounds: Many sulfonamides are "old" drugs lacking modern toxicological studies (e.g., specific carcinogenicity/mutagenicity studies). • Hypersensitivity Focus: Due to the risk of allergic reactions, the committee recommends that MRLs for sulfonamides be set as low as practically achievable.	
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- **Microbial Ecology Study:** Assessment of residues on the microbial ecology of the human intestinal tract is required for these antimicrobial agents.

- **Data Requirement:** evaluation of residue in honey

12. Countries Where Veterinary Drugs are Registered

- **Global Registration:** Sulphonamides (e.g., sulfadiazine, sulfadimethoxine, sulfamethazine) are widely registered for use in cattle, pigs, poultry, and fish.
- **European Union:** Registered, with strict compliance to Regulation 2019/6 and 2021/578 requiring registration in SANITEL-MED or VAMREG.
- **United States:** Registered with FARAD listing (e.g., sulfadimethoxine, sulfabromomethazine, sulfaethoxy pyridazine).
- **Other:** Commonly used in China and Australia.

13. National/Regional MRLs or Applicable Tolerances

No safe level of residues of Sulfonamides or its metabolites in honey representing an acceptable risk to consumers, significant health concerns were identified. For this reason, Egypt prevent residues of Sulfonamides in honey

14. List of Available Data

- **Toxicology:** Older studies are available, but modern long-term, reproductive, and genotoxicity studies are often missing for many sulfonamides in honey
- **Pharmacology/Metabolism:** studies are often missing for many sulfonamides in honey
- **Residue Depletion:** studies are often missing for many sulfonamides in honey.
- **Analytical Methods:** HPLC-MS/MS methods are validated for multi-residue detection in various tissues and milk.
- **JMPR Evaluation:** Generally, sulfonamides are not heavily evaluated by JMPR as they are primarily used as veterinary medicines rather than pesticides, although some compounds (e.g., those acting as fungicides) might have legacy data.

15. Timetable for Data Submission

Table:Linearity, limits of detection (LOD) and limits of quantification (LOQ) of the 41 target analytes in honey.

Analyte	R ²	Range (µg/kg)	LOD (µg/kg)	LOQ (µg/kg)
Sulfacetamide	0.9996	2.5-50	0.18	0.30
Sulfachloropyridazine	0.9997	2.5-50	0.45	0.75
Sulfadiazine	0.9987	2.5-50	0.35	0.58
Sulfadimethoxine	0.9995	2.5-50	0.30	0.51
Sulfadoxine	0.9960	2.5-50	0.47	0.79

	Sulfaguanidine	1.0000	2.5-50	0.26	0.44		
	Sulfamerazine	0.9966	2.5-50	0.19	0.32		
	Sulfamethazine	0.9997	2.5-50	0.32	0.54		
	Sulfamethizol	0.9958	2.5-50	0.35	0.58		
	Sulfamethoxazole	0.9990	2.5-50	0.41	0.68		
	Sulfamethoxypyridazine	0.9957	2.5-50	0.47	0.79		
	Sulfamonomethoxine	0.9977	2.5-50	0.61	1.02		
	Sulfamoxol	0.9984	2.5-50	0.32	0.54		
	Sulfanilamide	0.9980	2.5-50	0.62	1.04		
	Sulfapyridine	0.9979	2.5-50	0.38	0.63		
	Sulfathiazole	0.9994	2.5-50	0.27	0.45		
	Sulfisoxazole	0.9985	2.5-50	0.32	0.54		
	Ciprofloxacin	0.9994	2.5-50	0.29	0.49		
	Enrofloxacin	0.9994	2.5-50	0.29	0.49		
	Flumequine	0.9984	2.5-50	0.28	0.47		
	Oxolinic acid	0.9990	2.5-50	0.27	0.45		
	Sarafloxacin	0.9974	2.5-50	0.35	0.59		
	Chlortetracycline	0.9999	2.5-50	0.35	0.58		
	Doxycycline	0.9946	2.5-50	0.48	0.81		
	Oxytetracycline	0.9971	2.5-50	0.46	0.77		
	Tetracycline	0.9946	2.5-50	0.81	1.36		
	Ampicillin	1.0000	2.5-50	3.92	6.54		
	Penicillin V	0.9940	2.5-50	0.41	0.69		
	Erythromycin	0.9981	2.5-50	0.45	0.75		
	Tylosin	0.9948	2.5-50	0.42	0.71		

Dimetridazole	0.9996	0.75-15	0.10	0.18
Dimetridazole-OH	0.9999	0.75-15	0.69	1.15
Ipronidazole	0.9994	0.75-15	0.10	0.16
Ipronidazole-OH	0.9997	0.75-15	0.19	0.32
Metronidazole	0.9990	0.75-15	0.17	0.39
Ronidazole	0.9974	0.75-15	0.80	1.34
Tinidazole	0.9985	0.75-15	0.08	0.14
Ceftiofur	0.9988	2.5-50	0.35	0.72
Trimethoprim	0.9990	2.5-50	0.08	0.13
Chloramphenicol	0.9962	0.075-1.5	0.006	0.011

16. Additional Information

- **Key Sulfonamides:** Sulfadiazine, Sulfadimidine (Sulfamethazine), Sulfadimethoxine, Sulfamonomethoxine, Sulfathiazole, Sulfaquinoxaline, Sulfachloropyridazine, Sulfisoxazole.

COMMENT	MEMBER/OBSERVER
Template for submission of nominations The European Union and its Member States (EUMS) suggest that to submit nominations of compounds for MRL extrapolation, a specific template or section of the template is developed. 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. A brief, referenced analysis, demonstrating that extrapolation could be possible in line with the Risk analysis principles applied by CCRVDF, Annex C, Approach for extrapolation of MRLs of veterinary drugs to one or more species. 6. Additional information (optional) Rationale: The existing form is unnecessarily detailed for extrapolation requests. To date, CCRVDF has only agreed to undertake cross-species extrapolations (and not extrapolations to new food commodities), and consequently, this should be the focus of the new template/section of the template.	EU
Based on the results of discussions and meetings of the Indonesian MC CCRVDF, there are no new/extrapolated compounds proposed for review by JECFA.	Indonesia
1. Part 1 – Veterinary drugs for JECFA evaluation or re-evaluation Malaysia supports amoxicillin in chicken tissues and eggs, ethion in cattle tissues, and fumagillin DCH in fish fillet and honey for inclusion in the priority list. Malaysia supports the timely submission of nominations for veterinary drugs. 2. Part IV – New veterinary drugs for JECFA evaluation under the “parallel review” Malaysia supports the application of the parallel review approach. 3. Part V – Extrapolation Malaysia supports to prioritize albendazole, ivermectin, and oxytetracycline for extrapolation of MRLs to camelid tissues and milk. 4. Part VI – Action Levels Malaysia supports to prioritize nicarbazin and lasalocid in chicken eggs for the establishment of Action Levels. Other comments: Template for submission of nominations Malaysia supports Option (iii): There is no need to develop or revise the template provided in Annex A to the Risk analysis principles applied by CCRVDF.	Malaysia

COMMENT						MEMBER/OBSERVER
Part IV: New veterinary drugs for JECFA evaluation under the “parallel review” - Delays in availability of Bromoform data New Zealand has been informed that the availability of the complete data package for Bromoform has been delayed along with New Zealand's parallel assessment. New Zealand's parallel review identified several areas where it was desirable to have some new data generated to support more practical good agricultural practices and the use of the proposed slow-release ruminal bolus in dairy cattle. A new ADME study is underway with the results projected to be available the first quarter of 2027 at which stage the Commercial sponsor has indicated they will be in a position to make a full pack available. Part V: Extrapolation <i>Potential candidates for extrapolation</i> New Zealand has reviewed those veterinary drugs that Codex has an MRL in cattle and NZ has also approved the use in sheep. Some of these registrations have also been the result of New Zealand's own extrapolation policies which in turn can allow for some approved uses to be allowed based on minimal species-specific data combined with much longer withholding periods. This is often the case for example with respect to the potential use in milking sheep and goats - a new and small but growing sector. New Zealand is partly through assessing the fuller data packages available so as to be able to comment whether they meet the current extrapolation criteria, but as the comment period closes shortly, the following table of vet drugs approved for use in deer, sheep, and or goats in NZ, where there are corresponding cattle MRLs, is provided. All of the below have established cattle MRLs and are approved for use in sheep, goats, and or deer in New Zealand, so could be extrapolation candidates. Noting some may have been registered for use in New Zealand, largely based on our own data extrapolation policies, with longer withholding periods set where the available data was limited.						New Zealand
COMPOUND	Sheep milk	Sheep tissues	Goat milk	Goat tissues	Deer tissues	
Abamectin	Possible	Possible	--	--	Possible	
Alpha-cypermethrin	Possible	Already set	--	--	--	
Benzylpenicillins	Possible	Possible	--	--	--	
Deltamethrin	Possible	Already set	Possible	Possible	--	
Dexamethasone	Possible	Possible	Possible	Possible	--	
Doramectin	Possible	Possible	--	--	--	
Eprinomectin	Possible	Possible	--	--	Possible	
Fenbendazole/ Oxfendazole	Already set	Already set	Possible	Possible	Possible	
Oxytetracyclin	Already set	Already set	Possible	Possible	Possible	
Sulphadimidine	“not specified?”	Possible	“not specified?”	Possible	--	
Tylosin	Possible	Already set	Possible	Possible	--	

COMMENT	MEMBER/OBSERVER
Within the framework of Panama's ongoing commitment to strengthening the scientific basis underpinning the decisions of the Codex Alimentarius Commission and to promoting harmonized measures that ensure food safety and facilitate international trade, our country reiterates the importance of advancing, in a timely and transparent manner, the evaluation of veterinary drugs by the competent scientific bodies. In this regard, Panama has previously expressed its support, both through its Country Position and within the framework of the CCLAC Region, in previous meetings specifically since the 21st session of the CCRVDF endorsing progress in the evaluation of MRLs or the development of guidelines by JECFA for the priority list of veterinary drugs requiring evaluation or re-evaluation, in accordance with robust scientific criteria and the needs identified by Members.	Panama
Saudi Arabia agrees with the proposed priority lists as presented in Parts I, IV, V, and VI. (template)	Saudi Arabia
Senegal proposes that the priority list take into account the drugs most commonly used at the local level, in particular albendazol, ivermectin, and oxytetracycline, for the extrapolation of MRLs to camelid tissues and milk. Senegal takes note of the decision by JECFA, given that large quantities of these molecules are used in our farms.	Senegal
The United Arab Emirates (UAE) presents its compliments to the Codex Secretariat and has the honor to submit its comments and information in response to Circular Letter CL 2026/15-RVDF regarding the priority list of veterinary drugs for evaluation or re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The UAE recognizes the importance of a transparent, risk-based prioritization process for JECFA evaluations to support the establishment of Codex maximum residue limits (MRLs), facilitate international trade, and protect consumer health. After reviewing Parts I, IV, V, and VI, the UAE provides the following comments: Part I: Veterinary drugs for JECFA evaluation or re-evaluation The UAE takes note of the prioritization agreed by CCRVDF27, including: 1. Amoxicillin in chicken tissues and eggs 2. Ethion in cattle tissues 3. Fumagillin dicyclohexylamine (DCH) in fish (fillet) and honey. The UAE supports the use of the established criteria under the Risk analysis principles applied by CCRVDF when considering compounds for inclusion in the priority list. The UAE further supports requests to Codex Members to confirm the timing of data availability for previously nominated compounds, as this information is essential for effective planning of JECFA work. Part IV: New veterinary drugs under parallel review The UAE notes the prioritization of umifoxolaner and bromoform for evaluation under the parallel review process and supports continued application of the agreed principles and approach for parallel review, including confirmation that national approval and good veterinary practices are expected prior to the relevant JECFA meeting. Part V: Extrapolation The UAE supports the prioritization of: 1. Albendazole 2. Ivermectin 3. Oxytetracycline for extrapolation of MRLs to camelid tissues and milk. The UAE considers MRL extrapolation particularly relevant for regions with significant camelid production and consumption, and encourages Members to provide data in accordance with Annex C of the Risk Analysis Principles applied by CCRVDF.	UAE

COMMENT	MEMBER/OBSERVER
Part VI: Action Levels The UAE supports prioritizing nicarbazin and lasalocid in chicken eggs for establishing Action Levels and encourages the use of Annex D criteria to ensure consistent, health-protective outcomes. Comments on templates Template for submission of nominations The UAE supports further consideration of whether additional or adapted templates may be beneficial for nominations related to MRL extrapolation, action levels, and parallel review, while noting that any revision should maintain consistency with the Risk analysis principles applied by CCRVDF and avoid unnecessary administrative burden.	
The United States of America is pleased to nominate three veterinary drugs to the Part 1 of the Priority List. • Doramectin: request JECFA to establish an acute reference dose (ARfD) • Ketoprofen: request JECFA to establish an ADI and ARfD and MRLs in cattle muscle, liver, kidney and fat. • Pradofloxacin: request JECFA to establish an ADI and MRLs in cattle muscle, liver, kidney and fat and pig muscle, liver, kidney and fat. Complete dossiers are available for each veterinary drug to enable the requested evaluations, and the sponsoring companies are willing to supply the data at the next call for data made by JECFA. Nomination forms are provided for each veterinary drug below. Nomination Form to add DORAMECTIN to the Priority List. ADMINISTRATIVE INFORMATION Member(s) submitting the request for inclusion United States of America Veterinary drug names Doramectin Trade names Dectomax® Injectable Solution for Cattle and Swine; Dectomax® Pour on Solution for Cattle; DECTOMAX® CA1 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]pentacos-10,14,16,22-tetraene]-2'-one 117704-25-3	USA

COMMENT	MEMBER/OBSERVER
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: • <u>Cattle</u>: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. • <u>Cattle</u>: To control infections and to protect from reinfection with <i>Cooperia oncophora</i> and <i>Haemonchus placei</i> for 14 days, <i>Ostertagia ostertagi</i> for 21 days, and <i>C. punctata</i>, <i>Oesophagostomum radiatum</i>, and <i>Dictyocaulus viviparus</i> for 28 days after treatment.	

COMMENT	MEMBER/OBSERVER
• <u>Swine</u>: 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: <i>Ostertagia ostertagi</i> (adults and fourth-stage larvae), <i>Ostertagia ostertagi</i> (inhibited fourth-stage larvae), <i>Ostertagia lyrata</i> (adults), <i>Haemonchus placei</i> (adults and fourth-stage larvae), <i>Trichostrongylus axei</i> (adults and fourth-stage larvae), <i>Trichostrongylus colubriformis</i> (adults and fourth-stage larvae), <i>Cooperia oncophora</i> (adults and fourth-stage larvae), <i>Cooperia punctata</i> (adults and fourth-stage larvae), <i>Cooperia pectinata</i> (adults), <i>Cooperia surnabada</i> (adults), <i>Bunostomum phlebotomum</i> (adults), <i>Oesophagostomum radiatum</i> (adults and fourth-stage larvae), <i>Trichuris</i> spp. (adults); lungworms: <i>Dictyocaulus viviparus</i> (adults and fourth-stage larvae); eyeworms: <i>Thelazia gulosa</i> (adults), <i>Thelazia skrjabini</i> (adults); grubs: <i>Hypoderma bovis</i> and <i>Hypoderma lineatum</i>; sucking lice: <i>Linognathus vituli</i>, <i>Haematopinus eurysternus</i>, and <i>Solenopotes capillatus</i>; biting lice: <i>Bovicola</i> (<i>Damalinia</i>) <i>bovis</i>; mange mites: <i>Chorioptes bovis</i> and <i>Sarcoptes scabiei</i>; horn flies: <i>Haematobia irritans</i>. • To control infections and to protect from reinfection with <i>Cooperia oncophora</i>, <i>Dictyocaulus viviparus</i>, <i>Ostertagia ostertagi</i>, and <i>Oesophagostomum radiatum</i> for 28 days; and with <i>Cooperia punctata</i> and <i>Haemonchus placei</i> for 35 days after treatment • To control infestations and to protect from reinfestation with <i>Linognathus vituli</i> for 42 days and with <i>Bovicola</i> (<i>Damalinia</i>) <i>bovis</i> for 77 days after treatment. DECTOMAX® CA1 is indicated for prevention and treatment of infestations caused by larvae of <i>Cochliomyia hominivorax</i> (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.	

COMMENT	MEMBER/OBSERVER
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	

COMMENT	MEMBER/OBSERVER
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 ***** 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	

COMMENT	MEMBER/OBSERVER
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.	

COMMENT	MEMBER/OBSERVER
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://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/140-269 *****	

COMMENT	MEMBER/OBSERVER
<u>Nomination Form to Add PRADOFLOXACIN to the Priority List</u> 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) 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.	

COMMENT	MEMBER/OBSERVER
• 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 <i>Mannheimia haemolytica</i>, <i>Pasteurella multocida</i>, <i>Histophilus somni</i>, and <i>Mycoplasma bovis</i>; and in swine for the treatment of swine respiratory disease (SRD) associated with <i>Bordetella bronchiseptica</i>, <i>Glaesserella (Haemophilus) parasuis</i>, <i>Pasteurella multocida</i>, <i>Streptococcus suis</i>, and <i>Mycoplasma hyopneumoniae</i>. 9. Veterinary use pattern, including information on approved uses if available <u>Cattle</u>: 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. <u>Swine</u>: 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	

COMMENT	MEMBER/OBSERVER
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.	