



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**  
**Twenty-fourth Session**

**DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA**

(Replies to CL 2016/41-RVDF of Costa Rica and European Union)

## COSTA RICA

Costa Rica appreciates the opportunity share its comments. In view of the parameters necessary for including a veterinary drug on the priority list, Costa Rica cannot provide the requested information on the list of available data and, thus, cannot propose any veterinary drug for the priority list.

## EUROPEAN UNION

The European Union and its Member States would like to propose the inclusion of flumethrin on the JECFA Priority List for MRLs in bovine tissues and milk. The template with the necessary details is attached.

**ANNEX**

**TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

### ADMINISTRATIVE INFORMATION

1. Member(s) submitting the request for inclusion  
The European Union
2. Veterinary drug names  
Flumethrin
3. Trade names  
Bayticol, Bayticol Pour-On, Bayticol Pour-On 1%, Bayticol 2% EC, Bayticol EC 3%, Bayticol EC 6%, Bayticol dip, Bayticol Cattle Dip and Spray, Bayticol Plus Pour-on, Bayticol Pour on 1%, Drastic Deadline, Drastic Deadline Extreme, Bayticol Pour On sol, Bacdip Plus Aerosol.
4. Chemical names and CAS registry number  
International non-proprietary name: Flumethrin  
IUPAC name: (±)-α-Cyano-4-fluoro-3-phenoxybenzyl-3-(β,4-dichlorostyryl)-2,2-dimethylcyclopropanecarboxylate  
CAS name: Cyclopropane carboxylic acid, 3-[2-chloro-2-(4-chlorophenyl) ethenyl]-2,2-dimethyl-, cyano (4-fluoro-3-phenoxyphenyl) methyl ester  
CAS no.: 69770-45-2
5. Names and addresses of basic producers  
Bayer Animal Health GmbH  
Kaiser-Wilhelm-Allee 10  
Leverkusen  
51373  
Germany

**PURPOSE, SCOPE AND RATIONALE**

6. Identification of the food safety issue (residue hazard)  
Residues in bovine muscle, liver, kidney, fat and milk
7. Assessment against the criteria for the inclusion on the priority list  
A member has proposed the compound for evaluation (European Union)  
A member has established good veterinary practices with regards to the compound  
The compound has the potential to cause international trade problems.  
The compound is available as a commercial product  
There is a commitment that a dossier will be made available.

**RISK PROFILE ELEMENTS**

8. Justification for use  
For the control of ticks, lice (biting and sucking) and mange in cattle
9. Veterinary use pattern, including information on approved uses if available (*this should include product labels or other evidence of official use authorization*)  
Veterinary medicinal product  
Please see, accompanying this application, the Summary of Product Characteristics approved in Germany as evidence of official use authorisation, together with an English translation.
10. Commodities for which Codex MRLs are required  
Bovine muscle, liver, kidney, fat and milk

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

11. Specific request to risk assessors  
To establish MRLs for bovine muscle, liver, kidney, fat and milk at CCRVDF.  
A renewal is due in 2018 at JMPR. As agreed with the WHO Secretariat, Bayer Animal Health submitted a dossier for bovine muscle, liver, kidney, fat and milk MRLs in December 2017 to JMPR but requested that the process of establishment of the MRLs is moved to JECFA CCRVDF. Bayer Animal Health confirmed there are no pesticide uses of Flumethrin. Therefore, Bayer Animal Health requested that there is no sharing of ADI between both committees anymore.

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

12. Countries where the veterinary drugs are registered  
Afghanistan, Albania, Algeria, Antigua and Barbuda, Argentina, Australia, Austria, Bahrain, Barbados, Belgium, Benin, Brazil, Botswana, Chile, Colombia, Costa-Rica, Cuba, Denmark, Dominican Republic, Ecuador, El Salvador, France, Germany, Ghana, Guatemala, Honduras, India, Indonesia, Iran, Iraq, Ireland, Italy, Ivory coast, Japan, Kenya, Kuwait, Lebanon, Lesotho, Malawi, Malaysia, Mali, Mexico, Mozambique, Namibia, New Zealand, Nicaragua, Nigeria, New-Zealand, Norway, Oman, Panama, Paraguay, Qatar, Rwanda, South-Africa, Spain, Sri Lanka, Switzerland, Syria, Swaziland, Sweden, Switzerland, Tanzania, Thailand, Togo, Turkey, Ukraine, United Arab Emirates, United Kingdom, Uganda, Uruguay, Venezuela, Vietnam, Yemen, Zambia, Zimbabwe
13. National/Regional MRLs or any other applicable tolerances

Codex MRL (JMPR/CCPR)

Cattle	Meat	0.2 mg/kg
	Milk	0.05 mg/kg

Codex MRL (JECFA evaluation - proposed MRL pending)

Bee	Honey	0.006 mg/kg
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<sup>1</sup> When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.

EU MRL (Commission Regulation (EU) No 37/2010)

Bees	Honey	No MRL required
Bovine	Muscle	10 µg/kg
	Fat:	150 µg/kg
	Liver	20 µg/kg
	Kidney	10 µg/kg
Ovine	Milk	30 µg/kg
	Muscle	10 µg/kg
	Fat	150 µg/kg
	Liver	20 µg/kg
	Kidney	10 µg/kg

Australia MRL

Bees	Honey (temporary)	0.005 mg/kg
Bovine	Edible offal	0.05 mg/kg
	Meat (in the fat)	0.2 mg/kg
Horse	Edible offal	0.1 mg/kg
	Meat	0.1mg/kg
Milks		0.05 mg/kg

Argentina MRL (Resolucion 559/2011 Anexo I)

Bees	Honey	No MRL required
Cattle	Muscle	10 µg/kg
	Fat	150 µg/kg
	Liver	20 µg/kg
	Kidney	10 µg/kg
Sheep	Milk	30 µg/kg
	Muscle	10 µg/kg
	Fat	150 µg/kg
	Liver	20 µg/kg
	Kidney	10 µg/kg

Japan MRLs (flumethrin MRLs are currently under revision)

		<b>Provisional MRL (current) (ppm)</b>	<b>Final MRL (proposed) (ppm)</b>
Bees	Honey	0.005	0.005
Cattle/Cow/Calf	Muscle	0.01	0.2
	Fat	0.2	0.2
	Liver	0.04	0.05
	Kidney	0.03	0.05
	Other edible parts	0.03	0.05
Swine/Piglet	Muscle	0.005	0.005
	Fat	0.005	0.005
	Liver	0.005	0.005
	Kidney	0.005	0.005
	Other edible parts	0.005	0.005
Other land-dwelling animals *	Muscle	0.06	0.01
	Fat	0.2	0.2

		Provisional MRL (current) (ppm)	Final MRL (proposed) (ppm)
	Liver	0.06	0.02
	Kidney	0.06	0.01
	Other edible parts	0.1	0.02
Milk		0.05	0.05
Chicken	Muscle	0.03	0.01
	Fat (inc skin)	0.03	0.6
	Liver	0.03	0.01
	Kidney	0.03	0.01
	Other edible parts	0.03	0.01
	Egg	0.03	0.03
Other poultry	Muscle	0.005	0.005
	Fat (inc skin)	0.005	0.005
	Liver	0.005	0.005
	Kidney	0.005	0.005
	Other edible parts	0.005	0.005
	Egg	0.03	0.03
Fish		0.005	0.005

\* except cattle/ cow/ calf and swine/piglet

14. List of data (pharmacology\*, toxicology\*, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles*)

Complete residue package including validated analytical methods for milk and edible tissues.

\*The toxicology package evaluated by JECFA in 2017 for establishment of honey MRL was not re-submitted in December 2017 to JMPR since the package remains unchanged since submission to JECFA.

#### TIMETABLE

15. Date when data could be submitted to JECFA

Dossier could be submitted to JECFA anytime on request.

Dossier has been submitted to JMPR in December 2017 and be transferred to JECFA once accepted on the CCRVDF priority list.