## CODEX ALIMENTARIUS COMMISSION







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Agenda Item 11

CX/RVDF 18/24/11

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# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

#### **Twenty-fourth Session**

#### **DATABASE ON COUNTRIES' NEEDS FOR MRLs**

Report of the EWG-CCRVDF: Argentina, Australia, Belgium, Bolivia, Brazil, Chile, Costa Rica, Cuba, Egypt, France, India, Iran, Italy, Japan, Malaysia, New Zealand, Nigeria, Panama, Paraguay, Peru, Republic of Korea, South Africa, Thailand, Uganda, United States, Uruguay, Venezuela, Food and Agriculture Organization of the United Nations (FAO), World Organization for Animal Health (OIE), FoodDrinkEurope, International Dairy Federation (IDF), and Safe Supply of Affordable Food Everywhere (SSAFE).

#### **BACKGROUND**

- 1. The CCRVDF at its 23<sup>rd</sup> session agreed to establish an electronic working group (EWG) co-hosted by Costa Rica and the United States of America, with the following Terms of Reference:
  - To consider the complete results of the global survey in order to identify priority veterinary drugs;
     and
  - To identify information gaps for a successful and comprehensive assessment by JECFA.

#### **Procedures Electronic Working Group**

- 2. The goal of this EWG is to identify ten high-priority veterinary drugs to enable Members to work together to fill information gaps that impede a JECFA evaluation. The EWG membership were by electronic mail and the Codex Alimentarius web platform.
- 3. In the first round of comments, members were asked to review the initial list of high priority veterinary drugs. Comments were received from Argentina, Bolivia, Costa Rica, Cuba, Japan, Peru and Venezuela. The initial list of high priority veterinary drugs was updated to include additional veterinary drugs presented in the country comments and can be found in Appendix 1. Then, the EWG members were requested to suggest "criteria" that could be used to arrive at the list of high priority veterinary drugs that need MRLs.
- 4. In the second round of comments, EWG members were asked to comment on the complete list of suggested "criteria". In the interest of transparency, the second round of comments included all suggested criteria from EWG members and can be found in Appendix 2. Comments were received from Argentina, Brazil, Chile, Costa Rica, Japan, Panama, Peru, and Thailand. Several members commented that there was significant overlap among some of the criteria and suggested that the many criteria could be grouped together. Some EWG members also suggested that the criteria may vary in priority and should be applied differently. Based on the comments received, the Co-Chairs grouped similar criteria and proposed a step-wise process for narrowing the starting list of high priority veterinary drugs.
- 5. In the third round of comments, the EWG members were asked to apply the criteria to the list of high priority veterinary drugs. EWG members were asked to respond with a "yes" or "no" to indicate whether the specific veterinary drug met each criterion included in Appendix 3. The criteria for prioritization are presented in Table 1 below. Some of the questions provided had been answered by the Co-Chairs based on publicly available information such as Codex MRLs, JECFA reports, EU published MRLs and FDA published tolerances. Other questions required input from EWG members to determine if the criteria were met. Comments were received from Argentina, Brazil, Costa Rica, Cuba, Japan, Peru, Thailand, and Uganda.
- 6. All country comments included responses to many of the criteria for each veterinary drug in the Starting List. Many countries also identified the top ten veterinary drugs based on their own responses to the criteria. The Co-Chair performed two different analyses of the country responses. Each analysis resulted in a different top ten list, but both are presented for discussion.

**Table 1.** Prioritization for application of criteria to the starting list of high priority veterinary drugs in need of Codex MRLs.

Criteria	Priority
Must meet both high priority criteria to remain in the	starting list.
There are no Codex MRLs for the veterinary drug in the requested species and tissues	High
There is a specific human health concern or trade implication associated with this veterinary drug	High
Must meet at least one of the moderate priority criteria to rema	ain in the starting list.
This veterinary drug is widely used in animal drug production systems	Moderate
This is the only veterinary drug for a particular purpose or disease	Moderate
This veterinary drug is for a species with few Codex MRLs available	Moderate
Low priority criteria for consideration in narrowing the sta	urting list to ten.
This veterinary drug does not have EMA MRLs or FDA tolerances	Low
This veterinary drug has a JECFA or JMPR toxicological evaluation	Low
This veterinary drug has Codex MRLs in other species or tissues	Low

<sup>7.</sup> The countries provided comments for the third round on Appendix 3 and their respective application of the decision tree and compliance with the "high priority criteria," and many determined the ten priority veterinary drugs in need of MRLs for their country. In the first analysis, the veterinary drugs identified by each participating country were compared in a comprehensive manner to arrive at a single list based on the country lists. List A considers the veterinary drugs of greater coincidence or similarity between the responses of the six countries' high priority lists. Appendix 4a shows the comparison of responding countries' top ten lists.

**Table 2**: List A: Top ten highest priority veterinary drugs in need of MRLs determined by analysis of individual country prioritizations.

	L	IST A
N.	Veterinary drug	Number of Countries that agree on the priority of the veterinary drug
1	Enrofloxacin	6
2	Amitraz	5
3	Cloxacylin	4
4	Florphenicol	4
5	Fosfomicin	4
6	Toltrazuril	4
7	Tulatromicin	4
8	Ampicillin	3
9	Cefquinome	3
10	Trimetropim	3

<sup>8.</sup> In the second analysis, the responses from EWG members were compiled for each criterion to narrow the list to ten highest priority veterinary drugs. The starting list of veterinary drugs was prioritized in the following manner:

A. A veterinary drug was eliminated from further prioritization if none of the country responses indicated both high priority criteria were met. Twelve veterinary drugs were eliminated from further prioritization for this reason.

B. A veterinary drug was eliminated from further prioritization if none of the country responses indicated at least one moderate priority criterion was met. One veterinary drug was eliminated from further prioritization for this reason.

- C. The low priority criteria were considered when 30 products remained in the list after the high and moderate priority criteria were assessed. At this stage, veterinary drugs were prioritized based on the total number of criteria met. A veterinary drug meeting all 8 criteria was considered the highest priority.
- D. The proportion of responses for a given criterion was considered when many veterinary drugs had met the same number of criteria.
- 9. Six veterinary drugs met 7 or more criteria based on the cumulative country responses. An additional five veterinary drugs met 6 criteria based on the cumulative country responses, and were further analyzed to determine which one had the most responses from countries for inclusion in the top ten list. List B considers the veterinary drugs meeting the most criteria based on cumulative country responses found in Appendix 4b.

**Table 3:** List B: Top ten highest priority veterinary drugs in need of MRLs determined by analysis of cumulative country responses.

	LIST B						
N.	Veterinary drug	Number of criteria met for the veterinary drug based on cumulative country responses					
1	Diminazene	8					
2	Amoxicilin, Thihidrat Amoxicilin	7					
3	Dipropionate imidocarb	7					
4	Gentamicin	7					
5	Ivermectin	7					
6	Oxitetracycline	7					
7	Amitraz	6					
8	Ethion	6					
9	Fipronil	6					
10	Fosfomicin	6					

- 10. List A and List B have two veterinary drugs in common. Both lists represent priorities from responding countries, but were developed with two different approaches to analyzing country responses. The lists are presented for consideration by EWG members and by CCRVDF24.
- 11. In the fourth round, the EWG members were asked to consider the draft report of the EWG on Prioritization of Countries Needs for MRLs and comment on the two approaches to analyze country responses. Argentina, Brazil, Costa Rica, Peru and Uganda provided comments on the report and lists. Comments were received in support of both prioritization approaches, along with requests to ensure enrofloxacin would be included in the final top ten list.

#### **RECOMMENDATIONS FROM THE CO-CHAIRS**

- 12. Based on the comments received, the Co-Chairs would like to propose an in-session working group. An in-session working group would allow discussion of the prioritization approaches presented in this report. Such discussion could help to build consensus on a single top-ten list of veterinary drugs in need of Codex MRLs to be considered by the CCRVDF.
- 13. The EWG was also tasked with identifying data gaps for a successful and comprehensive assessment by JECFA. Once there is agreement on the approach and the top ten list to be used, the CCRVDF may consider additional work to identify existing data and data gaps preventing evaluation or re-evaluation of the highest priority veterinary drugs in need of Codex MRLs. At the same time, Members could then work together to fill information gaps that impede a JECFA evaluation.

### **Appendices:**

Appendix 1: Starting list of high priority veterinary drugs in need of Codex MRLs

Appendix 2: Prioritization of High Priority Veterinary Drugs in need of Codex MRLs

Appendix 3: Application of criteria for Prioritization of high priority veterinary drugs that require Codex MRLs

**Appendix 4a:** Ranking of high priority veterinary drugs that require Codex MRLs based on comparison of responding countries' top ten priorities

**Appendix 4b:** Ranking of high priority veterinary drugs that require Codex MRLs based on analysis of cumulative country responses.

Appendix 1: Starting List of High Priority Veterinary Drugs in need of Codex MRLs (This is the starting list with the comments and corrections added for the countries)

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
1	Starting List	Albendazol, albendazol of sulfoxid (Ricobendazol), sulfon albendazol	Yes. Adoption in 1993 Not especificate	Swine, Horse, Goats and Poultry, Sudamerican camels	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endoparasites	Latest evaluation in 1989			
2	Starting List	Abamectin	Yes. Adoption in 2003 for Cattle	Pig, Horse, Goats and Sheep.	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of parasites infections	Latest evaluation in 1989	Codex Alimentarius is only in Fat, Liver and Kidney of Cattle	Latest evaluation in 2015. AD of: 0– 0.001 mg/kg bw was set. The ADI also applies to the 8,9-Z isomer and the 24- hydroxymethy I metabolite of abamectin.	Plant commodities only
3	Starting List	Amoxicilin, Thihidrat Amoxicilin	Yes. Adoption in 2012 for Cattle, Pig and Sheep	Fish, Goats and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Control of bacterial infections	Latest evaluation in 2011			
4	Starting List	Ampicilin Sodic Ampicilin, Trihidrat ampicillin	No	Cattle, Pig, Horse, Goats, Sheep, Fish and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of pneumonia and Control of bacterial infections.	No			
5	Starting List	Amitraz	No		Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Parasitosis, acariosis	No		Latest evaluation in 1998. ADI of 0.01 mg/kg bw was set.	Plant commodities Cattle*, Pig*, Sheep*  *The MRL accommodate s external animal treatment.

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
6	Starting List	Amprolium	No	Cattle, Pig, Goats, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Control of coccidiosis	Prevention and control of coccidiosis,	No			
7	Starting List	Bacitracin, Bacitracin Zinc, Bacitracin metilen disilicato	No	Cattle, Pig, Rabbit, Goat, Sheep, Turkey and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No			
8	Added by Appendix 2	Bencidamin	No	Cattle, horse and pig	N.I.	Antimicrobial agent	N.I		Veterinary Drug used and registered in the country		
9	Added by Appendix 2	Bromhexin	No	Poultry, Cattle and pig	N.I.	Antimicrobial agent			Veterinary Drug used and registered in the country		
10	Starting List	Cefalexin	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Antimastitic, Treatment of enteric and respiratory diseases	No			
11	Starting List	Cefquinoma	No	Cattle, Pig, Horse and Goat	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Control and treatment of bacterial infections.	No			
12	Starting List	Ceftiofur	Yes. Adoption in 1999 for Cattle and Pig	Horse, Sheep, Goat and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicrobial agent	Treatment of enteric and respiratory diseases	Latest evaluation in 1997			
13	Added by Appendix 2	Ceftriaxone	No	Cattle	N.I.	Antimicrobial agent	Control of bacterial infections.		Veterinary drug register and use in the country		
14	Starting List	Cipermetrin and alfa-cipermetrin	Yes. Adoption in 2006 for Cattle and Sheep	Bees, Pig, Horse, Goat	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Parasitosis, acariosis	Latest evaluation 2004		Latest evaluation in 2005. 0-0.02 mg/kg bw (2006) Group ADI for cypermethrins	Plant commodities mammals other than marine Poultry Milk

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
										, including alpha- cypermethrin and zeta- cypermethrin, was set.	
15	Starting List	Cloxacylin	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No			
16	Starting List	Colistin	Yes. Adoption in 2008 for Goats, Rabbits, Sheep, Turkey, Poultry and Cattle	Pig and Horse	Muscle, Liver, Fat, Milk and Kidney	Antimicrobial agent	Growrh promoter, Treatment of enteric infection	Latest evaluation in 2006			
17	Added by Appendix 2	Coumaphos	No	Cattle	Muscle, Liver, Fat, Milk and Kidney	Antiparasitic agent	Control and prevention of endo/ectoparasit es infections	No	MRL by Australia		
18	Starting List	Diminazene	Yes. Adoption in 1997 for Cattle	Cattle, Sheep, and Goats	Muscle, Liver, Fat, Kidney, Milk	Trypanocide	Trypanosomosis	Latest evaluation in 1994			
19	Added by Appendix 2	Dipropionate imidocarb	No	Cattle and horse	N.I.	External antiparasitic agent	N.I.		Veterinary Drug used and registered in the country		
20	Added by Appendix 2	Enramicin	No	Poultry and pig	Muscle, peel+fat, liver, Kidney	Treatment for bacteral infections for gram - or gram +. Activity against Clostridium Perfringens.	Necrotic enteritis	No			

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
21	Starting List	Enrofloxacin	No	Cattle, Cuyes, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicrobial agent	Treatment of enteric and respiratory diseases	No			
22	Added by Appendix 2	Enrofloxacin	No	Shrimp	Tissue	Antimicrobial agent	Infections by bacterial gener as Vibrio		Veterinary drug register and use in the country		
23	Added by Appendix 2	Ethion	No	Cattle	N.I.	External antiparasitic agent	N.I		Veterinary Drug used and registered in the country		
24	Starting List	Fipronil	No	Bees, Cattle, Pig, Cuyes, Goat and Sheep	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Control of ectoparasites	No		Latest evaluation in 2000. 0-0.0002 mg/kg bw Group ADI for fipronil and fipronil- desulfinyl was set.	Plant commodities Cattle Poultry Milk
25	Starting List	Florfenicol	No	Cattle, Cuyes, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No			
26	Added by Appendix 2	Florphenicol	No	Shrimp	Tissue	Antimicrobial agent	Infections by bacterial gener as Vibrio		Veterinary drug register and use in the country		
27	Added by Appendix 2	Flavofosfolipol	No	Poultry and Cattle	Muscle	Antimicrobial agent	Regulator of intestinal microflora.	No	Priority 3		
28	Starting List	Flumetrin	No	Bees and Cattle	Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Control of ectoparasites	No		Latest evaluation in 1996. ADI of 0.004 mg/kg bw was	Cattle Cattle milk  *The MRL accommodate

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
										set. And nowdays is included in the priority list (REP17/RVD F, Appendix VI)	s external animal treatment.
29	Added by Appendix 2	Fosfomicin	No	Poultry and pig	Muscle	Antimicrobial agent	Treatment of enteric and respiratory diseases by E. coli, Mucoplasma, Salmonella and Pasteurella	No	Priority 2		
30	Added by Appendix 2	Fumagilin	No	Bees	Honey	Antimicrobial agent	Nosemosis	No	Because there are not MRL, it has authorization to use just in a time with not flow of honey. Priority 1		
31	Starting List	Gentamicin	Yes. Adoption in 2001 for Cattle and Pig	Rabbit, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicrobial agent	Treatment of enteric and respiratory diseases	Latest evaluation in 1998			
32	Starting List	Ivermectin	Yes. Adoption in 1993 for Sheep, Pig and 2017 for Cattle.	Horse, Goat, Camel and Poultry.	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endo/ectoparasit es infections	Latest evaluation in 2015			
33	Added by Appendix 2	Ivermectin	Yes. Adoption in 1993 for Sheep Pig and 2017 for Cattle.	Sheep and pig	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endo/ectoparasit es infections	Last evaluation 2015 in Cattle. Previous evaluation for Sheep in 2002.	Re-evaluation for Sheep and pig, considering a new ADA recommending by JECFA 2015		

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
34	Starting List	Isometamedium Chloride	Yes. Adoption in 1995 for Cattle	Cattle	Muscle, Liver, Fat, Milk and Kidney	Trypanocide	Trypanosomosis	Latest evaluation in 1992			
35	Added by Appendix 2	Metilparaben	No	Cattle	N.I.	External antiparasitic agent	N.I.		Veterinary Drug used and registered in the country		
36	Starting List	Oxitetracyclin	Yes. Adoption in 2003 for Cattle, Pig, Sheep. Oxitetracyclin e just for Fish and giant shrimp	Bees, Camel, Horse and Goat	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	Latest evaluation in 1998	JECFA recommended this LMR about active ingredient combined or individual		
37	Added by Appendix 2	Pirrolidon	No	Cattle	N.I.	Antimicrobial agent	N.I.		Veterinary Drug used and registered in the country		
38	Added by Appendix 2	Propilparaben	No	Cattle	N.I.	External antiparasitic agent	N.I.		Veterinary Drug used and registered in the country		
39	Added by Appendix 2	Proporxur	No	Cattle and pig	Muscle, Liver, Fat, Milk and Kidney	Antiparasitic agent	Control and prevention of endo/ectoparasit es infections	No	MRL by Japan		
40	Starting List	Tiamulin	No	Cattle, Pig, Horse, Goat, Sheep, Turkey and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory disseases	No			
41	Starting List	Toltrazuril	No	Cattle, Camel, Pig, Rabbit, Goose, Goat, Poultry and Sheep	Muscle, Liver, Fat, Milk and Kidney.	Control of coccidiosis	Prevention and control of coccidiosis	No	http://www.ema. europa.eu/docs/ en_GB/docume nt_library/Maxim um_Residue_Li mits _Report/2009/11		

N.	Origin/Countr y	Name (active ingredient)	Existing Codex MRLs (CCRVDF)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	Comments	JMPR Evaluation	Codex MRL (CCPR)
									/WC500015632. pdf		
42	Starting List	Trimetropin	No	Cattle, Rabbit, Camel, Pig, Horse, Goat and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No	http://www.ema. europa.eu/docs/ en_GB/docume nt_library/Maxim um_Residue_Li mits _Report/2009/11 /WC500015681. pdf		
43	Starting List	Tulatromicin	No	Cattle, Pig, Goat, Sheep, and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicrobial agent	Treatment of enteric and respiratory diseases	No			
44	Added by Appendix 2	Tilvalosin	No	Pig, poultry, turkey y pheasants	Muscle and eggs	Antimicrobial agent	Treatment of enteric and respiratory diseases	No			

N.I.: Not indicated

Appendix 2 Prioritization of High Priority Veterinary Drugs in need of Codex MRLs (this is the criterial list purpose for the participant countries in this first round of comments)

N.	Selection of Criterial	Criterial description	Justification
1	Conserve or maintain in the starting list	Include or maintain active ingredient of importance for a country /region for which there are not MRLs Codex as an international reference, or regional or national agencies such as EMA or FDA, whose MRLs and tolerances are internationally accepted by developing countries as quoted the RTCA.	The lack of international reference of MRLs is the main problem facing developing countries in conducting a risk analysis for the establishment of national MRLs and withdrawal periods for veterinary drugs.
2	Conserve or maintain in the starting list	Veterinary Drugs without MRL from CODEX. (Codex scope). Interest in evaluating widely used products without an MRL CODEX	MRL JECFA evaluation, for countries that do not carry out this evaluation
3	Conserve or maintain in the starting list	Maintain veterinary drugs Widely used in animal production systems. Interest in evaluating widely used products without an MRL CODEX	Veterinary drugs with greater use, greater need for definition
4	Conserve or maintain in the starting list	Maintain veterinary drugs, which are the only product available for a particular purpose, specific products for a specific disease.	They are of Critical use and therefore it is relevant to have a JECFA evaluation
5	Conserve or maintain in the starting list	Only for antibiotics and their relationship with Antimicrobial resistance and human use	It is advisable to apply Criterial used by OIE to define criticality of a drug according to document "LIST OF IMPORTANT ANTIMICROBIAL AGENTS FOR VETERINARY MEDICINE"
6	Conserve or maintain in the starting list	Veterinary drugs for species that do not have alternatives, since there are no MRLs. There are species for which there are very few drugs with defined MRLs, as is the case with bees.	It necessary to evaluate this production and the residues of drugs in matrix Honey. Currently CODEX does not have MRLs for this matrix and international honey trade has increased over time
7	Elimination from the starting list	Exclude veterinary drugs, which that already have MRLs from the JMPR.	The veterinary drug has Codex MRLs from JMPR, which can be used as a reference.
8	Elimination from the starting list	Exclude veterinary drugs that have FDA and EMEA MRLs	Our country has Central American regulation to establish the order of adoption of MRLs, which in addition to Codex Alimentarius also includes agencies such as FDA and EMEA.
9	Conserve or maintain in the starting list	Maintain veterinary drugs that already have an initial evaluation for some species.	This would be a starting point for JECFA and scientific sponsors for research on other non-traditional species.
10	Conserve or maintain in the starting list (Putting in a high priority)	A substance, which has already been toxicologically evaluated by JECFA or JMPR.	It seems to be easy to evaluate these compounds.

N.	Selection of Criterial	Criterial description	Justification
11	Conserve or maintain in the starting list (Putting in a high priority)	A substance, which is being, used as veterinary drug for certain food producing animals in several countries, and Codex MRLs in such animal tissues do not exist.	It is meaningful to set MRLs for these compounds to improve food safety and fair practice in food trade.
12	Conserve or maintain in the starting list (Putting in a high priority)	A substance whose health concern and/or food trade implication are identify.	It is meaningful to set MRLs for these compounds to improve food safety and fair practice in food trade.
13	Conserve or maintain in the starting list	Veterinary drugs that have initial evaluation by JECFA in one or more species	The initial assessment would serve as a starting point for JECFA to expand to other species in which it is used.
14	Conserve or maintain in the starting list	Veterinary drugs which has Codex MRLs on specific tissues of one or more matrices	The initial evaluation will serve as a starting point for JECFA to expand the research and establish the MRL for other tissues of interest in species in which it is used.
15	Elimination from the starting list	Veterinary medicinal products that have Codex MRLs in different tissues and species in which they are used	There is no need to update the Codex MRL or further research by JECFA.
16	Conserve or maintain in the starting list	Maintain Veterinary drugs without an MRLs by Codex	MRL JECFA evaluation, for countries that do not carry out this evaluation
17	Conserve or maintain in the starting list	Active principle of importance as a country for which there are no internationally agreed CODEX MRLs	The lack of information on MRLs is one of the major problems in our regions when evaluating a risk analysis.

Appendix 4: Application of Criteria to Starting List of High Priority Veterinary Drugs in need of Codex MRLs

			Starting	List of Hig	ah Priority	Veterinary	Drugs in Ne	eed of Codex			high p criteria t	eet both priority o remain e list	the m	eet at leas oderate p o remain i	riority	consider	iority crite ation in na e list to te	arrowing	
N .	Origin/C ountry	Name (active ingredie nt)	Existin g Codex MRLs (CCRV DF)	Food produci ng species in which this veterin ary drug is used	Tissue s	Purpos e for which this veterin ary drug is used in this species	Disease of concern	Evaluatio n JECFA	Comments	JMPR Evaluat ion	Codex MRL (CCPR)	There are no Codex MRLs for the veterin ary drug in the request ed specie s and tissues . (If there are existin g MRLs, please indicat e which specie s or tissues for which you need MRLs)	There is a specifi c human health concer n or trade implica tions associ ated with this veterin ary drug.	This veterin ary drug is widely used in animal produc tion system s.	This is the only veterin ary drug for a particu lar purpos e or diseas e. (If yes, please indicat e purpos e/disea se.)	This veterin ary drug is for a specie s with few Codex MRLs. (If yes, please specify specie s of interes t.)	This veterin ary drug does not have EMA MRLs or FDA toleran ces.	This veterin ary drug has a JECFA or JMPR toxicol ogical evaluat ion.	This veterin ary drug has Codex MRLs in other specie s or tissues
1	Starting List	Albendaz ol, albendaz ol of sulfoxid (Ricoben dazol), sulfon albendaz ol	Yes. Adoptio n in 1993 Not especifi cate	Swine, Horse, Goats and Poultry, Sudam erican camels	Muscle, Liver, Fat, Milk and Kidney.	Antipar asitic agent	Control and prevention of endopara sites	Latest evaluation in 1989										Yes, JECFA	Yes
2	Starting List	Abamecti n	Yes. Adoptio n in 2003 for Cattle	Pig, Horse, Goats and Sheep.	Muscle, Liver, Fat, Milk and Kidney.	Antipar asitic agent	Control and prevention of parasites infections	Latest evaluation in 1989	Codex Alimentar ius is only in Fat, Liver and	Latest evaluati on in 2015. AD of: 0-0.001	Plant commo dities only							Yes, JECFA	Yes

									Kidney of Cattle	mg/kg bw was set. The ADI also applies to the 8,9-Z isomer and the 24- hydroxy methyl metabol ite of abamec tin.						
3	List	Amoxicili n, Thihidrat Amoxicili n	Yes. Adoptio n in 2012 for Cattle, Pig and Sheep	Fish, Goats and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Control of bacterial infections	Latest evaluation in 2011							Yes, JECFA	Yes
4	Starting List	Ampicilin Sodic Ampicilin, Trihidrat ampicillin	No	Cattle, Pig, Horse, Goats, Sheep, Fish and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Treatment of pneumoni a and Control of bacterial infections.	No				Yes, No Codex MRLs in any species			No	No
5	Starting List	Amitraz	No		Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectopar asitic	Parasitosi s, acariosis	No		Latest evaluati on in 1998. ADI of 0.01 mg/kg bw was set.	Plant commo dities Cattle*, Pig*, Sheep*  *The MRL accom modate s external animal treatme nt.	Yes, No Codex MRLs in any species			Yes, JMPR	No
6	Starting List	Amproliu m	No	Cattle, Pig, Goats, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Control of coccidio sis	Preventio n and control of coccidiosi s,	No				Yes, No Codex MRLs in any species			No	No

7	Starting List	Bacitraci n, Bacitraci n Zinc, Bacitraci n metilen disilicato	No	Cattle, Pig, Rabbit, Goat, Sheep, Turkey and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Treatment of enteric and respirator y diseases	No				Yes, No Codex MRLs in any species			No	No
8	Added by Appendix 2	Bencida min	No	Cattle, horse and pig	N.I.	Antimicr obial agent	N.I		Veterinar y Drug used and registere d in the country			Yes, No Codex MRLs in any species			No	No
9	Added by Appendix 2	Bromhexi n	No	Poultry, Cattle and pig	N.I.	Antimicr obial agent			Veterinar y Drug used and registere d in the country			Yes, No Codex MRLs in any species			No	No
1 0	Starting List	Cefalexin	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Antimastiti c, Treatment of enteric and respirator y diseases	No				Yes, No Codex MRLs in any species			No	No
1	Starting List	Cefquino ma	No	Cattle, Pig, Horse and Goat	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Control and treatment of bacterial infections.	No				Yes, No Codex MRLs in any species			No	No
1 2	Starting List	Ceftiofur	Yes. Adoptio n in 1999 for Cattle and Pig	Horse, Sheep, Goat and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicr obial agent	Treatment of enteric and respirator y diseases	Latest evaluation in 1997							Yes, JECFA	Yes
1 3	Added by Appendix 2	Ceftriaxo ne	No	Cattle	N.I.	Antimicr obial agent	Control of bacterial infections.		Veterinar y drug register and use in the country			Yes, No Codex MRLs in any species			No	No
1 4	Starting List	Cipermet rin and alfa- cipermetr in	Yes. Adoptio n in 2006 for Cattle and Sheep	Bees, Pig, Horse, Goat	Honey (Bees), Muscle, Liver, Fat, Milk	Ectopar asitic	Parasitosi s, acariosis	Latest evaluation 2004		Latest evaluati on in 2005. 0-0.02 mg/kg bw	Plant commo dities mamma Is other than marine				Yes, JECFA and JMPR	Yes

					and Kidney.					(2006) Group ADI for cyperm ethrins, includin g alpha- cyperm ethrin and zeta- cyperm ethrin, was set.	Poultry Milk					
1 5	Starting List	Cloxacyli n	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Treatment of enteric and respirator y diseases	No				Yes, No Codex MRLs in any species			No	
1 6	Starting List	Colistin	Yes. Adoptio n in 2008 for Goats, Rabbits, Sheep, Turkey, Poultry and Cattle	Pig and Horse	Muscle, Liver, Fat, Milk and Kidney	Antimicr obial agent	Growth promoter, Treatment of enteric infection	Latest evaluation in 2006							Yes, JECFA	Yes
1 7	Added by Appendix 2	Coumap hos	No	Cattle	Muscle, Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and prevention of endo/ecto parasites infections	No	MRL by Australia			Yes, No Codex MRLs in any species			No	
1 8	Starting List	Diminaze ne	Yes. Adoptio n in 1997 for Cattle	Cattle, Sheep, and Goats	Muscle, Liver, Fat, Kidney, Milk	Trypano cide	Trypanos omosis	Latest evaluation in 1994							Yes, JECFA	Yes
9	Added by Appendix 2	Dipropion ate imidocar b	No	Cattle and horse	N.I.	External antipara sitic agent	N.I.		Veterinar y Drug used and registere d in the country			Yes, No Codex MRLs in any species			No	
2	Added by Appendix 2	Enramici n	No	Poultry and pig	Muscle, peel+fat	Treatm ent for bacteria	Necrotic enteritis	No				Yes, No Codex MRLs			No	

					, liver, Kidney	I infections for gram - or gram +. Activity against Clostridium perfring ens.						in any species				
2	Starting List	Enrofloxa cin	No	Cattle, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicr obial agent	Treatment of enteric and respirator y diseases	No				Yes, No Codex MRLs in any species			No	
2 2	Added by Appendix 2	Enrofloxa cin	No	Shrimp	Tissue	Antimicr obial agent	Infections by bacterial genus such as Vibrio		Veterinar y drug registere d and used in the country			Yes, No Codex MRLs in any species			No	
2 3	Added by Appendix 2	Ethion	No	Cattle	N.I.	External antipara sitic agent	N.I.		Veterinar y Drug used and registere d in the country			Yes, No Codex MRLs in any species			No	
2 4	Starting List	Fipronil	No	Bees, Cattle, Pig, Rabbit, Goat and Sheep	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectopar asitic	Control of ectoparasi tes	No		Latest evaluati on in 2000. 0- 0.0002 mg/kg bw Group ADI for fipronil and fipronil- desulfin yl was set.	Plant commo dities Cattle Poultry Milk	Yes, No Codex MRLs in any species			Yes, JMPR	
5	Starting List /Added by	Florfenic ol	No	Cattle, Rabbit, Pig,	Muscle, Liver, Fat,	Antimicr obial agent	Treatment of enteric and	No	Veterinar y drug register			Yes, No Codex MRLs			No	

2 6	Appendix 2  Added by Appendix	Flavofosf olipol	No	Horse, Goat, Sheep, Duck, Goose and Poultry, Shrimp	Milk and Kidney.	Antimicr obial	respirator y diseases; Infections by bacterial gener as Vibrio Regulator of	No	and use in the country			in any species			No	
	2			Cattle		agent	intestinal microflora.									
7	Starting List	Flumetrin	No	Bees and Cattle	Muscle, Liver, Fat, Milk and Kidney.	Ectopar asitic	Control of ectoparasi tes	No		Latest evaluati on in 1996. ADI of 0.004 mg/kg bw was set. And nowday s is include d in tnhe priority list (REP17 /RVDF, Apendix VI)	Cattle Cattle milk  *The MRL accom modate s external animal treatme nt.				Yes, JMPR	
8	Added by Appendix 2	Fosfomici n	No	Poultry and pig	Muscle	Antimicr obial agent	Treatment of enteric and respirator y diseases by <i>E. coli</i> , Mucoplas ma, Salmonell a and Pasteurell a	No	Priority 2						No	
9	Added by Appendix 2	Fumagili n	No	Bees	Honey	Antimicr obial agent	Nosemosi s	No	Because there are no MRL, it has authorizat ion to use just in a time with not flow						No	

									of honey. Priority 1						
3 0	Starting List	Gentamic in	Yes. Adoptio n in 2001 for Cattle and Pig	Rabbit, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicr obial agent	Treatment of enteric and respirator y diseases	Latest evaluation in 1998						Yes, JECFA	Yes
3 1	Starting List	lvermecti n	Yes. Adoptio n in 1993 forShe ep Pig and 2017 for Cattle.	Horse, Goat, Camel and Poultry.	Muscle, Liver, Fat, Milk and Kidney.	Antipar asitic agent	Control and prevention of endo/ecto parasites infections	Latest evaluation in 2015						Yes, JECFA	Yes
3 2	Added by Appendix 2	lvermecti n	Yes. Adoptio n in 1993 for Sheep Pig and 2017 for Cattle	Sheep and pig	Muscle, Liver, Fat, Milk and Kidney.	Antipar asitic agent	Control and prevention of endo/ecto parasites infections	Last evaluation 2015 in Cattle. Previous evaluation for Sheep in 2002.	Re- evaluatio n for Sheep and pig, consideri ng a new ADA recomme nding by JECFA 2015					Yea, JECFA	Yes
3	Starting List	Isometa medium Chloride	Yes. Adoptio n in 1995 for Cattle	Cattle	Muscle, Liver, Fat, Milk and Kidney	Trypano cide	Trypanos omosis	Latest evaluation in 1992						Yes, JECFA	Yes
3 4	Added by Appendix 2	Metilpara ben	No	Cattle	N.I.	External antipara sitic agent	N.I.		Veterinar y Drug used and registere d in the country					No	
3 5	Starting List	Oxitetrac yclin	Yes. Adoptio n in 2003 for Cattle, Pig, Sheep. Oxitetra cycline just for Fish	Bees, Camel, Horse and Goat	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Treatment of enteric and respirator y diseases	Latest evaluation in 1998	JECFA recomme nded this LMR about active ingredient combined or individual					Yes, JECFA	Yes

			and giant shrimp												
3 6	Added by Appendix 2	Pirrolidon	No	Cattle	N.I.	Antimicr obial agent	N.I.		Veterinar y Drug used and registere d in the country					No	
3 7	Added by Appendix 2	Propilpar aben	No	Cattle	N.I.	External antipara sitic agent	N.I.		Veterinar y Drug used and registere d in the country					No	
3 8	Added by Appendix 2	Proporxu r	No	Cattle and pig	Muscle, Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and prevention of endo/ecto parasites infections	No	MRL by Japan					No	
3 9	Starting List	Tiamulin	No	Cattle, Pig, Horse, Goat, Sheep, Turkey and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Treatment of enteric and respirator y diseases	No						No	
4 0	Starting List	Toltrazuri I	No	Cattle, Camel, Pig, Rabbit, Goose, Goat, Poultry and Sheep	Muscle, Liver, Fat, Milk and Kidney.	Control of coccidio sis	Prevention and control of coccidiosis	No	http://ww w.ema.eu ropa.eu/d ocs/en_G B/docum ent_librar y/Maximu m_Resid ue_Limits  _Report/2 009/11/W C500015 632.pdf					No	
4	Starting List	Trimetrop in	No	Cattle, Rabbit, Camel, Pig, Horse, Goat and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicr obial agent	Treatment of enteric and respirator y diseases	No	http://ww w.ema.eu ropa.eu/d ocs/en_G B/docum ent_librar y/Maximu m_Resid ue_Limits					No	

									 _Report/2 009/11/W C500015 681.pdf						
4 2	Starting List	Tulatromi cin	No	Cattle, Pig, Goat, Sheep, and Poultry	Muscle, Liver, Fat, Milk and Kidney	Antimicr obial agent	Treatment of enteric and respirator y diseases	No						No	
4 3	Added by Appendix 2	Tilvalosin	No	Pig, Poultry, Turkey y Pheasa nts	Muscle and eggs	Antimicr obial agent	Treatment of enteric and respirator y diseases	No						No	

**Appendix 4a**: Analysis of the list with veterinary drugs prioritized by greater to less agreement regarding the responses of the countries to get the List A

Priority	Veterinary drugs in order for agreement countries	Number of countries agreement with the veterinary drug
	Enrofloxacin	6
	Amitraz	5
	Cloxacylin	4
	Florphenicol	4
High	Fosfomicin	4
(in countries agrement order)	Toltrazuril	4
	Tulatromicin	4
	Ampicillin	3
	Cefquinome	3
	Trimetroprim	3
	Amoxicillin	2
	Amprolium	2
	Fipronil	2
	Flumetrin	2
	Tiamulin	2
	Tilvalusin	2
	Bacitracin	1
	Bromhexin	1
Medium	Cefalexin	1
(in countries agreementorder)	Ceftiofur	1
	Coumaphos	1
	Diminazene	1
	Ethion	1
	Gentamicin	1
	Isometamedium cloride	1
	lvermectin	1
	Oxytetracyline	1
	Proporxur	1

Appendix 4b: Analysis of Cumulative Country Responses on Prioritization of Starting List of High Priority Veterinary Drugs in need of Codex MRLs to get the List B

		<u>\$</u>	Starting L	ist of Higl	n Priority	Veterinary	/ Drugs in N	leed of Cod	ex MRLs			high p crite remair	eet both priority ria to n in the st	the m	eet at leas oderate p to remai	riority	cor	iority crit sideratio ing the lis	n in		is of Cum Response	
	Origin/C ountry	Veterin ary Drug Name (active ingredie nt)	Existin g Codex MRLs (CCRV DF	Food produ cing specie s in which this veterin ary drug is used	Tissue s	Purpo se for which this veterin ary drug is used in this specie s	Disease of concern	Evaluati on JECFA	Comme	JMPR Evalua tion	Codex MRL (CCPR )	There are no Codex MRLs for the veteri nary drug in the reque sted specie s and tissue s. (If there are existin g MRLs, please indicat e which specie s or tissue s for which you need MRLs)	There is a specific huma n health conce rn or trade implic ations associ ated with this veteri nary drug.	This veteri nary drug is widely used in animal produ ction syste ms.	This is the only veteri nary drug for a partic ular purpo se or disease e. (If yes, please indica te purpo se/dis ease)	This veteri nary drug is for a specie s with few Codex MRLs. (If yes, please specif y specie s of intere st.	This veteri nary drug does not have EMA MRLs or FDA tolera nces.	This veteri nary drug has a JECF A or JMPR toxico logical evalua tion.	This veteri nary drug has Codex MRLs in other specie s or tissue s.	Total criteri a met per categ ory with numb er of countr y respo nses indica ted.	Total Criteri a Met	Ten Highe st Priorit y Veteri nary Drugs
	Starting List	Albenda zol, albenda zol of sulfoxid (Ricobe ndazol), sulfon albenda zol	Yes. Adopti on in 1993 Not especif icate	Swine, Horse, Goats and Poultry, Sudam erican camels	Muscle , Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and preventio n of endopar asites	Latest evaluatio n in 1989						2 countri es		countri es: south americ an cameli ds, equine s	FDA (goat and sheep) ; EMA (all rumina nts)	Yes, JECFA	Yes	High:0	0	
	Starting List	Abamec tin	Yes. Adopti on in 2003 for Cattle	Pig, Horse, Goats and Sheep.	Muscle , Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and preventio n of parasites infection s	Latest evaluatio n in 1989	Codex Alimenta rius is only in Fat, Liver and Kidney of Cattle	Latest evaluat ion in 2015. AD of: 0– 0.001 mg/kg bw	Plant comm odities only			1 countr y		countri es: goats, equine s	EMA (cattle and swine)	Yes, JECFA	Yes	High:0	0	

									was set. The ADI also applies to the 8,9-Z isomer and the 24- hydrox ymethy I metab olite of abame ctin.												
3	Starting List	Amoxicil in, Thihidrat Amoxicil in	Yes. Adopti on in 2012 for Cattle, Pig and Sheep	Fish, Goats and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Control of bacterial infection s	Latest evaluatio n in 2011			1 countr y	2 countri es	4 countri es	1 countr y	countri es: goats, poultry	FDA & EMA (all food specie s)	Yes, JECFA	Yes	High: 2 (2 countri es) Moder ate: 3 (4;1;2 countri es) Low: 2	7	2
4	Starting List	Ampicili n Sodic Ampicili n, Trihidrat ampicilli n	No	Cattle, Pig, Horse, Goats, Sheep, Fish and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of pneumon ia and Control of bacterial infection s.	No			Yes, No Codex MRLs in any specie s	3 countri es	4 countri es		countri es: south americ an cameli ds, sheep, goat, swine	EMA	No	No	High: 2 (3 countri es) Moder ate: 2 (4;2 countri es) Low: 0	4	
5	Starting List	Amitraz	No		Honey (Bees), Muscle , Liver, Fat, Milk and Kidney	Ectopa rasitic	Parasitos is, acariosis	No	Latest evaluat ion in 1998. ADI of 0.01 mg/kg bw was set.	Plant comm odities Cattle* , Pig* , Sheep *  *The MRL accom modat es extern al animal treatm ent.	Yes, No Codex MRLs in any specie s	5 countri es	5 countri es	1 countr y	4 countri es: honey bees, goats	EMA	Yes, JMPR	No	High: 2 (5 countri es) Moder ate: 3 (5;1;4 countri es) Low: 1	6	7

6	Starting List	Amproli um	No	Cattle, Pig, Goats, Sheep and Poultry	Muscle , Liver, Fat, Milk and Kidney	Control of coccidi osis	Preventi on and control of coccidios is,	No			Yes, No Codex MRLs in any specie s	1 countr y	4 countri es	1 countr y	3 countri es: birds, goats, sheep	ЕМА	No	No	High: 2 (1 countr y) Moder ate: 3 (5;1;4 countri es) Low: 0	5	
7	Starting List	Bacitraci n, Bacitraci n Zinc, Bacitraci n metilen disilicato	No	Cattle, Pig, Rabbit, Goat, Sheep, Turkey and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agen	Treatme nt of enteric and respirato ry diseases	No			Yes, No Codex MRLs in any specie s	2 countri es	5 countri es			None	No	No	High: 2 (2 countri es) Moder ate: 1 (5 countri es) Low: 1	4	
8	Added by Appendi x 2	Bencida min	No	Cattle, horse and pig	N.I.	Antimic robial agent	N.I		Veterina ry Drug used and registere d in the country		Yes, No Codex MRLs in any specie s		1 countr y			None	No	No	High: 1	1	
9	Added by Appendi x 2	Bromhe xin	No	Poultry , Cattle and pig	N.I.	Antimic robial agent			Veterina ry Drug used and registere d in the country		Yes, No Codex MRLs in any specie s	1 countr y	1 countr y			None	No	No	High: 2 (1 countr y) Moder ate: 1 (1 countr y) Low: 1	4	
1 0	Starting List	Cefalexi n	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Antimasti tic, Treatme nt of enteric and respirato ry diseases	No			Yes, No Codex MRLs in any specie s	1 countr y	3 countri es		1 countr y: equine , goats, sheep, poultry	None	No	No	High: 2 (1 countr y) Moder ate: 2 (3; 1 countri es) Low: 1	5	
1	Starting List	Cefquin oma	No	Cattle, Pig, Horse and Goat	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Control and treatmen t of bacterial infection s.	No			Yes, No Codex MRLs in any specie s	3 countri es	2 countri es			None	No	No	High: 2 (3 countri es) Moder ate: 1 (2	4	

																				countri es) Low: 1		
1 2	Starting List	Ceftiofur	Yes. Adopti on in 1999 for Cattle and Pig	Horse, Sheep, Goat and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	Latest evaluatio n in 1997					1 countr y	2 countri es	1 countr y	1 countr y: sheep, goat, poultry	EMA	Yes, JECFA	Yes	High: 1	1	
1 3	Added by Appendi x 2	Ceftriax one	No	Cattle	N.I.	Antimic robial agent	Control of bacterial infection s.		Veterina ry drug register and use in the country			Yes, No Codex MRLs in any specie s	1 countr y				None	No	No	High:2 Moder ate: 0	2	
1 4	Starting List	Ciperme trin and alfa- cipermet rin	Yes. Adopti on in 2006 for Cattle and Sheep	Bees, Pig, Horse, Goat	Honey (Bees), Muscle , Liver, Fat, Milk and Kidney	Ectopa rasitic	Parasitos is, acariosis	Latest evaluatio n 2004		Latest evaluat ion in 2005. 0-0.02 mg/kg bw (2006) Group ADI for cyperm ethrins , includi ng alpha-cyperm ethrin and zeta-cyperm ethrin, was set.	Plant comm odities mamm als other than marine Poultry Milk			2 countri es			FDA	Yes, JECFA and JMPR	Yes	High: 0	0	
5	Starting List	Cloxacyl in	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	No				Yes, No Codex MRLs in any specie s	4 countri es	3 countri es		1 countr y: equine	None	No	No	High: 2 (4 countri es) Moder ate: 1 (3 countri es) Low: 1	5	
1 6	Starting List	Colistin	Yes. Adopti on in 2008 for	Pig and Horse	Muscle , Liver, Fat, Milk	Antimic robial agent	Growth promoter , Treatme nt of	Latest evaluatio n in 2006				1 countr y	1 countr y	3 countri es			Yes	Yes, JECFA	Yes	High: 2 (1 countr y)	5	

			Goats, Rabbit s, Sheep, Turkey, Poultry and Cattle		and Kidney		enteric infection												Moder ate: 1 (3 countri es) Low: 2		
1 7	Added by Appendi x 2	Coumap hos	No	Cattle	Muscle , Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and preventio n of endo/ect oparasite s infection s	No	MRL by Australia		Yes, No Codex MRLs in any specie s	2 countri es	2 countri es			None	No		High: 2 (2 countri es) Moder ate: 1 (2 countri es) Low: 1	4	
1 8	Starting List	Diminaz ene	Yes. Adopti on in 1997 for Cattle	Cattle, Sheep, and Goats	Muscle , Liver, Fat, Kidney , Milk	Trypan ocide	Trypanos omosis	Latest evaluatio n in 1994			1 countr y: goat and sheep tissues and milk	1 countr y	2 countri es	1 countr y	countr y: goats, sheep	None	Yes, JECFA	Yes	High: 2 (1 countr y) Moder ate: 3 (2; 1; 1 countri es) Low: 3	ω	1
1 9	Added by Appendi x 2	Dipropio nate imidocar b	No	Cattle and horse	N.I.	Extern al antipar asitic agent	N.I.		Veterina ry Drug used and registere d in the country		Codex MRLs exist in cattle	1 countr y	1 countr y	1 countr y		None	Yes, JECFA	Yes	High: 2 (1 countr y) Moder ate: 2 (1; 1 countri es) Low: 3	7	3
2 0	Added by Appendi x 2	Enramici n	No	Poultry and pig	Muscle , peel+f at, liver, Kidney	Treatm ent for bacteri al infectio ns for gram - or gram +. Activity against Clostri dium perfrin gens.	Necrotic enteritis	No			Yes, No Codex MRLs in any specie s		2 countri es			None	No		High: 1		

2 1	Starting List	Enroflox acin	No	Cattle, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	No				Yes, No Codex MRLs in any specie s	6 countri es	7 countri es	1 countr y	countri es: equine poultry , shrimp	EMA	No	High: 2 (6 countri es) Moder ate: 3 (7; 1; 2 countri es) Low: 0	5	
2 2	Added by Appendi x 2	Enroflox acin	No	Shrimp	Tissue	Antimic robial agent	Infection s by bacterial genus such as Vibrio		Veterina ry drug registere d and used in the country			Yes, No Codex MRLs in any specie s	2 countri es	3 countri es	1 countr y	countr y: white shrimp	EMA	No	High: 2 (2 countri es) Moder ate: 3 (3; 1; 2 countri es) Low: 0	5	
2 3	Added by Appendi x 2	Ethion	No	Cattle	N.I.	Extern al antipar asitic agent	N.I.		Veterina ry Drug used and registere d in the country			Yes, No Codex MRLs in any specie s	2 countri es	3 countri es	1 countr y		None	Yes, JMPR	High: 2 (2 countri es) Moder ate: 2 (3; 1 countri es) Low: 2	6	8
2 4	Starting List	Fipronil	No	Bees, Cattle, Pig, Rabbit, Goat and Sheep	Honey (Bees), Muscle , Liver, Fat, Milk and Kidney	Ectopa rasitic	Control of ectopara sites	No		Latest evaluat ion in 2000. 0- 0.0002 mg/kg bw Group ADI for fipronil and fipronil - desulfi nyl was set.	Plant comm odities Cattle Poultry Milk	Yes, No Codex MRLs in any specie s	3 countri es	3 countri es		1 countr y: bees, goats, sheep	None	Yes, JMPR	High: 2 (3 countri es) Moder ate: 2 (3; 1; countri es) Low: 2	6	9
2 5	Starting List /Added by Appendi x 2	Florfenic ol	No	Cattle, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases ;	No	Veterina ry drug register and use in the country			Yes, No Codex MRLs in any specie s	4 countri es	5 countri es		1 countr y: equine s, goats, sheep, poultry	None	No	High: 2 (4 countri es) Moder ate: 2 (5; 1;	5	

				and Poultry , Shrimp			Infection s by bacterial gener as Vibrio									, shrimp			countri es) Low: 1		
6	Added by Appendi x 2	Flavofos folipol	No	Poultry and Cattle	Muscle	Antimic robial agent	Regulato r of intestinal microflor a.	No	Priority 3					1 countr y			None	No	High: 1	1	
7	Starting List	Flumetri	No	Bees and Cattle	Muscle , Liver, Fat, Milk and Kidney	Ectopa rasitic	Control of ectopara sites	No		Latest evaluat ion in 1996. ADI of 0.004 mg/kg bw was set. And nowda ys is include d in tnhe priority list (REP1 7/RVD F, Apendi x VI)	Cattle Cattle milk  *The MRL accom modat es extern al animal treatm ent.	Y1 countr y: alpaca s/came lids Codex MRLs exist in cattle	4 countri es	2 countri es		2 countri es: equine s, sheep, goats, cameli ds, bees	EMA	Yes, JMPR	High: 2 (4 countri es) Moder ate: 2 2; 2 countri es) Low: 1	5	
8	Added by Appendi x 2	Fosfomi cin	No	Poultry and pig	Muscle	Antimic robial agent	Treatme nt of enteric and respirato ry diseases by E. coli, Mucopla sma, Salmonel la and Pasteure lla	No	Priority 2			Yes, No Codex MRLs in any specie s	4 countri es	3 countri es	1 countr y	2 countri es	None	No	High: 2 (4 countri es) Moder ate: 3 (3; 1; 2 countri es) Low: 1	6	10
2 9	Added by Appendi x 2	Fumagili n	No	Bees	Honey	Antimic robial agent	Nosemo sis	No	Because there are no MRL, it has authoriz ation to use just in a time with not			Yes, No Codex MRLs in any specie s				1 countr y		No	High: 1	1	

									flow of honey. Priority 1												
3 0	Starting List	Gentami cin	Yes. Adopti on in 2001 for Cattle and Pig	Rabbit, Horse, Goat, Sheep and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	Latest evaluatio n in 1998			2 countri es	3 countri es	4 countri es	1 countr y	countri es: birds, cameli ds	EMA, FDA	Yes, JECFA	Yes	High: 2 (3 countri es) Moder ate: 3 (4; 1; 2 countri es) Low: 2	7	4
3 1	Starting List	Ivermect in	Yes. Adopti on in 1993 for Cattle, Sheep and Pig	Horse, Goat, Camel and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and preventio n of endo/ect oparasite s infection s	Latest evaluatio n in 2015	The actual adoption of JECFA recomm endation is		1 countr y	2 countri es	4 countri es	1 countr y	countri es: birds, cameli ds	EMA, FDA	Yes, JECFA	Yes	High: 2 (2 countri es) Moder ate: 3 (4; 1; 2 countri es) Low: 2	7	5
3 2	Added by Appendi x 2	Ivermect in	Yes. Adopti on in 1993 for, sheep and pig and 2017 for Cattle	Sheep and pig	Muscle , Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and preventio n of endo/ect oparasite s infection s	Last evaluatio n 2015 in Cattle. Previous evaluatio n for Sheep in 2002.	Re- evaluati on for Sheep and pig, consider ing a new ADA recomm ending by JECFA 2015				3 countri es		1 countr y: birds, cameli ds	Canad a	Yea, JECFA	Yes	High: 0	0	
3 3	Starting List	Isometa medium Chloride	Yes. Adopti on in 1995 for Cattle	Cattle	Muscle , Liver, Fat, Milk and Kidney	Trypan ocide	Trypanos omosis	Latest evaluatio n in 1992			countr y: goat and sheep tissues and milk	1 countr y	1 countr y				Yes, JECFA	Yes	High: 1 (1 countr y) Moder ate: 1 (1 countr y Low: 2	5	
3 4	Added by Appendi x 2	Metilpar aben	No	Cattle	N.I.	Extern al antipar asitic agent	N.I.		Veterina ry Drug used and registere d in the country		Yes, No Codex MRLs in any specie s						No		High: 1	1	

3 5	Starting List	Oxitetra cyclin	Yes. Adopti on in 2003 for Cattle, Pig, Sheep. Oxitetr acyclin e just for Fish and giant shrimp	Bees, Camel, Horse and Goat	Honey (Bees), Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	Latest evaluatio n in 1998	JECFA recomm ended this LMR about active ingredie nt combine d or individua		2 countri es	3 countri es	3 countri es	1 countr y	3 countri es: bees, honey bees	EMA	Yes, JECFA	Yes	High: 2 (3 countri es) Moder ate: 3 (3; 1; 3 countri es) Low: 2	7	6
3 6	Added by Appendi x 2	Pirrolido n	No	Cattle	N.I.	Antimic robial agent	N.I.		Veterina ry Drug used and registere d in the country		Yes, No Codex MRLs in any specie s						No		High: 1	1	
3 7	Added by Appendi x 2	Propilpa raben	No	Cattle	N.I.	Extern al antipar asitic agent	N.I.		Veterina ry Drug used and registere d in the country		Yes, No Codex MRLs in any specie s					None	No		High: 1	1	
3 8	Added by Appendi x 2	Proporx ur	No	Cattle and pig	Muscle , Liver, Fat, Milk and Kidney	Antipar asitic agent	Control and preventio n of endo/ect oparasite s infection s	No	MRL by Japan		Yes, No Codex MRLs in any specie s	2 countri es	2 countri es			None	No		High: 2 (2 countri es) Moder ate: 1 (2 countri es) Low: 1	4	
3 9	Starting List	Tiamulin	No	Cattle, Pig, Horse, Goat, Sheep, Turkey and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	No			Yes, No Codex MRLs in any specie s	3 countri es	5 countri es	1 countr y	2 countri es: poultry	EMA	No		High: 2 (3 countri es) Moder ate: 3 (5; 1; 2 countri es) Low: 0	5	
4 0	Starting List	Toltrazu ril	No	Cattle, Camel, Pig, Rabbit, Goose, Goat, Poultry	Muscle , Liver, Fat, Milk and Kidney	Control of coccidi osis	Preventi on and control of coccidios is	No	http://ww w.ema.e uropa.eu /docs/en _GB/doc ument_li brary/Ma ximum_		Yes, No Codex MRLs in any specie s	2 countri es	6 countri es	1 countr y	3 countri es: birds, poultry	ЕМА	No		High: 2 (2 countri es) Moder ate: 3 (6; 1; 3	5	

				and Sheep					Residue _Limits_ - _Report/ 2009/11/ WC5000 15632.p df									countri es) Low: 0		
4 1	Starting List	Trimetro pin	No	Cattle, Rabbit, Camel, Pig, Horse, Goat and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	No	http://ww w.ema.e uropa.eu /docs/en _GB/doc ument_li brary/Ma ximum_ Residue _Limits _Report/ 2009/11/ WC5000 15681.p df		Yes, No Codex MRLs in any specie s	3 countri es	4 countri es		2 countri es: birds, equine goats	EMA	No	High: 2 (3 countri es) Moder ate: 2 (4; 2 countri es) Low: 0	4	
4 2	Starting List	Tulatro micin	No	Cattle, Pig, Goat, Sheep, and Poultry	Muscle , Liver, Fat, Milk and Kidney	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	No			Yes, No Codex MRLs in any specie s	4 countri es	5 countri es			EMA	No	High: 2 (4 countri es) Moder ate: 1 (5 countri es) Low: 0	σ	
4 3	Added by Appendi x 2	Tilvalosi n	No	Pig, Poultry , Turkey y Pheas ants	Muscle and eggs	Antimic robial agent	Treatme nt of enteric and respirato ry diseases	No			Yes, No Codex MRLs in any specie s	1 countr y	1 countr y	1 countr y	1 countr y	None	No	High: 2 (1 countr y) Moder ate: 3 (1; 1; 1 countri es) Low: 1	6	