



# PRIORITIZATION OF COUNTRIES' NEEDS FOR MRLS

In Session Working Group



# Electronic Working Group

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# History

- In 2010, work began to collect veterinary drugs in need of Codex MRLs by member countries.
- In 2015, Global survey to collect information on what veterinary drugs are used and what diseases are prevalent
- In 2017, Electronic Working Group to prioritize Countries' Needs for MRLs to a top-ten needs list

# ELECTRONIC WORKING GROUP

CCRVDF



# EWG Participants

**Countries (27):** 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 and Venezuela.

**Observers (5) :** 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).

# Goals

- Find 10 veterinary drugs in need of Codex MRLs which are most needed by Codex MRLs through a transparent and inclusive process
- Codex members and regions focus efforts to identify and/or develop data to allow a JECFA evaluation

# EWG Tasks

1. Ensure the “starting list” of veterinary drugs is inclusive of countries’ highest priority needs.
2. Develop criteria for prioritization and the strategy for applying criteria to the list of needs.
3. Apply the prioritization criteria to the list of needs.
4. Analyze the EWG member prioritizations.

# List of Needs

- The list of veterinary drugs identified most in the Global Survey conducted for CCRVDF23 served as the starting point.
- EWG members were asked to review the starting list and provide up to three veterinary drugs if the highest priority needs were not already on the list.
- List of Needs for prioritization combined to 41 veterinary drugs.



# Prioritization Criteria

- EWG members were asked to submit suggested criteria for prioritizing the list of needs.
- EWG members provided comments on the proposed criteria and suggested a tiered approach for application
- EWG members applied the criteria independently to the list of needs
  - *Countries filled out the prioritization template with their respective responses to the criteria*
  - *Some countries further identified their own top ten list after applying the criteria*

# Prioritization Criteria

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

# Analyses of EWG Comments to get the lists

## Analysis A

- Many EWG members submitted top ten prioritization lists
- Individual top ten lists were compared for overlap
- The ten veterinary drugs which overlapped the most were identified in List A.

## Analysis B

- Many EWG members submitted responses to the prioritization criteria
- Responses were compiled and the prioritization criteria were applied
- The ten veterinary drugs that met the most criteria were identified in List B.

# Prioritization Results

## List A

- Enrofloxacin
- **Amitraz**
- Cloxacilin
- Florphenicol
- **Fosfomycin**
- Toltrazuril
- Tulatromicin
- Ampicillin
- Cefquinome
- Trimetoprim

## List B

- Diminazene
- Amoxicillin, Trihidrat Amoxicillin
- Dipropionate imidocard
- Gentamicin
- Ivermectin
- Oxitetracycline
- **Amitraz**
- Ethion
- Fipronil
- **Fosfomycin**

# Comparative general results between the lists

## List A

1. All veterinary drugs do not have MRL by the Codex Alimentarius.
2. It has 8 antibiotics agents and 2 anti-parasitic agents.
3. The Amitraz and fosfomycin are in the List B as well.
4. List A considers most traditional production animal species request.

## List B

1. Most veterinary drugs (80%) have Codex MRLs in an animal species. Ethion and Fipronil do not have MRL by Codex.
2. It has 4 antibiotics agents and 6 antiparasitic agents.
3. The Amitraz and fosfomycin are in the List A .
4. List B considers more minor production animal species and not traditional animal species request.

DISCUSSION



# Goal

- Recommend a single list of needed products to CCRVDF24.
- Ask Codex Member countries and regions to focus data generation and collection efforts on the list of needed products
- When sufficient data are available and there is a commitment to provide data, products can be nominated to the Priority List of Veterinary Drugs for Evaluation or Re-evaluation

# Proposals to selection for the Committee

1. To take 3 veterinary drugs of each list and to combine it.
2. To take 5 Veterinary drugs of each list and to combine it.
3. Select one List (A or B).
4. To take one list now and to leave the other one for the future.
5. Combine both Lists (A and B).



# Proposed Approach for Combining Lists

Products which may be more feasible for data collection

- Abamectin
- Amoxicillin
- Ampicillin
- Ceftiofur\*
- Colistin
- Cyperthmethrin
- Diminazene\*
- Ethion
- Florfenicol\*
- Flumethrin
- Fosfomicin
- Imidocarb
- Ivermectin
- Oxitetracycline
- Proporxur\*
- Tiamulin\*
- Toltrazuril\*
- Tulathromcyin\*
- Tivalosin\*

\*May require support from a pharmaceutical sponsor to provide toxicology data or require additional data development.

# Prioritization Results

## List A

- Enrofloxacin - No
- **Amitraz - No**
- Cloxacilin - No
- Florphenicol – Yes if Sponsor assists
- **Fosfomycin – On the Priority List**
- Toltrazuril – Yes if Sponsor assists
- Tulatromicin – Yes if Sponsor assists
- Ampicillin - Yes
- Cefquinome - No
- Trimetroprim - No

## List B

- Diminazene – Yes with reevaluation or more data
- Amoxicillin, Trihidrat Amoxicillin - Yes
- Dipropionate imidocard - Yes
- Gentamicin - No
- Ivermectin - Yes
- Oxitetracycline - Yes
- **Amitraz - No**
- Ethion – On the Priority List
- Fipronil - No
- **Fosfomycin – On the Priority List**

# Feasible Products from Prioritization

## Using existing data and extrapolation

- Amoxicillin
- Ampicillin
- Diminazene
- Imidocarb
- Ivermectin
- Oxytetracycline

## If Sponsors willing to provide toxicology

- Florphenicol
- Toltrazuril
- Tulathromicin

# Next Steps

- Who is willing to take the lead for each product to collect available information, assemble a dossier according to Priority List template, and nominate to the Priority for CCRVDF25?
- Examples:
  - *Literature search*
  - *Approaching authors of researches papers to provide raw data*
  - *Approaching pharmaceutical sponsors for willingness to provide any available data*
  - *Lead efforts to develop additional data, if needed*