

30/01/2018

EU reply to CL 2016/41-RVDF
Request for Comments/Information on Priority List of Veterinary Drugs for
Evaluation or Re-evaluation by JECFA

Mixed Competence

European Union Vote

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 INFORMATION¹

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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¹ 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
	Milk	30 µg/kg
Ovine	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
	Milk	30 µg/kg
Sheep	Muscle	10 µg/kg
	Fat	150 µg/kg
	Liver	20 µg/kg
	Kidney	10 µg/kg

Japan MRLs (flumethrin MRLs are currently under revision)

		Provisional MRL (current) (ppm)	Final MRL (proposed) (ppm)
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
	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 and be transferred to JECFA once accepted on the CCRVDF priority list.