

# THE MINISTRY OF AGRICULTURE, FISHERIES AND RURAL DEVELOPMENT

Pursuant to Article 15, paragraph 1, subparagraph 2 of the Food Act (Official Gazette 46/07) and Article 87, paragraph 6 of the Veterinary Act (Official Gazette 41/07), the Minister of Agriculture, Fisheries and Rural Development hereby issues the

## ORDINANCE ON MAXIMUM RESIDUE LIMITS OF VETERINARY MEDICINAL PRODUCTS IN FOODSTUFFS OF ANIMAL ORIGIN <sup>1</sup>

### Article 1

- 1) This Ordinance lays down the maximum residue limits of veterinary medicinal products (hereinafter: VMP) in foodstuffs of animal origin.
- (2) This Ordinance shall not apply to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity used in immunological VMPs.
- (3) This Ordinance shall not prejudice the application of special regulations prohibiting the use in livestock farming of certain substances having a hormonal action nor shall it prejudice the measures taken to prevent the unauthorised use of VMPs.

### *Definitions*

### Article 2

- 1) For the purposes of this Ordinance, the following definitions shall apply:
  - (a) ‘*residues of veterinary medicinal products*’ means all pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the VMP in question has been administered;
  - b) ‘*maximum residue limit*’ (hereinafter: MRL) means the maximum concentration of residue resulting from the use of a VMP (expressed in mg/kg or µg/kg on a fresh weight basis) which may be legally permitted or recognised as acceptable in or on a food. MRL is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake, or on the basis of a temporary acceptable daily intake that utilises an additional safety factor. It also takes into account other relevant public health risks as well as food technology (food production) aspects. When establishing a MRL, consideration is also given to residues

that occur in food of plant origin and/or come from the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of VMPs and to the extent that practical analytical methods are available.

#### Article 3

The list of pharmacologically active substances used in VMPs in respect of which MRLs have been established is contained in Annex I to this Ordinance.

#### Article 4

The list of pharmacologically active substances used in VMP in respect of which it is considered that it is not necessary for the protection of public health to establish a MRL are contained in Annex II to this Ordinance.

#### Article 5

The list of pharmacologically active substances used in VMPs in respect of which provisional MRLs have been established is contained in Annex III to this Ordinance.

#### Article 6

- (1) The list of pharmacologically active substances used in VMPs in respect of which MRLs cannot be established because residues of the substances concerned, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer is contained in Annex II to this Ordinance.
- (2) The administration of the substances referred to in paragraph 1 of this Article to food-producing animals shall be prohibited.

#### Article 7

- (1) In order to obtain the inclusion in Annexes I, II or III to this Ordinance of a pharmacologically active substance which is intended for use in VMPs for administration to food-producing animals, an application to establish a MRL shall be submitted to the European Agency for the Evaluation of Medicinal Products.
- (2) The application referred to in paragraph 1 of this Article shall contain the information and particulars referred to in Annex V to this Ordinance.

#### Article 8

The import of foodstuffs of animal origin shall be permitted if the level of residue does not exceed the MRL laid down in Annexes I or III to this Ordinance or if it contains the substance listed in Annex II to this Ordinance.

#### Article 9

Where a competent authority, as a result of new information or a reassessment of existing information, considers that the urgent amendment of a provision contained in Annexes I to IV is necessary in order to protect human or animal health, that competent authority may temporarily suspend the application of the provision concerned in its own territory. In that case, it shall immediately notify the Member States of the European Union and the European Commission about the measures, attaching a statement of the reasons therefor.

#### Article 10

- 1) The administration to food-producing animals of VMPs containing pharmacologically active substances which are not mentioned in Annexes I, II, III shall be prohibited.
- 2) The administration of VMPs referred to in paragraph 1 of this Article shall be permitted only in the case of clinical trials accepted by the competent authority in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

#### *Final provisions*

#### Article 11

Annexes I to V are printed along with this Ordinance and form an integral part thereof.

#### Article 12

The regulation referred to in Annex II, Table 5. Substances used as food additives in foodstuffs for human consumption shall be adopted by 30 June 2008.

#### Article 13

The regulation referred to in Annex V, item 1.6. of this Ordinance shall be adopted by 30 June 2009.

#### Article 14

On the day of entry into force of this Ordinance, the Ordinance on maximum residue limits of veterinary medicines in foodstuffs (Official Gazette 29/05) shall cease to have effect.

#### Article 15

- 1) This Ordinance shall enter into force on the eighth day after the day of its publication in the Official Gazette.

2) By way of derogation from paragraph 1 of this Article, Article 9 of this Ordinance shall enter into force on the day of the entry of the Republic of Croatia into the European Union.

Class: 011-02/08-01/06  
Reg. No.: 525-06-08-1  
Zagreb, 24 June 2006

The Minister  
**Božidar Pankrećić, m.p.**

<sup>1</sup>The Ordinance transposes the Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

## ANNEX I

### LIST OF PHARMACOLOGICALLY ACTIVE SUBSTANCES USED IN VMPs FOR WHICH MRLs HAVE BEEN FIXED

#### 1. Anti-infectious agents

##### 1.1. Chemotherapeutics

##### 1.1.1. Sulfonamides

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Sulfonamidi (sve tvari iz skupine sulfonamida)	All substances belonging to the sulfonamide group	Parent drug	All food-producing species	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg
			Bovine, ovine, caprine	100 µg/kg	Milk	

##### 1.1.2. Diamino pyrimidine derivatives

	<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Marker residue</b>	<b>Animal species</b>	<b>MRLs</b>
	Bakiloprim	Baquiloprim	Baquiloprim	Bovine	10 µg/kg 300 µg/kg 150 µg/kg 30 µg/kg
				Porcine	40 µg/kg 50 µg/kg 50 µg/kg
	Trimetoprim	Trimethoprim	Trimethoprim	All food-producing species except equidae	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg
				Equidae	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg

(1) = For porcine species and poultry this MRL relates to „skin and fat in natural proportions“

2) = For fish this MRL relates to „muscle and skin in natural proportions“

## 1.2. Antibiotics

### 1.2.1. Penicillins

	<b>Pharmacologically active substance(s)</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Marker residue</b>	<b>Animal species</b>	<b>MRLs</b>	<b>Tar tissues</b>
	Amoksicilin	Amoxicyllin	Amoxicyllin	All food-producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Mu Fat Liv Kid Mil
	Ampicilin	Ampicillin	Ampicillin	All food-producing species	50 µg/kg 50 µg/kg 50 µg/kg	Mu Fat Liv Kid Mil

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Tissues
				µg/kg 50 µg/kg 4 µg/kg	
Benzilpenicilin	Benzylpenicillin	Benzylpenicillin	All food-producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Mu Fat Liv Kid Mil
Kloksacilin	Cloxacillin	Cloxacillin	All food-producing species	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Mu Fat Liv Kid Mil
Dikloksacilin	Dicloxacillin	Dicloxacillin	All food-producing species	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Mu Fat Liv Kid Mil
Nafcilin	Nafcillin	Nafcillin	All ruminants	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg	Mu Fat Liv Kid Mil

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Tar tiss
				30 µg/kg	
Oksacilin	Oxacillin	Oxacillin	All food-producing species	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Mu Fat Liv Kid Mil
Penetamat	Penethamate	Benzylpenicillin	Bovine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Mu Fat Liv Kid Mil
			Porcine	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Mu Fat Liv Kid
			All mammalian-food producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 4 µg/kg	Mu Fat Liv Kid Mil
Fenoksimetilpenicilin	Phenoxymethylpenicillin	Phenoxymethylpenicillin	Porcine	25 µg/kg 25	Mu Liv Kid

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues
				µg/kg 25 µg/kg	
			Poultry	25 µg/kg 25 µg/kg 25 µg/kg 25 µg/kg	Muscle Skin fat Liver Kidney

### 1.2.2. Cephalosporins

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Cefacetil	Cefacetrile	Cefacetrile	Bovine	125 µg/kg	Milk	For intramammary use only
Cefaleksin	Cefalexin	Cefalexin	Bovine	200 µg/kg 200 µg/kg 200 µg/kg 1 000 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
Cefalonij	Cefalonium	Cefalonium	Bovine	20 µg/kg	Milk	
Cefapirin	Cephapirin	Sum of cephapirin and desacetylcephapirin	Bovine	50 µg/kg 50 µg/kg 100 µg/kg	Muscle Fat Kidney Milk	



Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				60 µg/kg		
Cefazolin	Cefazolin	Cefazolin	Bovine, ovine and caprine	50 µg/kg	Milk	
Cefoperazon	Cefoperazone	Cefoperazon	Bovine	50 µg/kg	Milk	
Cefkinom	Cefquinome	Cefquinome	Bovine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg	Muscle Skin and fat Liver Kidney	
			Equidae	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	
Ceftiofur	Ceftiofur	Sum of all residues retaining the betalactam structure expressed as desfuroylceftiofur	All mammalian food-producing species	1 000 µg/kg 2 000 µg/kg 2 000 µg/kg 6 000 µg/kg 100	Muscle Fat <sup>(1)</sup> Liver Kidney Milk	<sup>(1)</sup> = For porcine species MRL related to „skin fat in n... proportion

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg		

### 1.2.3. Quinolones

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Danofloksacin	Danofloxacin	Danofloksacin	All food-producing species except bovine, ovine, caprine, porcine and poultry	100 µg/kg 50 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg	Muscle (2) Fat (1) Liver Kidney	
			Bovine, ovine and caprine	200 µg/kg 100 µg/kg 400 µg/kg 400 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	
			Poultry	200 µg/kg 100 µg/kg 400 µg/kg 400 µg/kg	Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
Difloksacin	Difloxacin	Difloxacin	All food-producing species except bovine, ovine,	300 µg/kg 100 µg/kg 800 µg/kg	Muscle (2) Fat Liver Kidney	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			caprine and poultry	600 µg/kg		
			Bovine, ovine and caprine	400 µg/kg 100 µg/kg 1 400 µg/kg 800 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
			Porcine	400 µg/kg 100 µg/kg 800 µg/kg 800 µg/kg	Muscle Skin and fat Liver Kidney	
			Poultry	300 µg/kg 400 µg/kg 1 900 µg/kg 600 µg/kg	Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
Enrofloksacin	Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	All food-producing species except bovine, ovine, caprine, porcine, rabbits and poultry	100 µg/kg 100 µg/kg 200 µg/kg 200 µg/kg	Muscle (2) Fat Liver Kidney	
			Bovine, ovine and caprine	100 µg/kg 100 µg/kg 300 µg/kg	Muscle Fat Liver Kidney Milk	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				200 µg/kg 100 µg/kg		
			Porcine and rabbits	100 µg/kg 100 µg/kg 200 µg/kg 300 µg/kg	Muscle Fat (1) Liver Kidney	
			Poultry	100 µg/kg 100 µg/kg 200 µg/kg 300 µg/kg	Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
Flumekin	Flumequine	Flumequine	All food-producing species except bovine, ovine, caprine, porcine, poultry and fin fish	200 µg/kg 250 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	
			Bovine, ovine, caprine and porcine	200 µg/kg 300 µg/kg 500 µg/kg 1 500 µg/kg 50 µg/kg	Muscle Fat (1) Liver Kidney Milk	
			Poultry	400 µg/kg	Muscle Skin and	Not for use in animals

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				250 µg/kg 800 µg/kg 1 000 µg/kg	fat Liver Kidney	from wh eggs are produce human consump
			Fin fish	600 µg/kg	Muscle and skin in natural proportions	
Marbofloksacin	Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg 75 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	150 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Skin and fat Liver Kidney	
Oksolinska kiselina	Oxolinic acid	Oxolinic acid	Porcine	100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Skin and fat Liver Kidney	
			Chicken	100 µg/kg 50 µg/kg 150 µg/kg	Muscle Skin and fat Liver Kidney	Not for in anima from wh eggs are produce human

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				150 µg/kg		consumption
			Fin fish	100 µg/kg	Muscle i koža in natural proportions	
			All food-producing species (3)	100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle (1) Fat (4) Liver Kidney	
Sarafloksacin	Sarafloxacin	Sarafloxacin	Chicken	10 µg/kg 100 µg/kg	Skin and fat Liver	
			Salmonidae	30 µg/kg	Muscle and skin in natural proportions	

(1) = For fin fish this MRL relates to „muscle and skin in natural proportions“.

(2) = For porcine species this MRL relates to „skin and fat in natural proportions“.

(3) = Not for use in animals from which milk or eggs are produced for human consumption; MRLs for fat, liver and kidney do not apply to fin fish.

(4) = For porcine species and poultry this MRL relates to „skin and fat in natural proportions“.

#### 1.2.4. Macrolides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs
Tilvalozin	Tylvalosin	Sum of tylvalosin and 3-O-acetyltylosin	Porcine	50 µg/k 50 µg/k 50 µg/k 50 µg/k
			Poultry	50 µg/k 50 µg/k

	Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs
	Eritromicin	Erythromycin	Erythromycin A	All food-producing species	200 µg/k 200 µg/k 200 µg/k 200 µg/k 40 µg/k 150 µg/k
	Spiramicin	Spiramycin	Sum of spiramycin and neospiramycin	Bovine	200 µg/k 300 µg/k 300 µg/k 300 µg/k 200 µg/k
				Chicken	200 µg/k 300 µg/k 400 µg/k
			Spiramycin 1	Porcine	250 µg/k 2 000 µg/k 1 000 µg/k
	Tilmikozin	Tilmicosin	Tilmicosin	All food-producing species except poultry	50 µg/k 50 µg/k 1 000 µg/k 1 000 µg/k 50 µg/k
				Poultry	75 µg/k 75 µg/k 1 000 µg/k 250 µg/k
	Tulatromicin	Tulathromycin	(2R, 3S,4R,5R, 8R,10R,11R,12S,13S, 14R)-2-ethyl-3,4,10,13 - tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[[(3,4,6,-tri-deoxy-3-(di-methylamino)-β-D-xylo-hexo-	Bovine	100 µg/k 3 000 µg/k 3 000 µg/k

	Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs
			pyranoxyl]ox]-1-oxa-6-aza-cyclopentadecan-15-one expressed as tulathromycin equivalents		
				Porcine	100 µg/k 3 000 µg/k 3 000 µg/k
	Tilozin	Tylosin	Tylosin A	All food-producing species	100 µg/k 100 µg/k 100 µg/k 100 µg/k 50 µg/k 200 µg/k

- (1) = For porcine species this MRL relates to „skin and fat in natural proportions“.
- (2) = For poultry this MRL relates to „skin and fat in natural proportions“.
- (3) = For fin fish this MRL relates to „muscle and skin in natural proportions“.
- (4) = For porcine species and poultry this MRL relates to „skin and fat in natural proportions“.

#### 1.2.5. Fluorfenicol and related compounds

	Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs
	Tiamfenikol	Thiamphenicol	Thiamphenicol	All food-producing species	50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg

- (1) = For fin fish „Muscle“ relates to „muscle and skin in natural proportions“
- (2) = For porcine species and poultry this MRL relates to „skin and fat in natural proportions“

#### 1.2.6. Tetracyclines



	<b>Pharmacologically active substance(s)</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Marker residue</b>	<b>Animal species</b>	<b>MRLs</b>
	Klortetraciklin	Chlortetracycline	Sum of parent drug and its 4-epimer	All food-producing species	100 µg/kg 300 µg/kg 600 µg/kg 100 µg/kg 200 µg/kg
	Doksiciklin	Doxycycline	Doxycycline	Bovine	100 µg/kg 300 µg/kg 600 µg/kg
				Porcine	100 µg/kg 300 µg/kg 300 µg/kg 600 µg/kg
				Poultry	100 µg/kg 300 µg/kg 300 µg/kg 600 µg/kg
	Oksitetraciklin	Oxytetracycline	Sum of parent drug and its 4-epimer	All food-producing species	100 µg/kg 300 µg/kg 600 µg/kg 100 µg/kg 200 µg/kg
	Tetraciklin	Tetracycline	Sum of parent drug and its 4-epimer	All food-producing species	100 µg/kg 300 µg/kg 600 µg/kg 100 µg/kg 200 µg/kg

#### 1.2.7. Naphtalene-ringed ansamycin

<b>Pharmacologically active substance(s)</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Marker residue</b>	<b>Animal species</b>	<b>MRLs</b>	<b>Target tissues</b>	<b>Other provisions</b>
Rifaksimin	Rifaximin	Rifaximin	Bovine	60 µg/kg	Milk	

#### 1.2.8. Pleuromutilines

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tiamulin	Tiamulin	Sum of metabolites that may be hydrolysed to 8-a-hydroxymutilin	Porcine	100 µg/kg 500 µg/kg	Muscle Liver	
			Chicken	100 µg/kg 100 µg/kg 1 000 µg/kg	Muscle Skin and fat Liver	
			Rabbits	100 µg/kg 500 µg/kg	Muscle Liver	
			Turkey	100 µg/kg 100 µg/kg 300 µg/kg	Muscle Skin and fat Liver	
		Tiamulin		1 000 µg/kg	Eggs	
Valnemulin	Valnemulin	Valnemulin	Porcine	50 µg/kg 500 µg/kg 100 µg/kg	Muscle Liver Kidney	

### 1.2.9. Linkozamidi

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Linkomicin	Lincomycin	Lincomycin	All food-producing species	50 µg/kg 100 µg/kg	Fat <sup>(1)</sup> Muscle <sup>(2)</sup> Liver	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				500 µg/kg 1 500 µg/kg 150 µg/kg 50 µg/kg	Kidney Milk Eggs	
Pirlimicin	Pirlimycin	Pirlimycin	Bovine	100 µg/kg 100 µg/kg 1 000 µg/kg 400 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	100 µg/kg 50 µg/kg 500 µg/kg 1 500 µg/kg	Muscle Skin and fat Liver Kidney	
			Chicken	100 µg/kg 50 µg/kg 500 µg/kg 1 500 µg/kg 50 µg/kg	Muscle Skin and fat Liver Kidney Eggs	

(1) = For porcine and poultry this MRL relates to „skin and fat in natural proportions“.

(2) = For fin fish this MRL relates to „muscle and skin in natural proportions“.

### 1.2.10. Aminoglycosides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Apramicin	Apramycin	Apramycin	Bovine	1 000 µg/kg 1 000 µg/kg 10 000 µg/kg 20 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Dihydrostreptomycin	Dihydrostreptomycin	Dihydrostreptomycin	All ruminants	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Koža i masno Liver Kidney	
			Rabbits	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	
Streptomycin	Streptomycin	Streptomycin	All ruminants	500 µg/kg 500	Muscle Fat Liver	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 500 µg/kg 1 000 µg/kg 200 µg/kg	Kidney Milk	
			Porcine	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Koža i masno Liver Kidney	
			Rabbits	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Masno tk Liver Kidney	
Gentamicin	Gentamicin	Sum of gentamicin C1, gentamicin C1a, gentamicin C2 and gentamicin C2a	Bovine	50 µg/kg 50 µg/kg 200 µg/kg 750 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	50 µg/kg 50 µg/kg 200 µg/kg 750 µg/kg	Muscle Koža i masno Liver Kidney	
Kanamycin	Kanamycin	Kanamycin A	All food-producing	100 µg/kg	Muscle Fat (1)	Not for use in animals

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			species except fin fish	100 µg/kg 600 µg/kg 2 500 µg/kg 150 µg/kg	Liver Kidney Milk	from eggs & products of human consumption
Neomicin (uključujući i framycetin)	Neomycin (including framycetin)	Neomycin B	All food-producing species	500 µg/kg 500 µg/kg 500 µg/kg 5 000 µg/kg 1 500 µg/kg 500 µg/kg	Fat (1) Muscle (2) Liver Kidney Milk Eggs	
Paromomicin	Paromomycin	Paromomycin	All food-producing species	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle (2) Liver Kidney	Not found in animal products from milk & are products of human consumption
Spektinomycin	Spectinomycin	Spectinomycin	All food-producing species except sheep	500 µg/kg 300 µg/kg 1 000 µg/kg 5 000 µg/kg 200 µg/kg	Fat (1) Muscle (2) Liver Kidney Milk	Not found in animal products from eggs & products of human consumption
			Ovine	300 µg/kg 500 µg/kg 2 000 µg/kg	Muscle Fat Liver Kidney Milk	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 5 000 µg/kg 200 µg/kg		
Streptomycin	Streptomycin	Streptomycin	All ruminants	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Skin and fat Liver Kidney	
			Rabbits	500 µg/kg 500 µg/kg 500 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	

(1) = For porcine species and poultry this MRL relates to „skin and fat in natural proportions“.

(2) = For fin fish this MRL relates to „Muscle and skin in natural proportions“.

#### 1.2.11. Other antibiotics

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Novobiocin	Novobiocin	Novobiocin	Bovine	50	Milk	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg		

### 1.2.12. Polypeptides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs
Bacitracin	Bacitracin	Sum of bacitracin A, bacitracin B, and bacitracin C	Bovine	100 µg/kg
			Rabbits	150 µg/kg 150 µg/kg 150 µg/kg 150 µg/kg

### 1.2.13. Beta-lactamase inhibitors

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Klavulanska kiselina	Clavulanic acid	Clavulanic acid	Bovine	100 µg/kg 100 µg/kg 200 µg/kg 400 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	100 µg/kg 100 µg/kg 200 µg/kg 400 µg/kg	Muscle Skin and fat Liver Kidney	



### 1.2.14. Polymyxins

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Kolistin	Colistin	Colistin	All food-producing species	150 µg/kg 150 µg/kg 150 µg/kg 200 µg/kg 50 µg/kg 300 µg/kg	Fat <sup>(1)</sup> Muscle <sup>(2)</sup> Liver Kidney Milk Eggs	

(1) = For porcine species and poultry this MRL relates to „skin and fat in natural proportions“.

(2) = For fin fish this MRL relates to „muscle and skin in natural proportions“.

### 1.2.15. Orthosomycins

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Avilamicin	Avilamycin	Dichloroisoevernic acid	Porcine	50 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg	Muscle Fat <sup>(1)</sup> Liver Kidney	
			Kunić	50 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	
			Poultry	50	Muscle	Not for use

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 100 µg/kg 300 µg/kg 200 µg/kg	Fat <sup>(1)</sup> Liver Kidney	in animals from which eggs are produced for human consumption

<sup>(1)</sup> = For porcine species and poultry this MRLs relates to „skin and fat in natural proportions“

### 1.2.16. Ionophores

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Monenzin	Monensin	Monensin A	Bovine	2 µg/kg 10 µg/kg 30 µg/kg 2 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk	
Lasalocid	Lasalocid	Lasalocid A	Poultry	20 µg/kg 100 µg/kg 100 µg/kg 50 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Eggs	For fat MRL relates to „skin and fat in natural proportions“

## 2. Antiparasitic agents

### 2.1. Agents acting against endoparasites

#### 2.1.1. Salicylanilides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Klozantel	Closantel	Closantel	Bovine	1 000 µg/kg 3 000 µg/kg 1 000 µg/kg 3 000 µg/kg	Muscle Fat Liver Kidney	
			Ovine	1 500 µg/kg 2 000 µg/kg 1 500 µg/kg 5 000 µg/kg	Muscle Fat Liver Kidney	
Rafoksanid	Rafoxanide	Rafoxanide	Bovine	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
			Ovine	100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney	

#### 2.1.2. Tetra-hydro-imidazoles (imidazolthiazoles)

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Levamisol	Levamisole	Levamisole	Bovine, ovine, porcine	10 µg/kg 10	Muscle Fat Liver	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			and poultry	µg/kg 100 µg/kg 10 µg/kg	Kidney	

### 2.1.3. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs
Albendazol	Albendazole	Sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	All ruminants	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg
Albendazol oksid	Albendazole oxide	Sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine and ovine	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg
Febantel	Febantel	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All ruminants	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg
Fenbendazol	Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All ruminants	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg
Flubendazol	Flubendazole	Sum of flubendazole and (2-amino-1H-benzimidazol-5-yl) (4fluorophenyl)	Poultry and porcine	50 µg/kg 50 µg/kg 400 µg/kg 300 µg/kg

	<b>Pharmacologically active substance(s)</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Marker residue</b>	<b>Animal species</b>	<b>MRLs</b>
			methanone		
	Flubendazol	Flubendazole	Flubendazol	Poultry	400 µg/kg
	Mebendazol	Mebendazole	Sum of mebendazolemethyl (5-(1-hydroxy,1-phenyl)methyl-1H-benzimidazol-2-yl) carbamateand (2-amino-1H-benzimidazol-5-yl) phenyl methanone, expressed as mebendazole equivalents	Ovine, caprine and equidae	60 µg/kg 60 µg/kg 400 µg/kg 60 µg/kg
	Netobimin	Netobimin	Sum of albendazole oxide, albendazole sulphone and albendazole 2-amino sulphone, expressed as albendazole	Bovine i ovine	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg
	Oksfendazol	Oxfendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All ruminants	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg
	Oksibendazol	Oxibendazole	Oxibendazole	Porcine	100 µg/kg 500 µg/kg 200 µg/kg 100 µg/kg
	Tiabendazol	Thiabendazole	Sum of thiabendazole and 5-hydroxythiabendazole	Caprine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg
	Triklabendazol	Triclabendazole	Sum of extractable residues that may be oxidised to ketotriclabendazole	All ruminants	225 µg/kg 100 µg/kg 250 µg/kg 150 µg/kg

#### 2.1.4. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Nitroksinil	Nitroxinil	Nitroxinil	Bovine and ovine	400 µg/kg 200 µg/kg 20 µg/kg 400 µg/kg	Muscle Fat Liver Kidney	
Oksiklozanid	Oxyclozanide	Oxyclozanide	All ruminants	20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk	

#### 2.1.5. Benzenesulphonamides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Klorsulon	Clorsulon	Clorsulon	Bovine	35 µg/kg 100 µg/kg 200 µg/kg	Muscle Liver Kidney	

#### 2.1.6. Piperazine derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Piperazin	Piperazine	Piperazine	Porcine	400 µg/kg 800 µg/kg 2 000 µg/kg 1 000 µg/kg	Muscle Skin and fat Liver Kidney	
			Chicken	2 000 µg/kg	Eggs	

### 2.1.7. Tetrahydropyrimides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Morantel	Morantel	Sum of residues which may be hydrolysed to N-methyl-1,3-propane diamine and expressed as morantel equivalents	Bovine and ovine	100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	
			All ruminants	100 µg/kg 100 µg/kg 800 µg/kg 200 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	

2.2. Agents acting against ectoparasites

2.2.1. Organophosphates

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Kumafos	Coumafos	Coumafos	Bees	100 µg/kg	Med	
Diazinon	Diazinon	Diazinon	Bovine, ovine and caprine	20 µg/kg	Milk	
			Bovine, porcine, ovine and caprine	20 µg/kg 700 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	
Foksim	Phoxim	Phoxim	Ovine	50 µg/kg 400 µg/kg 50 µg/kg	Muscle Fat Kidney	Not for use in animals from which milk is produced for human consumption
			Porcine	20 µg/kg 700 µg/kg 20 µg/kg 20 µg/kg	Muscle Skin and fat Liver Kidney	
			Chicken	25 µg/kg 550	Muscle Skin and fat	



Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 50 µg/kg 30 µg/kg 60 µg/kg	Liver Kidney Eggs	

### 2.2.2. Formamidines

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Amitraz	Amitraz	Sum of amitraz and all metabolites containing the 2,4-DMA moiety, expressed as amitraz	Bovine	200 µg/kg 200 µg/kg 200 µg/kg 10 µg/kg	Fat Liver Kidney Milk	
			Ovine	400 µg/kg 100 µg/kg 200 µg/kg 10 µg/kg	Fat Liver Kidney Milk	
			Porcine	400 µg/kg 200 µg/kg	Skin and fat Liver Kidney	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				200 µg/kg		
			Bees (honey)	200 µg/kg	Honey	
			Caprine	200 µg/kg 100 µg/kg 200 µg/kg 10 µg/kg	Fat Liver Kidney Milk	

### 2.2.3. Pyrethroids

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provision
Cihalotrin	Cyhalothrin	Cyhalothrin (sum of isomers)	Bovine	500 µg/kg 50 µg/kg 50 µg/kg	Fat Kidney Milk	Further provisions of Ordinance on maximum residue levels of pesticides in food and feed (Official Gazette 119/07) to

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provision
						be observed <sup>1</sup>
Ciflutrin	Cyfluthrin	Cyfluthrin (sum of isomers)	Bovine	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
Deltametrin	Deltamethrin	Deltamethrin	All ruminants	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	
			Fin fish	10 µg/kg	Muscle and skin in natural proportions	
Fenvalerat	Fenvalerate	Fenvalerate (sum RR, SS, RS and isomers)	Bovine	25 µg/kg 250 µg/kg	Muscle Fat Liver Kidney	

<sup>1</sup> Propis će se uskladiti s odredbama Uredbe Europskog Parlamenta i Vijeća (EC) 396/2005 od 23. veljače 2005. godine o maksimalnim razinama ostataka pesticida u i na hrani i hrani za životinje biljnog i životinjskog podrijetla koja nadopunjuje Direktivu Vijeća 91/414/EEC; Uredbe Komisije (EC) 178/2006 od 1. veljače 2006. godine kojom se dopunjuje Uredba Europskog Parlamenta i Vijeća (EC) 396/2005 uspostavljanjem Aneksa I. popisa hrane i hrane za životinje na koju se maksimalne razine ostataka pesticida odnose, Uredbe Komisije (EC) 149/2008 od 29. siječnja 2008. godine kojom se dopunjuje Uredba Europskog Parlamenta i Vijeća (EC) 396/2005 uspostavljanjem Aneksa II., III. i IV. koji određuju maksimalne razine ostataka pesticida za proizvode navedene u Aneksu I., Uredbe Komisije (EC) 260/2008 od 18. ožujka 2008. godine kojom se dopunjuje Uredba Europskog Parlamenta i Vijeća (EC) 396/2005 uspostavljanjem Aneksa VII. popisom aktivnih tvari/kombinacija proizvoda navedenim u odredbama o iznimkama u vezi s tretiranjem fumigantima poslije žetve i Uredbe Europskog Parlamenta i Vijeća (EC) 299/2008 od 11. ožujka 2008. godine kojom se dopunjuje Uredba (EC) 396/2005 o maksimalnim razinama ostataka pesticida u i na hrani i hrani za životinje biljnog i životinjskog podrijetla u pogledu provedbe vlasti povjerene Komisiji.

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provision
				25 µg/kg 25 µg/kg 40 µg/kg	Milk	
Flumetrin	Flumethrin	Flumethrin (sum trans-Z isomers)	Bovine	10 µg/kg 150 µg/kg 20 µg/kg 10 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	
			Ovine	10 µg/kg 150 µg/kg 20 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Permetrin	Permethrin	Permethrin (sum of isomers)	Bovine	50 µg/kg 500 µg/kg 50 µg/kg 50 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk*	
Cipermetrin	Cypermethrin	Cypermethrin (sum of isomers)	Pastrvske vrste riba	50 µg/kg	Muscle and skin in natural proportions	
			All ruminants	20 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	* Further provisions of Ordinance

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provision
				20 µg/kg 20 µg/kg 20 µg/kg	Milk*	on maximum residue levels of pesticides in food and feed (Official Gazette 119/07) to be observe
Alfacipermetrin	Alphacypermethrin	Cipermetrin (sum of isomers)	Bovine and ovine	20 µg/kg 200 µg/kg 20 µg/kg 20 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk*	* Further provisions of Ordinance on maximum residue levels of pesticides in food and feed (Official Gazette 119/07) to be observe

\* The regulation will be aligned with the provisions of the Regulation (EC) 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC; Commission Regulation (EC) 178/2006 of 1 February 2006 amending Regulation (EC) 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply, Commission Regulation (EC) 149/2008 of 29 January 2008 amending Regulation (EC) No. 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex 1 thereto, Commission Regulation (EC) 260/2008 of 18 March 2008 amending Regulation (EC) 396/2005 of the European Parliament and of the Council by establishing Annex VII listing active substances/product combinations covered by a derogation as regards post harvest treatments with a fumigant and Regulation (EC) 299/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission.

#### 2.2.4. Acyl urea derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diflubenzuron	Diflubenzuron	Diflubenzuron	Salmonidae	1 000 µg/kg	Muscle and skin in natural proportions	
Fluazuron	Fluazuron	Fluazuron	Bovine	200 µg/kg 7 000 µg/kg 500 µg/kg 500 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Teflubenzuron	Teflubenzuron	Teflubenzuron	Salmonidae	500 µg/kg	Muscle and skin in natural proportions	

#### 2.2.5. Pyrimidines derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diciklanil	Dicyclanil	Sum of dicyclanil and 2, 4, 6-triamino-pyrimidine-5-carbonitrile	Ovine	200 µg/kg 150 µg/kg 400 µg/kg 400 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

#### 2.2.6. Triazine derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Ciromazin	Cyromazine	Cyromazine	Ovine	300 µg/kg	Muscle Fat	Not for use in animals

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				300 µg/kg 300 µg/kg 300 µg/kg	Liver Kidney	from which milk is produced for human consumption

### 2.3. Agents acting against endo- and ectoparasites

#### 2.3.1. Avermectins

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Abamektin	Abamectin	Avermektin B1a	Bovine	10 µg/kg 20 µg/kg	Fat Liver	
			Ovine	20 µg/kg 50 µg/kg 25 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Doramektin	Doramectin	Doramectin	All mammalian food producing species	40 µg/kg 150 µg/kg 100 µg/kg 60 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Enamektin	Enamectin	Enamectin B1a	Fin fish	100 µg/kg	Muscle and skin in natural proportions	
Eprinomektin	Eprinomectin	Eprinomectin B1a	Bovine	50 µg/kg 250 µg/kg	Muscle Fat Liver	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 1 500 µg/kg 300 µg/kg 20 µg/kg	Kidney Milk	
Ivermektin	Ivermectin	22, 23-Dihydro-avermectin B1a	Bovine	40 µg/kg 100 µg/kg	Fat Liver	
			Porcine, ovine, equidae	20 µg/kg 15 µg/kg	Fat Liver	
			Deer, including reindeer	20 µg/kg 100 µg/kg 50 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	
			All mammalian food producing species	100 µg/kg 100 µg/kg 30 µg/kg	Muscle Liver Kidney	Not for use in animals from which milk is produced for human consumption
Moksidektin	Moxidectin	Moxidectin	Bovine and ovine	50 µg/kg 500 µg/kg 100 µg/kg 50 µg/kg	Muscle Fat Liver Kidney	
			Bovine	40 µg/kg	Milk	
			Equidae	50 µg/kg	Muscle Fat	



Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				500 µg/kg 100 µg/kg 50 µg/kg	Liver Kidney	
			Ovine	40 µg/kg	Milk	

## 2.4. Agents acting against protozoa

### 2.4.1. Triazinetrione derivative

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Toltrazuril	Toltrazuril	Toltrazuril sulfon	Chicken	100 µg/kg 200 µg/kg 600 µg/kg 400 µg/kg	Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
			Purani	100 µg/kg 200 µg/kg 600 µg/kg 400 µg/kg	Muscle Skin and fat Liver Kidney	
			Porcine	100 µg/kg 150 µg/kg 500 µg/kg 250 µg/kg	Muscle Skin and fat Liver Kidney	
			All mammalian food	100 µg/kg 150 µg/kg	Muscle Fat <sup>(1)</sup> Liver	Not for use in animals from which

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
			producing species	µg/kg 500 µg/kg 250 µg/kg	Kidney	milk is produced for human consumption
			Poultry	100 µg/kg 200 µg/kg 600 µg/kg 400 µg/kg	Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption

(1) = For porcine species this MRL relates to „skin and fat in natural proportions“

#### 2.4.2. Quinazolone derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Halofuginon	Halofuginone	Halofuginone	Bovine	10 µg/kg 25 µg/kg 30 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

#### 2.4.3. Carbanilides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Imidokarb	imidocarb	Imidocarb	Bovine	300 µg/kg 50 µg/kg 2 000 µg/kg 1 500	Muscle Fat Liver Kidney Milk	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 50 µg/kg		
			Ovine	300 µg/kg 50 µg/kg 2 000 µg/kg 1 500 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption

### 3. Agents acting on the nervous system

#### 3.1. Agents acting on the central nervous system

##### 3.1.1. Butyrophenone tranquillisers

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Azaperon	Azaperone	Sum of azaperone and azaperol	Porcine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Skin and fat Liver Kidney	

#### 3.2. Agents acting on the autonomic nervous system

##### 3.2.1. Anti-adrenergics

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Karazolol	Carazolol	Carazolol	Porcine	5 µg/kg 5 µg/kg 25 µg/kg 25	Muscle Koža i masno tki. Liver Kidney	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg		
			Bovine	5 µg/kg 5 µg/kg 15 µg/kg 15 µg/kg 1 µg/kg µg/kg	Muscle Fat Liver Kidney Milk	

### 3.2.2. β<sub>2</sub>-sympathomimetic agents

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Klenbuterolklorid	Clenbuterol hydrochloride	Clenbuterol	Bovine	0,1 µg/kg 0,5 µg/kg 0,5 µg/kg 0,05 µg/kg µg/kg	Muscle Liver Kidney Milk	
			Equidae	0,1 µg/kg 0,5 µg/kg 0,5 µg/kg	Muscle Liver Kidney	

## 4. Anti-inflammatory agents

### 4.1. Nonsteroidal anti-inflammatory agents

#### 4.1.1. Arylpropionic acid derivative

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
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Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Karprofen	Carprofen	Carprofen	Bovine	500 µg/kg 1 000 µg/kg 1 000 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
			Equidae	500 µg/kg 1 000 µg/kg 1 000 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	
Vedaprofen	Vedaprofen	Vedaprofen	Equidae	50 µg/kg 20 µg/kg 100 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	
Karprofen	Carprofen	Sum of carprofen and carprofen glucuronide conjugate	Bovine i Equidae	500 µg/kg 1 000 µg/kg 1 000 µg/kg 1 000 µg/kg	Muscle Fat Liver Kidney	

#### 4.1.2. Fenamate group derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flunixin	Flunixin	Flunixin	Bovine	20 µg/kg	Muscle Fat	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				30 µg/kg 300 µg/kg 100 µg/kg	Liver Kidney	
		5-Hydroxyflunixin	Bovine	40 µg/kg	Milk	
		Flunixin	Porcine	50 µg/kg 10 µg/kg 200 µg/kg 30 µg/kg	Muscle Skin and fat Liver Kidney	
			Equidae	10 µg/kg 20 µg/kg 100 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	
Tolfenamatna kiselina	Tolfenamic acid	Tolfenamic acid	Bovine	50 µg/kg 400 µg/kg 100 µg/kg 50 µg/kg	Muscle Liver Kidney Milk	
			Porcine	50 µg/kg 400 µg/kg 100 µg/kg	Muscle Liver Kidney	

#### 4.1.3. Enolic acid derivates

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
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#### 4.1.4. Oxican derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Meloksikam	Meloxicam	Meloxicam	Porcine, equidae and rabbits	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	
			Bovine and caprine	20 µg/kg 65 µg/kg 65 µg/kg 15 µg/kg	Muscle Liver Kidney Milk	

#### 4.1.5. Pyrazolone derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Metamizol	Metamizole	4-Methylaminoantipyrin	Bovine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 50 µg/kg	Muscle Fat Liver Kidney Milk	
			Porcine	100 µg/kg 100 µg/kg	Muscle Skin and fat	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 100 µg/kg 100 µg/kg	Liver Kidney	
			Equidae	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	

#### 4.1.6. Phenyl acetic acid derivatives

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Diklofenak	Diclofenac	Diclofenak	Bovine	5 µg/kg 1 µg/kg 5 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
			Porcine	5 µg/kg 1 µg/kg 5 µg/kg 10 µg/kg	Muscle Skin and fat Liver Kidney	

#### 4.1.7. Sulphonated fenyl lactones



Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Firokoksib	Firocoxib	Firocoxib	Equidae	10 µg/kg 15 µg/kg 60 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	

## 5. Corticoides

### 5.1. Glucocorticoides

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provision
Betametazon	Betamethasone	Betamethasone	Bovine	0,75 µg/kg 2 µg/kg 0,75 µg/kg 0,3 µg/kg	Muscle Liver Kidney Milk	
			Porcine	0,75 µg/kg 2 µg/kg 0,75 µg/kg	Muscle Liver Kidney	
Deksametazon	Dexamethasone	Dexamethasone	Bovine	0,3 µg/kg	Milk	
			Bovine, porcine and equidae	0,75 µg/kg 2 µg/kg 0,75 µg/kg	Muscle Liver Kidney	
			Caprine	0,75 µg/kg 2 µg/kg 0,75 µg/kg	Muscle Liver Kidney Milk	

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg 0,3 µg/kg		
Metilprednizolon	Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
Prednizolon	Prednisolone	Prednisolone	Bovine	4 µg/kg 4 µg/kg 10 µg/kg 10 µg/kg 6 µg/kg	Muscle Fat Liver Kidney Milk	

## 6. Agents acting on the reproductive system

### 6.1. Progestogens

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Klormadinon	Chlormadinone	Chlormadinone	Bovine	4 µg/kg 2 µg/kg 2,5 µg/kg	Fat Liver Milk	For zootechnical use only
Flugeston acetat	Flugestone acetate	Flugestone acetate	Ovine	1 µg/kg	Milk	For intravaginal use for zootechnical purposes only
			Caprine	1	Milk	For

Pharmacologically active substance(s)	Pharmacologically active substance(s) - English	Marker residue	Animal species	MRLs	Target tissues	Other provisions
				µg/kg		intravaginal use for zootechnical purposes only
			Ovine i caprine	0,5 µg/kg 0,5 µg/kg 0,5 µg/kg 0,5 µg/kg	Muscle Fat Liver Kidney	For therapeutic and zootechnical purposes only
Altrenogest	Altrenogest <sup>(1)</sup>	Altrenogest	Porcine	1 µg/kg 0,4 µg/kg	Skin and fat Liver	
			Equidae	1 µg/kg 0,9 µg/kg	Fat Liver	
Norgestomet	Norgestomet	Norgestomet	Bovine	0,2 µg/kg 0,2 µg/kg 0,2 µg/kg 0,2 µg/kg 0,12 µg/kg	Muscle Fat Liver Kidney Milk	For therapeutic and zootechnical purposes only

(1) = For zootechnical purposes only in accordance with Order prohibiting the use in stockfarming of certain beta-agonists and substances having a hormonal or thyrostatic action (Official Gazette 21/03) transposing the provisions of Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists.

## ANNEX II

### LIST OF PHARMACOLOGICALLY ACTIVE SUBSTANCES USED IN VMPs NOT SUBJECT TO MAXIMUM RESIDUE LIMITS

#### 1. Inorganic chemicals

	<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
1.	Aluminijev distearat	Aluminium distearate	All food-producing species	
2.	Aluminijev hidroksid acetat	Aluminium hydroxide acetate	All food-producing species	
3.	Aluminijev fosfat	Aluminium phosphate	All food-producing species	
4.	Aluminijev salicilat, bazični	Aluminium salicylate, basic	Bovine	For oral use only. Not for use in animals from which milk is produced for human consumption
5.	Aluminijev tristearat	Aluminium tristearate	All food-producing species	
6.	Aluminijev klorid	Aluminium chloride	All food-producing species	
7.	Barijev selenat	Barium selenate	Bovine, ovine	
8.	Bizmutov subkarbonat	Bismuth subcarbonate	All food-producing species	For oral use only
9.	Bizmutov subgalat	Bismuth subgallate	All food-producing species	For oral use only
10.	Bizmutov subnitrat	Bismuth subnitrate	All food-producing species	For oral use only
11.	Bizmutov subsalicilat	Bismuth subsalicylate	All food-producing species	For oral use only
12.	Borna kiselina i borati	Boric acid and borates	All food-producing species	
13.	Bromid, kalijeva sol	Bromide, potassium salt	All food-producing species	For topical use only
14.	Bromid, natrijeva sol	Bromide, sodium salt	All mammalian food-producing species	
15.	Kalcijev	Calcium acetate	All food-producing species	
16.	Kalcijev benzoat	Calcium benzoate	All food-producing species	
17.	Kalcijev karbonat	Calcium carbonate	All food-producing species	
18.	Kalcijev klorid	Calcium chloride	All food-producing species	
19.	Kalcijev glukonat	Calcium gluconate	All food-producing species	
20.	Kalcijev hidroksid	Calcium hydroxide	All food-producing species	
21.	Kalcijev hipofosfit	Calcium hypophosphite	All food-producing species	
22.	Kalcijev malat	Calcium malate	All food-producing species	
23.	Kalcijev oksid	Calcium oxide	All food-producing species	
24.	Kalcijev fosfat	Calcium phosphate	All food-producing species	
25.	Kalcijev polifosfat	Calcium polyphosphates	All food-producing species	
26.	Kalcijev propionat	Calcium propionate	All food-producing species	
27.	Kalcijev silikat	Calcium silicate	All food-producing species	
28.	Kalcijev stearat	Calcium stearate	All food-producing species	
29.	Kalcijev sulfat	Calcium sulphate	All food-producing species	
30.	Kalcijev glukohptonat	Calcium glucoheptonate	All food-producing species	
31.	Kalcijev glukonoglucoheptonat	Calcium glucono glucoheptonate	All food-producing species	
32.	Kalcijev glukonolaktat	Calcium	All food-producing species	

	<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
		gluconolactate		
33.	Kalcijev glutamat	Calcium glutamate	All food-producing species	
34.	Kalcijev glicerofosfat	Calcium glycerophosphate	All food-producing species	
35.	Kobaltov karbonat	Cobalt carbonate	All food-producing species	
36.	Kobaltov diklorid	Cobalt dichloride	All food-producing species	
37.	Kobaltov glukonat	Cobalt gluconate	All food-producing species	
38.	Kobaltov oksid	Cobalt oxide	All food-producing species	
39.	Kobaltov sulfat	Cobalt sulphate	All food-producing species	
40.	Kobaltov trioksid	Cobalt trioxide	All food-producing species	
41.	Bakrov klorid	Copper chloride	All food-producing species	
42.	Bakrov gluconat	Copper gluconate	All food-producing species	
43.	Bakrov heptanoat	Copper heptanoate	All food-producing species	
44.	Bakrov metionat	Copper methionate	All food-producing species	
45.	Bakrov oksid	Copper oxide	All food-producing species	
46.	Bakrov sulfat	Copper sulphate	All food-producing species	
47.		Dicopper oxide	All food-producing species	
48.	Kloridna kiselina	Hydrochloric acid	All food-producing species	For use as excipient
49.	Vodikov peroksid	Hydrogen peroxide	All food-producing species	
50.	Jod i anorganski spojevi joda uključujući: -Natrije i kalijev jodid -Natrijev i kalijev jodat -Jodofori uključujući polivinilpirolidone	Iodine and iodine inorganic compounds including: - Sodium and potassium-iodide - Sodium and potassium-iodate - Iodophors including polyvinylpyrrolidone-iodine	All food-producing species	
51.	Željezov diklorid	Iron dichloride	All food-producing species	
52.	Željezov sulfat	Iron sulphate	All food-producing species	
53.	Magnezij Magnezijev sulfat Magnezijev hidroksid Magnezijev stearat Magnezijev glutamat Magnezijev orotat Magnezijev aluminij silikat Magnezijev oksid Magnezijev karbonat Magnezijev fosfat Magnezijev glicerofosfat	Magnesium Magnesium sulphate Magnesium hydroxide Magnesium stearate Magnesium glutamate Magnesium orotate Magnesium aluminium silicate Magnesium oxide Magnesium carbonate Magnesium phosphate Magnesium	All food-producing species	

	<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
	Magnezijev aspartat Magnezijev citrat Magnezijev acetat Magnezijev trisilikat	glycerophosphate Magnesium aspartate Magnesium citrate Magnesium acetate Magnesium trisilicate		
54.	Niklov glukonat	Nickel gluconate	All food-producing species	
55.	Niklov sulfat	Nickel sulphate	All food-producing species	
56.	Kalijev DL aspartat	Potassium DL-aspartate	All food-producing species	
57.	Kalijev glukuronat	Potassium glucuronate	All food-producing species	
58.	Kalijev glicerofosfat	Potassium glycerophosphate	All food-producing species	
59.	Kalijev nitrat	Potassium nitrate	All food-producing species	
60.	Kalijev selenat	Potassium selenate	All food-producing species	
61.	Natrijev klorit	Sodium chlorite	Bovine	For topical use only
62.	Natrijev dikloroizocianurat	Sodium dichloroisocyanurate	Bovine, ovine, caprine	For topical use only
63.	Natrijev glicerofosfat	Sodium glycerophosphate	All food-producing species	
64.	Natrijev hipofosfit	Sodium hypophosphite	All food-producing species	
65.	Natrijev nitrit	Sodium nitrite	Bovine	For topical use only
66.	Natrijev propionat	Sodium propionate	All food-producing species	
67.	Natrijev selenat	Sodium selenate	All food-producing species	
68.	Natrijev selenit	Sodium selenite	All food-producing species	
69.	Sumpor	Sulphur	All food-producing species	
70.	Cinkov acetat	Zinc acetate	All food-producing species	
71.	Cinkov klorid	Zinc chloride	All food-producing species	
72.	Cinkov glukonat	Zinc gluconate	All food-producing species	
73.	Cinkov oleat	Zinc oleate	All food-producing species	
74.	Cinkov stearat	Zinc stearate	All food-producing species	

## 2. Organic compounds

<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
Oestradiol	17 $\beta$ -Oestradiol	All food-producing species	For therapeutic and zootechnical uses only
Ethanol	2-Aminoethanol	All food-producing species	
Adenine	2-Aminoethyl dihydrogenphosphate	All food-producing species	
Pyridone	2-Pyrrolidone	All food-producing species	At parenteral doses up to 40 mg/kg bw
Quinoline	8-Hydroxyquinoline	All mammalian food-producing species	For topical use in newborn animals only

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
Acetylcystein	Acetyl cysteine	All food-producing species	
Alfacalcidol	Alfacalcidol	Bovine	For parturient cows only
Alfaprostol	Alfaprostol	Rabbits, bovine, porcine, equidae	
Bacitracin	Bacitracin	Bovine	For intramammary use in lactating cows and for a except milk
Benzalkonijev klorid	Benzalkonium chloride	All food-producing species	For use as an excipient at concentrations up to 0.0
Benzocain	Benzocaine	All food-producing species	For use as local anaesthetic only
Benzilalkohol	Benzylalcohol	All food-producing species	For use as excipient
Betain	Betaine	All food-producing species	
Bronopol	Bronopol	Salmonidae	For use only on farmed fertilised eggs
Brotizolam	Brotizolam	Bovine	For therapeutic uses only
Buserelin	Buserelin	All food-producing species	
Butorphanol tartarat	Butorphanol tartrate	Equidae	For intravenous administration only
Butil 4-hidroksibenzoat	Butyl 4-hydroxybenzoate	All food-producing species	
Butylscopolaminiumov	Butylscopolaminium bromide	All food-producing species	
Caffeine	Caffeine	All food-producing species	
Carbetocin	Carbetocin	All mammalian food-producing species	
Cefazolin	Cefazolin	Bovine, ovine, caprine	For intramammary use, except if the udder may b food for human consumption
Cetostearilni alkohol	Cetostearyl alcohol	All food-producing species	
Cetrimide	Cetrimide	All food-producing species	
Chlorhexidin	Chlorhexidine	All food-producing species	For topical use only
Chlorocresol	Chlorocresol	All food-producing species	
Clazuril	Clazuril	Golubovi	
Cloprostenol	Cloprostenol	Bovine, porcine i equidae	
Coco alkyl dimetil betaines	Coco alkyl dimethyl betaines	All food-producing species	For use as excipient
Corticotropin	Corticotropin	All food-producing species	
D-Phe 6 -luteinizirajući hormon oslobađanja	D-Phe 6 -luteinising-hormone releasing hormone	All food-producing species	
Dembrexine	Dembrexine	Equidae	
Denaverine hidroklorid	Denaverine hydrochloride	Bovine	
Detomidine	Detomidine	Bovine, equidae	For therapeutic uses only
Diclazuril	Diclazuril	All ruminants, porcine	For oral use only
Diethyl phtalat	Diethyl phtalate	All food-producing species	

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
Diethyl ether Dietilov eter	Diethylene glycol monoethyl ether	Bovine, porcine	
Dimanganese trioxide Dimanoganov trioksid	Dimanganese trioxide	All food-producing species	For oral use only
Dimethyl phtalate Dimetilftalat	Dimethyl phtalate	All food-producing species	
Dinoprost Dinoprost	Dinoprost	All mammalian food-producing species	
Dinoprost tromethamine Dinoprost trometamin	Dinoprost tromethamine	All mammalian food-producing species	
Diprophylline Dipropililin	Diprophylline	All food-producing species	
Etamiphylline camsylate Etamifililin	Etamiphylline camsylate	All food-producing species	
Ethanol Etanol	Ethanol	All food-producing species	For use as excipient
Ethyl lactate Etilat	Ethyl lactate	All food-producing species	
Etiproston tromethamine Etiproston trometamin	Etiproston tromethamine	Bovine, porcine	
Fertirelin acetate Fertirelin acetat	Fertirelin acetate	Bovine	
Flumethrin Flumetrin	Flumethrin	Bees (honey)	
Folic acid Folna kiselina	Folic acid	All food-producing species	
Glycerol formal Glicerol formal	Glycerol formal	All food-producing species	
Gonadotrophin releasing hormone Gonadotropni hormon	Gonadotrophin releasing hormone	All food-producing species	
Heptaminol Heptaminol	Heptaminol	All food-producing species	
Hesperidin Hesperidin	Hesperidin	Equidae	
Hesperidin methyl chalcone Hesperidin metil	Hesperidin methyl chalcone	Equidae	
Hexetidine Heksitetidin	Hexetidine	Equidae	For topical use only
Human chorion gonadotrophin Ljudski korionski gonotropin	Human chorion gonadotrophin	All food-producing species	
Human menopausal urinary gonadotrophin Ljudski menopauzalni gonotropin	Human menopausal urinary gonadotrophin	Bovine	
Hydrocortisone Hidrokortizon	Hydrocortisone	All food-producing species	For topical use only
Iodine organic compounds — Iodoform Jodni spojevi - jodna kiselina	Iodine organic compounds — Iodoform	All food-producing species	
Isobutane Izobutan	Isobutane	All food-producing species	
Isoflurane Izofluran	Isoflurane	Equidae	For use as anaesthetic only
Isoxsuprine Izosuprin	Isoxsuprine	Bovine, equidae	For therapeutic use only in accordance with the C prohibiting the use in stockfarming of certain beta



Biologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
			and substances having a hormonal or thyrostatic action (Annex 21/03) <sup>2</sup>
	Ketamine	All food-producing species	
ketamin tartrat	Ketanserin tartrate	equidae	
ketoprofen	Ketoprofen	Bovine, porcine, equidae	
laktična kiselina I i di bazične soli, kalija i kalcija	L-tartaric acid and its mono- and di-basic salt of sodium, potassium and calcium	All food-producing species	For use as excipient
laktična kiselina	Lactic acid	All food-producing species	
lecirelin	Lecirelin	Bovine, equidae, rabbits	
lobelin	Lobeline	All food-producing species	
luprostiol	Luprostiol	All mammalian species	
malikova kiselina	Malic acid	All food-producing species	For use as excipient
manganov karbonat	Manganese carbonate	All food-producing species	For oral use only
manganov klorid	Manganese chloride	All food-producing species	For oral use only
manganov glukonat	Manganese gluconate	All food-producing species	For oral use only
manganov glicerofosfat	Manganese glycerophosphate	All food-producing species	For oral use only
manganov oksid	Manganese oxide	All food-producing species	For oral use only
manganov pidolat	Manganese pidolate	All food-producing species	For oral use only
manganov ribonukleat	Manganese ribonucleate	All food-producing species	For oral use only
manganov sulfat	Manganese sulphate	All food-producing species	For oral use only
mecilinam	Mecillinam	Bovine	For use as excipient
medrogesteronacetat	Medroxyprogesterone acetate	Ovine	For intravaginal use for zootechnical purposes only
melatonin	Melatonin	Ovine, caprine	
menadion	Menadione	All food-producing species	
menbutone	Menbutone	Bovine, ovine, caprine, porcine, equidae	
menthol	Menthol	All food-producing species	
metilnikotinat	Methyl nicotinate	Bovine, equidae	For topical use only
mineralni ugljikovodici, visoko viskozni i mikrokrystalini približno C10-čvrstinski, podjela na alifatične i ciklične	Mineral hydrocarbons, low to high viscosity including microcrystalline waxes, approximately C10-C60; aliphatic, cyclic	All food-producing species	Excludes aromatic and unsaturated compounds

<sup>2</sup>The Order transposes the provisions of Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
grančane spojevi	branched aliphatic and alicyclic compounds		
	N-butane	All food-producing species	
butanol	N-butanol	All food-producing species	For use as excipient
natamycin	Natamycin	Bovine, equidae	For topical use only
neostigmine	Neostigmine	All food-producing species	
nicoboxil	Nicoboxil	Equidae	For topical use only
nonivamide	Nonivamide	Equidae	For topical use only
oleyleate	Oleyloleate	All food-producing species	For topical use only
oxytocin	Oxytocin	All mammalian food-producing species	
pancreatin	Pancreatin	All mammalian food-producing species	For topical use only
	Papain	All food-producing species	
papaverine	Papaverine	Bovine	Newborn calves only
peracetic acid	Peracetic acid	All food-producing species	
phenol	Phenol	All food-producing species	
phloroglucinol	Phloroglucinol	All food-producing species	
phytomenadione	Phytomenadione	All food-producing species	
policresulen	Policresulen	All food-producing species	For topical use only
polyethylene glycol 15 hydroxystearate	Polyethylene glycol 15 hydroxystearate	All food-producing species	For use as excipient
polyethylene glycol 7 glyceryl cocoate	Polyethylene glycol 7 glyceryl cocoate	All food-producing species	For topical use only
polyethylene glycol stearate sa etilenskih	Polyethylene glycol stearates with 8-40 oxyethylene units	All food-producing species	For use as excipient
polysulphated glycosaminoglycan	Polysulphated glycosaminoglycan	Equidae	
praziquantel	Praziquantel	Ovine, equidae	For use in non-lactating sheep only
pregnant mare serum gonadotrophin	Pregnant mare serum gonadotrophin	All food-producing species	
prethcamide (crotethamide and cropropamide)	Prethcamide (crotethamide and cropropamide)	All mammalian food-producing species	
procaine	Procaine	All food-producing species	
propane	Propane	All food-producing species	
propylene glycol	Propylene glycol	All food-producing species	
quatresin	Quatresin	All food-producing species	For use as preservative only at concentrations of
R-Cloprostenol	R-Cloprostenol	Bovine, porcine, equidae	
rifaximin	Rifaximin	All mammalian food-producing species, bovine	For topical use only For intramammary use, except if the udder may b

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
			food for human consumption
in	Romifidine	Equidae	For therapeutic uses only
2-metil 2 fenoksi at	Sodium 2-methyl-2- phenoxy-propanoate	Bovine, porcine, caprine, equidae	
benzil 4 benzoat	Sodium benzyl 4- hydroxybenzoate	All food-producing species	
butil 4 benzoat	Sodium butyl 4- hydroxybenzoate	All food-producing species	
cetostearilsulfat	Sodium cetostearyl sulphate	All food-producing species	
alm	Somatosalm	Salmon	
m	Tanninum	All food-producing species	
alinat	Tau fluvalinate		
idrat	Terpin hydrate	Bovine, porcine, ovine, caprine	
n	Tetracaine	All food-producing species	For use as anaesthetic only
in	Theobromine	All food-producing species	
	Theophylline	All food-producing species	
al	Thiomersal	All food-producing species	For use only as preservatives in multidose vaccination concentration not exceeding 0.02 %
	Thymol	All food-producing species	
nat	Timerfonate	All food-producing species	For use only as preservatives in multidose vaccination concentration not exceeding 0.02 %
hidroglucinol	Trimethylphloroglucinol	All food-producing species	
D	Vitamin D	All food-producing species	
ki alkoholi	Wool alcohols	All food-producing species	For topical use only
2-pirolidon	1 -Methyl-2-pyrrolidone	Equidae	
il	Cefacetrile	Bovine	For intramammary use only and for all tissues exposed
azol	Enilconazole	Bovine, equidae	For topical use only
t	Etamsylate	All food-producing species	
	Strychnine	bovine	For oral use only, at dose to 0.1 mg/kg bw
azol	Parconazole	Guinea fowl	
	Biotin	All food-producing species	
ksin	Bromhexine	Bovine Not for use in animals from which milk is produced for human consumption Porcine Poultry Not for use in animals from which eggs are produced for human consumption	

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
aminhidroklorid	Mercaptamine hydrochloride	All mammalian food-producing species	
antel	Praziquantel	Ovine	
embonat	Pyrantel embonate	Equidae	
B1	Vitamin B1	All food-producing species	
B12	Vitamin B12	All food-producing species	
B2	Vitamin B2	All food-producing species	
B3	Vitamin B3	All food-producing species	
B5	Vitamin B5	All food-producing species	
B6	Vitamin B6	All food-producing species	
E	Vitamin E	All food-producing species	
	Tiaprost	Bovine, ovine, porcine, equidae	
in	Apramycin	Porcine, rabbits  Ovine Not for use in animals from which milk is produced for human consumption  Chicken Not for use in animals from which eggs are produced for human consumption	For oral use only
ifos	Azamethiphos	Salmonidae	
am	Doxapram	All mammalian food producing species	
l butoksid	Piperonyl butoxide	Bovine, ovine, caprine, equidae	For topical use only
akol	Sulfogaiacol	All food-producing species	
in hidroklorid	Vetrabutine hydrochloride	Porcine	
mid hidroklorid	Fenpipramide hydrochloride	Equidae	For intravenous use only
ortiazid	Hydrochlorothiazide	Bovine	
adon	Levomethadone	Equidae	For intravenous use only
mesilat	Tricaine mesilate	Fin fish	For water borne use only
etiazid	Trichlormethiazide	All mammalian food producing species	Not for use in animals from which milk is produced for human consumption
n	Vincamine	Bovine	For use in newborn animals only
	Atropine	All food-producing species	
azon	Cefoperazone	Bovine	For intramammary use in lactating cows only and

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
			tissues except milk
2-aminoglučuronat	2-aminoethanol glucuronate	All food-producing species	
glučuronat	Betaine glucuronate		
sulfonati, otopine i natrijeve soli	Bituminosulfonates, ammonium and sodium salts	All mammalian food producing species	For topical use only
amin	Chlorphenamine	All mammalian food producing species	For oral use only
Humične kiseline i natrijeve soli	Humic acids and their sodium salts	All food-producing species	
Paracetamol	Paracetamol	Porcine	For oral use only
Tosilamid natrij	Tosylchloramide sodium – m88, 125	Fin fish, Bovine Equidae	For water-borne use only For topical use only For topical use only
1-pirrolidon	1 -methyl-2-pyrrolidone	All food-producing species	
Ergometrin maleat	Ergometrine maleate	All mammalian food-producing species	For use in parturient animals only
Jecoris oleum	<i>Jecoris oleum</i>	All food-producing species	For topical use only
Mepivacain	Mepivacaine	Equidae	For intra-articular and epidural use as local anaesthetic
Novobiocin	Novobiocin	Bovine	For intramammary use only and for all tissues except milk
Piperazin dihidroklorid	Piperazine dihydrochloride	Chicken	For all tissues except eggs
Polioksil ricinus ulje sa oksietilenskih jedinica	Polyoxyl castor oil with 30 to 40 oxyethylene units	All food-producing species	For use as excipient
Polioksil hidrogenizirano ricinus ulje sa 40-60 oksietilenskih jedinica	Polyoxyl hydrogenated castor oil with 40 to 60 oxyethylene units	All food-producing species	For use as excipient
Xylazine hidroklorid	Xylazine hydrochloride	Bovine, equidae	Not for use in animals from which milk is produced for human consumption
Butafosfan	Butafosfan	Bovine	For intravenous use only
Cefalonium	Cefalonium	Bovine	For intramammary use and eye treatment only, and for all tissues except milk
Furosemid	Furosemide	Bovine, equidae	For intravenous administration only
Lidocain	Lidocaine	Equidae	For local-regional anaesthesia only
3,5-Diiodo-L-tirozin	3,5-Diiodo-L-tyrosine	All mammalian food-producing species	
Levo-tiroksin	Levothyroxine	All mammalian food-producing species	
Aluminijev	Aluminium salicylate,	All food producing species	For topical use only

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
	basic	except fish	
nitrat	Bismuth subnitrate	Bovine	For intramammary use only
aspartat	Calcium aspartate	All food-producing species	
salicilat	Methyl salicylate	All food-producing species, except fish	For topical use only
na kiselina	Salicylic acid	All food-producing species, except fish	For topical use only
salicilat	Sodium salicylate	Bovine, porcine	For oral use. Not for use in animals from which milk or eggs are produced for human consumption
aspartat	Zinc aspartate	All food-producing species	
fos	Toldimfos	All food-producing species	
nat	Decoquinat	Bovine, ovine	For oral use. Not for use in animals from which milk or eggs are produced for human consumption
boroformijat	Sodium boroformiate	All food-producing species	
	Thiamylal	All mammalian food producing species	For intravenous administration only
l natrij	Thiopental sodium	All food-producing species	For intravenous administration only
salicilna kiselina	Acetylsalicylic acid	All food-producing species, except fish	Not for use in animals from which milk or eggs are produced for human consumption
salicilna kiselina DL	Acetylsalicylic acid DL-lysine	All food-producing species, except fish	Not for use in animals from which milk or eggs are produced for human consumption
at kalcij	Carbasalate calcium	All food-producing species, except fish	Not for use in animals from which milk or eggs are produced for human consumption
acetilsalicilat	Sodium acetylsalicylate	All food-producing species, except fish	Not for use in animals from which milk or eggs are produced for human consumption
alkil benzen na kiselina s lancom dužine od 13 koja sadrži d 2,5% lanca dužih	Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from C9 to C13, containing less than 2,5 % of chains longer than C13	Bovine, ovine	For topical use only
oli	Amprolium	Poultry	For oral use only
ska kiselina, ve	Tiludronic acid, disodium salt	Equidae	For intravenous use only
trioleat	Sorbitan trioleate	All food-producing species	
A	Vitamin A	All food-producing species	
v laurilsulfat	Ammonium lauryl sulphate	All food-producing species	
l	Bronopol	Fin fish	
pantotenat	Calcium pantothenate	All food-producing species	
	Allantoin	All food-producing species	For topical use only

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
benzocain	Benzocaine	Salmonidae	
dexpanthenol	Dexpanthenol	All food-producing species	
azagly-nafarelin	Azagly-nafarelin	Salmonidae	Not for use in fish from which eggs are produced for consumption
deslorelin acetat	Deslorelin acetate	Equidae	
hidroksiacetilsalicilat	Hydroxyethylsalicylate	All food-producing species, except fish	For topical use only
xylazine hidroklorid	Xylazine hydrochloride	Bovine, equidae	
omeprazol	Omeprazole	Equidae	For oral use only
trichlormetiazid	Trichlormethiazide	All mammalian food producing species	
progesteron	Progesterone (*)	Bovine, ovine, caprine, Equidae (female)	Only for intravaginal therapeutic or zootechnical use in accordance with the Order prohibiting the use in stockfarming of certain beta-agonists and substances having a hormonal or thyrostatic action (OG 21/03) <sup>3</sup>
beclometazon dipropionat	Beclomethasone dipropionate	Equidae	For inhalation only
cloprostenol	Cloprostenol	Caprine	
R-cloprostenol	R-cloprostenol	Caprine	
sorbitan seskvioleat	Sorbitan sesquioleate	All food-producing species	
diethylene glikol monoetil eter	Diethylene glycol monoethyl ether	All ruminants and porcine	
peforelin	Peforelin	Porcine	

### 3. Substances generally recognised as safe

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
absint ekstrakt pelina	Absinthium extract	All food-producing species	
acetilmetonin	Acetylmethionine	All food-producing species	
aluminijev hidroksid	Aluminium hydroxide	All food-producing species	
aluminijev monostearat	Aluminium monostearate	All food-producing species	
amonijev sulfat	Ammonium sulfate	All food-producing species	
benzoil benzoat	Benzoyl benzoate	All food-producing species	
benzil p-hidroksibenzoat	Benzyl p-hydroxybenzoate	All food-producing species	
kalcijev borogluconat	Calcium borogluconate	All food-producing species	
kalcijev citrat	Calcium citrate	All food-producing species	

<sup>3</sup> The Order transposes the provisions of Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
Camfor	Camphor	All food-producing species	For topical use only
Ekstrakt kardamona	Cardamon extract	All food-producing species	
Dietil sebakat	Diethyl sebacate	All food-producing species	
Dimetikon	Dimethicone	All food-producing species	
Dimetil acetamid	Dimethyl acetamide	All food-producing species	
Dimetil sulfoksid	Dimethyl sulphoxide	All food-producing species	
Epinefrin	Epinephrine	All food-producing species	
Etiloleat	Ethyl oleate	All food-producing species	
Etilendiamintetraacetatna kiselina i njezine soli	Ethylenediaminetetraacetic acid and salts	All food-producing species	
Eukaliptol	Eucalyptol	All food-producing species	
Folikulostimulirajući hormon (prirodni FSH od svih vrsta i njihovih sintetskih analoga)	Follicle stimulating hormone (natural FSH from all species and their synthetic analogues)	All food-producing species	
Formaldehid	Formaldehyde	All food-producing species	
Formvlja kiselina	Formic acid	All food-producing species	
Glutaldehid	Glutaraldehyde	All food-producing species	
Guajakol	Guaiacol	All food-producing species	
Heparin i njegove soli	Heparin and its salts	All food-producing species	
Čovjekovski korionski gonadotropin (prirodni HCG i njegovi sintetski analozi)	Human chorionic gonadotropin (natural HCG and its synthetic analogues)	All food-producing species	
Željezov amonij citrat	Iron ammonium citrate	All food-producing species	
Željezov dekstran	Iron dextran	All food-producing species	
Željezov glukoheptonat	Iron glucoheptonate	All food-producing species	
Isopropanol	Isopropanol	All food-producing species	
Lanolin	Lanolin	All food-producing species	
Luteinizirajući hormon (prirodni LH od svih vrsta i njihovi sintetski analozi)	Luteinising hormone (natural LH from all species and their synthetic analogues)	All food-producing species	
Magnezijev klorid	Magnesium chloride	All food-producing species	
Magnezijev glukonat	Magnesium gluconate	All food-producing species	
Magnezijev hipofosfit	Magnesium hypophosphite	All food-producing species	
Manitol	Mannitol	All food-producing species	
Metilbenzoat	Methylbenzoate	All food-producing species	
Monotioglicerol	Monothioglycerol	All food-producing species	
Montanid	Montanide	All food-producing species	
Mygliol	Myglyol	All food-producing species	
Orgotein	Orgotein	All food-producing species	
Poloksalen	Poloxalene	All food-producing species	



<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
poloksamer	Poloxamer	All food-producing species	
polietilenski glikoli molekularne težine od 200-10000)	Polyethylene glycols (molecular weight ranging from 200 to 10 000)	All food-producing species	
polisorbat 80	Polysorbate 80	All food-producing species	
serotonin	Serotonin	All food-producing species	
atrijev klorid	Sodium chloride	All food-producing species	
atrijev kromoglikat	Sodium cromoglycate	All food-producing species	
atrijev dioktilsulfosukcinat	Sodium dioctylsulphosuccinate	All food-producing species	
atrijev formaldehidsulfoksilat	Sodium formaldehydesulphoxylate	All food-producing species	
atrijev lauril sulfat	Sodium lauryl sulphate	All food-producing species	
atrijev pirosulfit	Sodium pyrosulphite	All food-producing species	
atrijev stearat	Sodium stearate	All food-producing species	
atrijev tiosulfat	Sodium thiosulphate	All food-producing species	
tragant	Tragacanth	All food-producing species	
urea	Urea	All food-producing species	
činkov oksid	Zinc oxide	All food-producing species	
činkov sulfat	Zinc sulphate	All food-producing species	
adenozin i njegovi 5-mono-, 5-di i 5-trifosfati	Adenosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food-producing species	
alanin	Alanine	All food-producing species	
arginin	Arginine	All food-producing species	
asparagin	Asparagine	All food-producing species	
aspartatna kiselina	Aspartic acid	All food-producing species	
karnitin	Carnitine	All food-producing species	
holin	Choline	All food-producing species	
kimotripsin	Chymotrypsin	All food-producing species	
itrulin	Citrulline	All food-producing species	
cistein	Cysteine	All food-producing species	
itidin i njegovi 5-mono-, 5-di i 5-trifosfati	Cytidine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food-producing species	
glutamatna kiselina	Glutamic acid	All food-producing species	
glutamin	Glutamine	All food-producing species	
glicin	Glycine	All food-producing species	
vanozin i njegovi 5-mono-, 5-di i 5-trifosfati	Guanosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food-producing species	
istidin	Histidine	All food-producing species	
hijaluronska kiselina	Hyaluronic acid	All food-producing species	

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
Adenozin i njegovi 5'-mono-, 5'-di- i 5'-trifosfati	Inosine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food-producing species	
Inozitol	Inositol		
Isoleucin	Isoleucine		
Leucin	Leucine		
Lizin	Lysine	All food-producing species	
Metionin	Methionine	All food-producing species	
Ornitin	Ornithine	All food-producing species	
Orotna kiselina	Orotic acid	All food-producing species	
Pepsin	Pepsin	All food-producing species	
fenilalanin	Phenylalanine	All food-producing species	
Prolin	Proline	All food-producing species	
Serine	Serine	All food-producing species	
tioktina kiselina	Thioctic acid	All food-producing species	
reonin	Threonine	All food-producing species	
imidine	Thymidine	All food-producing species	
tripsin	Trypsin	All food-producing species	
riptofan	Tryptophan	All food-producing species	
Tirozin	Tyrosine	All food-producing species	
Uridine i njegovi 5'-mono-, 5'-di- i 5'-trifosfati	Uridine and its 5'-mono-, 5'-di- and 5'-triphosphates	All food-producing species	
Valin	Valine	All food-producing species	
Polioksietilen sorbitan monooleat	Polyoxyethylene sorbitan monooleate	All food-producing species	
Polioksietilen sorbitan monooleat i trioleat	Polyoxyethylene sorbitan monooleate and trioleate	All food-producing species	

#### 4. Substances used in homeopathic veterinary medicinal products (VMP)

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - Latin	Animal species	Other provisions
Substances used in homeopathic veterinary medicinal products provided their concentration in the product does not exceed one part per thousand		All food-producing species	
Adonisi gorcovijet	<i>Adonis vernalis</i>	All food-producing species	For use in homeopathic veterinary medicinal products

			according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per hundred only
	<i>Acqua levici</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias only
boilje	<i>Atropa belladonna</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per hundred only
ica	<i>Convallaria majalis</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per thousand only
ska konoplja	<i>Apocynum cannabinum</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per hundred only for use only
	<i>Harunga madagascariensis</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per hundred only
ica noći	<i>Selenicereus grandiflorus</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per hundred only
njačka tuja	<i>Thuja occidentalis</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per hundred only
	<i>Virola sebifera</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per thousand only
	<i>Ruta graveolens</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentration of the products not exceeding one part per thousand only for use in animals from which milk is produced for human consumption
i kesten	<i>Aesculus hippocastanum</i> 130	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentration of the products not exceeding one part per ten only
oplja	<i>Agnus castus</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentration corresponding to the mother tincture and dilutions thereof
en	<i>Ailanthus altissima</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentration corresponding to the mother tincture and dilutions thereof
ni luk (crveni)	<i>Allium cepa</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentration corresponding to the mother tincture and dilutions thereof
nklin korjen, ka	<i>Arnicae radix</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentration corresponding in the products not exceeding one part

			only
	<i>Artemisia abrotanum</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
čnica	<i>Bellis perennis</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
n	<i>Calendula officinalis</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per hundred only
for	<i>Camphora</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations the products not exceeding one part per hundred only
	<i>Cardiospermum halicacabum</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
ovi	<i>Crataegus</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
ekija, acea	<i>Echinacea</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof. For topical use only. For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations the products not exceeding one part per hundred only
liptus	<i>Eucalyptus globulus</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
zija/Vidac	<i>Euphrasia officinalis</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
o	<i>Ginkgo biloba</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations the products not exceeding one part per thousand only
eng	<i>Ginseng</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
amelis	<i>Hamamelis virginiana</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations the products not exceeding one part per ten only
ja kanda	<i>Harpagophytum procumbens</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
časta	<i>Hypericum</i>	All food-producing species	For use in homeopathic veterinary medicinal products

lavica	<i>perforatum</i>		according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
	<i>Lachnanthes tinctoria</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations the products not exceeding one part per thousand only
	<i>Lobaria pulmonaria</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
	<i>Okoubaka aubrevillei</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
tr-višnja	<i>Prunus laurocerasus</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations the products not exceeding one part per thousand only
l palma	<i>Serenoa repens</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
avica i stričak bad	<i>Silybum marianum</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
n europske ice	<i>Solidago virgaurea</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
ul	<i>Syzygium cumini</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
iana	<i>Turnera diffusa</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
a imela	<i>Viscum album</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof
rički kermes ili pojka	<i>Phytolacca americana</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentrations the products not exceeding one part per thousand only
ki luk	<i>Urginea maritima</i>	All food-producing species	For use in homeopathic veterinary medicinal products according to homeopathic pharmacopoeias, at concentrations the products not exceeding one part per hundred only use only

	<b>Pharmacologically active substance(s) - English</b>	<b>Animal species</b>	<b>Other provisions</b>
1.	Substances with an E number	All food-producing species	Only substances approved as additives in foodstuffs for human consumption, with the exception of preservatives listed in the Ordinance on additives <sup>4</sup>

6. Substances of vegetable origin

<b>Pharmacologically active substance(s) - Croatian</b>	<b>Pharmacologically active substance(s) - Latin</b>	<b>Animal species</b>	<b>Other provisions</b>
Aloj gel i ekstrakt cijelog lista aloje	Aloe vera gel and whole leaf extract of Aloe vera	All food-producing species	For topical use only
Aloji, barbadoški i kapski, njihovi standardizirani ekstrakti i njihovi pripravci	<i>Aloes, Barbados and Capae, their standardised dry extract and preparations thereof</i>	All food-producing species	
Eterično ulje anđelikina korjena	<i>Angelicae radix aetheroleum</i>	All food-producing species	
Aniševo eterično ulje	<i>Anisi aetheroleum</i>	All food-producing species	
Plod zvjezdastog anisa, standardizirani ekstrakti i njihovi pripravci	<i>Anisi stellati fructus, standardised extracts and preparations thereof</i>	All food-producing species	
Brđanka (cvijet i cijela biljka)	<i>Arnica montana (arnicae flos and arnicae planta tota)</i>	All food-producing species	For topical use only
Peruanski balzam	<i>Balsamum peruvianum</i>	All food-producing species	For topical use only
Boldov list	<i>Boldo folium</i>	All food-producing species	
Nevenov cvijet	<i>Calendulae flos</i>	All food-producing species	For topical use only
Paprikin plod	<i>Capsici fructus acer</i>	All food-producing species	
Korijen kravljaka	<i>Carlinae radix</i>	All food-producing species	For topical use only
Kimovo eterično ulje	<i>Carvi aetheroleum</i>	All food-producing species	
Klinčićevo eterično ulje	<i>Caryophylli aetheroleum</i>	All food-producing species	
Ekstrakt centelina, zeleni	<i>Centellae asiaticaer extractum</i>	All food-producing species	For topical use only

<sup>4</sup> Article 7 of the special ordinance will transpose the provisions of European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

Krizantema-cvijet	<i>Chrysanthemi cinerariifolii flos</i>	All food-producing species	For topical use only
Podanak cimicifuge	<i>Cimicifugae racemosae rhizoma</i>	All food-producing species	Not for use in animals from which milk is produced for human consumption
Kininovčeva kora, standardizirani ekstrakti i njihovi pripravci	<i>Cinchonae cortex</i> , standardised extracts and preparations thereof	All food-producing species	
Eterično ulje kineskog cimetovca	<i>Cinnamomi cassiae aetheroleum</i>	All food-producing species	
Kora kineskog cimetovca, standardizirani ekstrakti i njihovi pripravci	<i>Cinnamomi cassiae cortex</i> , standardised extracts and preparations thereof	All food-producing species	
Eterično ulje cejlonskog cimetovca	<i>Cinnamomi ceylanici aetheroleum</i>	All food-producing species	
Kora cejlonskog cimetovca, standardizirani ekstrakti i njihovi pripravci	<i>Cinnamomi ceylanici cortex</i> , standardised extracts and preparations thereof	All food-producing species	
Eterično ulje limuna	<i>Citri aetheroleum</i>	All food-producing species	
Eterično ulje oštre vlaske	<i>Citronellae aetheroleum</i>	All food-producing species	
Kora kondurago kondorvine	<i>Condurango cortex</i> , standardised extracts and preparations thereof	All food-producing species	
Korijanderovo eterično ulje	<i>Coriandri aetheroleum</i>	All food-producing species	
Eterično ulje čempresa	<i>Cupressi aetheroleum</i>	All food-producing species	For topical use only
Purpurna rudbekija	<i>Echinacea purpurea</i>	All food-producing species	For topical use only
Eukaliptusovo eterično ulje	<i>Eucalypti aetheroleum</i>	All food-producing species	
Komoračevo eterično ulje	<i>Foeniculi aetheroleum</i>	All food-producing species	
Krkavinina kora, standardizirani ekstrakti i njihovi pripravci	<i>Frangulae cortex</i> , standardised extracts and preparations thereof	All food-producing species	
Sirištavin korjen, standardizirani ekstrakti i njihovi pripravci	<i>Gentianae radix</i> , standardised extracts and preparations thereof	All food-producing species	

pripravci			
Ginseng, standardizirani ekstrakti i njihovi pripravci	<i>Ginseng</i> , standardised extracts and preparations thereof	All food-producing species	
Hamamelis	<i>Hamamelis virginiana</i>	All food-producing species	For topical use only
Sjeme divljeg kestena	<i>Hippocastani semen</i>	All food-producing species	For topical use only
Ulje gospine trave	<i>Hyperici oleum</i>	All food-producing species	For topical use only
Plod borovice	<i>Juniperi fructus</i>	All food-producing species	
Eterično ulje lovorova lista	<i>Lauri folii aetheroleum</i>	All food-producing species	
Lovorov plod	<i>Lauri fructus</i>	All food-producing species	
Lavandino eterično ulje	<i>Lavandulae aetheroleum</i>	All food-producing species	For topical use only
Glavica lesperdeza	<i>Lespedeza capitata</i>	All food-producing species	
Laneno ulje	<i>Lini oleum</i>	All food-producing species	
Mažuran-zelen	<i>Majoranae herba</i>	All food-producing species	
Kamilica i njezini pripravci	<i>Matricaria recutita</i> and preparations thereof	All food-producing species	
Kamiličin cvijet	<i>Matricariae flos</i>	All food-producing species	
Ekstrakt vije lucerne	<i>Medicago sativa extractum</i>	All food-producing species	For topical use only
Matičnjakovo eterično ulje	<i>Melissae aetheroleum</i>	All food-producing species	
Matičnjakov list	<i>Melissae folium</i>	All food-producing species	
Eterično ulje poljske metvice	<i>Menthae arvensis aetheroleum</i>	All food-producing species	
Eterično ulje paprene metvice	<i>Menthae piperitae aetheroleum</i>	All food-producing species	
Stolisnikova zelen	<i>Millefolii herba</i>	All food-producing species	
Eterično ulje muškarnog oraščića	<i>Myristicae aetheroleum</i>	All food-producing species	For use in newborn animals only
Ekstrakt turiona („mladice“ smreke)	<i>Piceae turiones recentes extractum</i>	All food-producing species	For oral use only
Oksidacijski produkti terpentinskog ulja	Oxidation products of <i>Terebinthinae oleum</i>	All food-producing species	
Ekstrakt buhača	<i>Pyrethrum</i> extract	All food-producing species	For topical use only
Hrastova kora	<i>Quercus cortex</i>	All food-producing species	
Quillaja ekstrakt	<i>Quillaia saponins</i>	All food-producing species	
Rabarbarin korjen, standardizirani	<i>Rhei radix</i> , standardised extracts and preparations	All food-producing species	



Ekstrakti i njihovi pripravci	thereof		
Ricinusovo ulje	<i>Ricini oleum</i>	All food-producing species	For use as excipient
Ružmarinovo eterično ulje	<i>Rosmarini aetheroleum</i>	All food-producing species	
Ružmarinov list	<i>Rosmarini folium</i>	All food-producing species	
Veprina	<i>Ruscus aculeatus</i>	All food-producing species	For topical use only
Kaduljin list	<i>Salviae folium</i>	All food-producing species	
Bazgov cvijet	<i>Sambuci flos</i>	All food-producing species	
Sjeme crne gorušice	<i>Sinapis nigrae semen</i>	All food-producing species	
Sjemenka strihinovca	<i>Strychni semen</i>	All food-producing species	For oral use only at doses up to the equivalent of 0.1 mg strychnine/l
Korijen gaveza	<i>Symphyti radix</i>	All food-producing species	For topical use on intact skin only
Terpetinsko eterično ulje	<i>Terebinthinae aetheroleum rectificatum</i>	All food-producing species	For topical use only
Balzam od ariša	<i>Terebinthinae laricina</i>	All food-producing species	For topical use only
Timijanovo eterično ulje	<i>Thymi aetheroleum</i>	All food-producing species	
Lipin cvijet	<i>Tiliae flos</i>	All food-producing species	
Kopriva	<i>Urticae herba</i>	All food-producing species	

#### 7. Anti-infectious agents

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
Oksalna kiselina	Oxalic acid	Honey bees	

#### 8. Anti-inflammatory agents

Pharmacologically active substance(s) - Croatian	Pharmacologically active substance(s) - English	Animal species	Other provisions
Karprofen	Carprofen	bovine	For bovine milk only

LIST OF PHARMACOLOGICALLY ACTIVE SUBSTANCES USED IN VMPs FOR WHICH PROVISIONAL MRLs HAVE BEEN ESTABLISHED

1. ANTIMICROBIAL AGENTS

1.2. ANTIBIOTICS

1.2.2. Macrolides

Pharmacologically active substance	English name of the pharmacologically active substance	Marker residue	Animal species	MRLs $\mu\text{g}/\text{kg}$ or $\mu\text{g}/\text{kg}$	Target tissues	Other provisions
Gamitromicin	Gamithromycin	Gamithromycin	Bovines	20 200 100	Fat Liver Kidney	Provisional MRLs expire on 1 July 2009; not for use in animals from which milk is produced for human consumption

ANNEX IV

LIST OF PROHIBITED PHARMACOLOGICALLY ACTIVE SUBSTANCES

	Pharmacologically active substance	English name of the pharmacologically active substance
1.	Vučja stopa ( <i>Aristolochia spp.</i> ) i njezini pripravci	<i>Aristolochia spp.</i> and preparations thereof
2.	Kloramfenikol	Chloramphenicol
3.	Kloroform	Chloroform
4.	Klorpromazin	Chlorpromazine
5.	Kolhicin	Colchicine
6.	Dapson	Dapsone
7.	Dimetridazol	Dimetridazole
8.	Metronidazol	Metronidazole
9.	Nitrofurani	Nitrofurans (including furazolidone)

## ANNEX V

INFORMATION AND PARTICULARS TO BE INCLUDED IN AN APPLICATION  
FOR THE ESTABLISHMENT OF A MRL FOR A PHARMACOLOGICALLY  
ACTIVE SUBSTANCE USED IN VMPs*Administrative particulars*

1. Name or corporate name and permanent address of the person submitting the application for placing the VMP on the market.
2. Name of the VMP
3. Qualitative and quantitative composition in terms of active principles, with mention of the international non-proprietary name (INN) recommended by the World Health Organisation, where such name exists
4. Manufacturing authorisation, if any.
5. VMP marketing authorisation, if any.
6. Summary of the characteristics of the VMP(s) prepared in accordance with Article 5a of a special regulation on veterinary medicinal products<sup>1</sup>
  - A. Safety documentation
    - A.0. Expert report
      - A.1. Precise identification of the substance concerned by the application for the establishment of a MRL
        - 1.1. International non-proprietary name (INN)
        - 1.2. International Union of Pure and Applied Chemistry Name (IUPAC)
        - 1.3. Chemical Abstract Service (CAS) name
        - 1.4. Classification
          - therapeutic
          - pharmacological
        - 1.5. Synonyms and abbreviations
        - 1.6. Structural formula
        - 1.7. Molecular formula
        - 1.8. Molecular weight
        - 1.9. Degree of purity
        - 1.10. Qualitative and quantitative composition of impurities
        - 1.11. Description of physical properties:
          - fusion point
          - boiling point
          - vapour pressure
          - solubility in water and organic solvents expressed in g/l, with indication of temperature
          - density
          - spectra of refraction, rotation, etc.
      - A.2. Relevant pharmacological studies
        - 2.1. Pharmacodynamic studies

- 2.2. Pharmacokinetic studies
- A.3. Toxicological studies
  - 3.1. Single dose toxicity (acute toxicity)
  - 3.2. Repeated dose toxicity (chronic toxicity)
  - 3.3. Tolerance in the target species of animal(s)
  - 3.4. Reproductive toxicity, including teratogenicity
    - 3.4.1. Study of the effects on reproduction
    - 3.4.2. Embryotoxicity/fetotoxicity, including teratogenicity
  - 3.5. Mutagenicity
  - 3.6. Carcinogenicity
- A.4. Studies of other effects

- 4.1. Immunotoxicity
- 4.2. Microbiological properties of residues
  - 4.2.1. Effects on the human gut flora
  - 4.2.2. Effects on the micro-organisms used for industrial food processing
- 4.3. Observations in humans

## B. VMP residue documentation

### B.0. Expert report

B.1. Precise identification of the substance concerned by the application for the establishment of a MRL

The substance concerned should be identified in accordance with item A.1. However, where the application relates to one or more veterinary medicinal products, the product itself should be identified in detail, including:

- qualitative and quantitative composition;
- purity;
- identification of the manufacturer's batch used in the studies; comparison with the final product;
- specific activity and purity of radioactive isotopes;
- position of labelled atoms on the molecule.

### B.2. Residue studies

2.1. Pharmacokinetics (resorption, distribution, biotransformation, excretion)

2.2. Depletion of residues

2.3. Elaboration of MRLs

### B.3. Routine analytical methods for the detection of residues

3.1. Description of the method

3.2. Validation of the method

3.2.1. Specificity

3.2.2. Accuracy, including sensitivity

3.2.3. Precision

3.2.4. Limit of detection (LOD)

3.2.5. Limit of quantitation (LOQ)

3.2.6. Practicability and applicability under normal laboratory conditions

3.2.7. Susceptibility to interference

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<sup>1</sup>A special regulation on veterinary medicinal products will transpose the provisions of Directive (EC) No 2001/82, on its entry into force Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products ceased to have effect. The regulation referred to in Annex V, item 1.6. shall be adopted by 30 June 2009.

PROVISIONAL TRANSLATION