



STATUS OF MRL PROCEDURES

MRL assessments in the context of Council Regulation (EEC) No 2377/90

Background and legislative framework

In order to protect the safety of the consumer of foodstuffs of animal origin, one of the most important principles laid down in the European Union (EU) legislation with regard to the marketing authorisation of veterinary medicines is that foodstuffs obtained from animals treated with veterinary medicinal products must not contain residues which might constitute a health hazard for the consumer. Before a veterinary medicinal product intended for food producing animals can be authorised in the EU, all pharmacologically active substances contained in the product have to undergo a safety and residues evaluation, and have to be included in Annex I, II, or III of Council Regulation (EEC) No 2377/90¹.

The safety and residue evaluation in accordance with Regulation 2377/90 is carried out by the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency (EMA), supported by safety and residues experts, upon receipt of a valid application for the establishment of maximum residue limits (MRLs).

Substances for which definitive MRLs have been established are included in Annex I of Regulation 2377/90. MRLs can be proposed as provisional, if all aspects are not yet fully addressed. In this case the substance is inserted in Annex III with an expiry date defining for the termination of the provisional status. However, no provisional MRLs can be proposed, if major issues with regard to safety remain to be addressed, as it must be assured that residues at the proposed levels do not present a hazard to the health of the consumer. Only, once the applicant has satisfactorily answered the outstanding questions, the substance can be included in Annex I. These questions are likely to relate to the provision of fully validated analytical methods.

Where, following the evaluation, it appears that it is not necessary for the protection of public health to establish MRLs, such substance is included in Annex II. It should be noted that an entry in Annex II is not

¹ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin (O.J. NO L 224, 18.8.1990, p.1), as amended by Commission Regulation (EEC) No 762/92 (O.J. No. L 83, 28.3.1992, p.14), Council Regulation (EC) No 434/97 (O.J. No L 67, 7.3.1997, p. 1), and Council Regulation (EC) No 1308/99 (O.J. L 156, 23.6.1999, p.1).

A new MRL Regulation (Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (O.J. L 152, 16.6.2009, p.11)) entered into force on 6 July 2009. In accordance with Art. 29 of this Regulation Annex I to IV of Regulation (EEC) No 2377/90 shall continue to apply until the entry into force of a new regulation incorporating the pharmacologically active substances and their classification regarding maximum residue limits as laid down in Annexes I to IV to Regulation (EEC) No 2377/90.

equivalent to the status “generally recognised as safe”. In fact only a sub-group of Annex II substances do fall under this category. For further details on the assessment of a substance you are advised to consult the MRL Summary report of the substances concerned. Please also note that Annex II comprises a specific entry, which provides that certain substances approved in the EU as food additives with a valid E-number are considered included in Annex II without listing the substances specifically. Relevant substances falling under these provisions are e.g. vitamin C, citric acid or several sodium and potassium salts, and these substances are only mentioned in the enclosed list if an MRL application was submitted.

A safety and residue evaluation may also result in the recommendation to include a substance in Annex IV of Regulation 2377/90, which means that the substance is prohibited from use in veterinary medicinal products for food producing animals. Another conclusion may be that due to the deficiencies of the data provided, no recommendation for inclusion in any of the annexes could be made; the net result in the latter case is the same as an inclusion in Annex IV, as no medicinal product containing such a substance can be authorised for food producing animals in the EU.

During the period from 1992 to January 2005 over 700 “old” substances were reviewed and applications concerning 58 “new” substances and 87 extensions and modifications have been submitted to the CVMP; MRLs recommendations for inclusion in Annex, I, II or III were made for 645 substances in total. 115 substances were recommended for inclusion in Annex I of Regulation 2377/90, 513 in Annex II and 6 remain currently in Annex III. For 11 substances it was considered that their residues, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer, and they have been placed in Annex IV. For 40 substances, the CVMP was unable to make a recommendation for inclusion in any of the annexes and for further 57 substances the applicants withdrew their applications after the receipt of the list of questions.

Procedure for MRL opinions

Following the evaluation of an MRL application the CVMP issues an opinion which includes the recommendation regarding the establishment of MRLs for the substances considered and a Summary Opinion is published on the EMEA website (<http://www.emea.europa.eu/index/indexv1.htm>). On the basis of the scientific recommendation of the CVMP for inclusion of a substance in Annex I, II, III or IV of Regulation 2377/90, the Commission prepares a draft regulation amending the respective Annex(es) accordingly. Any such Regulation requires a favourable opinion by qualified majority of the EU Member States, before the European Commission can adopt it. Once adopted, the European Commission publishes the Regulation amending the annexes of Regulation 2377/90 in the Official Journal of the European Communities. Following this publication the EMEA publishes the CVMP Summary Reports on the EMEA website: <http://www.emea.europa.eu/index/indexv1.htm>. The European Commission services also provides access to all adopted Regulations amending the annexes of Regulation 2377/90 (<http://eur-lex.europa.eu/en/index.htm>) and a non-official consolidated list of the annexes of the Regulation listing all MRLs established, on the following web-site: <http://ec.europa.eu/enterprise/pharmaceuticals/mrl/index.htm>.

Substances with MRLs assessments in the EU

Attached is an alphabetical list of all substances included in Annex I, II, III or IV of Regulation 2377/90 with the indication of the respective annex and the number of the Regulation which established these MRLs. In addition, the list includes substances for which MRL recommendations have been made by the CVMP and are now undergoing the decision-making procedure by the European Commission. The list also includes the substances for which the CVMP concluded that due to insufficient data provided a recommendation for inclusion of the substance in Annex I, II, III of Regulation 2377/90 could not be made.

Any enquiries regarding this connection may be directed to the attention of Dr Kornelia Grein, Head of Sector (Safety of Veterinary Medicines) at the EMEA, 7 Westferry Circus, Canary Wharf, London E14 4HB, telephone +44 20 7 418 8432; e-mail: MRL@emea.europa.eu

MRL assessments in the EU in the context of Council Regulation (EEC) No. 2377/90

Substance	Status	Regulation amending Annex of Regulation 2377/90
Abamectin	Annex I	Reg. 3425/93; 2728/99; 869/2002
<i>Absinthium extract</i>	Annex II	Reg. 2796/95
Acacia gum (gum arabica)	Annex II (E-number 414)	Reg. 2034/96
Acetyl cysteine	Annex II	Reg. 1430/94
Acetylmethionine	Annex II	Reg. 2796/95
Acetylsalicylic acid	Annex II	Regs 750/2001; 1029/2003
Acetylsalicylic acid DL-lysine	Annex II	Regs 750/2001; 1029/2003
Adenosine	Annex II	Reg. 1931/99
Adipic acid	Annex II (E-number 355)	Reg. 2034/96
<i>Adonis vernalis</i>	Annex II	Reg. 998/99
<i>Aesculus hippocastanum</i>	Annex II	Reg. 2728/99
<i>Agnus castus</i>	Annex II	Reg. 2728/99
<i>Ailanthus altissima</i>	Annex II	Reg. 2728/99
Alanine	Annex II	Reg. 1931/99
Albendazole	Annex I	Regs 3093/92; 1798/96; 1191/98; 1646/2004
Albendazole oxide	Annex I	Regs 17/97; 613/98; 2393/99
Alfacalcidol	Annex II	Reg. 1917/98
Alfaprostol	Annex II	Regs 270/97 ; 2560/98
Alginic acid	Annex II (E-number 400)	Reg. 2034/96
Allantoin	Annex II	Reg. 868/2002
<i>Allium cepa</i>	Annex II	Reg. 2728/99
Aloe vera gel and whole leaf extract of Aloe vera	Annex II	Reg. 2758/99
<i>Aloes, Barbados and Capae</i>	Annex II	Reg. 1931/99
Alpha-cypermethrin	Annex I	Regs 954/99; 869/2002 ; 2011/03
Altrenogest	Annex I	Regs 2584/2001; 1530/2002; 3332/2004
Aluminium	Annex II (E-number 173)	Reg. 2034/96
Aluminium distearate	Annex II	Reg. 1916/98
Aluminium hydroxide	Annex II	Reg. 2796/95
Aluminium hydroxide acetate	Annex II	Reg. 1916/98
Aluminium monostearate	Annex II	Reg. 2796/95
Aluminium phosphate	Annex II	Reg. 1916/98
Aluminium potassium sulfate	Annex II (E-number 522)	Reg. 2034/96
Aluminium salicylate, basic	Annex II	Regs 1286/2000; 1937/2002
Aluminium silicate (kaolin)	Annex II (E-number 559)	Reg. 2034/96
Aluminium tristearate	Annex II	Reg. 1916/98
Aminoethanol [2-Aminoethanol]	Annex II	Reg. 1076/98
Aminoethanol glucuronate (2-Aminoethanol glucuronate)	Annex II	Reg. 2393/99
Aminoethyl dihydrogenphosphate [2-Aminoethyl dihydrogenphosphate]	Annex II	Reg. 1568/98
Amitraz	Annex I	Regs 3093/92; 1430/94; 1742/96; 1916/98; 1836/97; 2395/99; 1646/2004
Ammonium chloride	Annex II	Reg. 508/99
Ammonium hydroxide	Annex II (E-number 527)	Reg. 2034/96
Ammonium lauryl sulphate	Annex II	Reg. 2162/2001

Substance	Status	Regulation amending Annex of Regulation 2377/90
Ammonium sulfate	Annex II	Reg. 2796/95
Amoxicillin	Annex I	Reg. 675/92
Ampicillin	Annex I	Reg. 675/92
Amprolium	Annex II	Regs 1295/2000; 1478/2001
<i>Angelicae radix aetheroleum</i>	Annex II	Reg. 2560/98
<i>Anisi aetheroleum</i>	Annex II	Reg. 2560/98
<i>Anisi stellati fructus</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
<i>Apis mellifica</i>	No recommendation	
<i>Apocynum cannabinum</i>	Annex II	Reg. 1942/99
Apramycin (bovine)	Annex I	Regs 1838/97; 1931/99
Apramycin (ovine, porcine, chicken, rabbits)	Annex II	Regs 1838/97 ; 1931/99
<i>Aqua levis</i>	Annex II	Reg. 998/99
Arginine	Annex II	Reg. 1931/99
<i>Aristolochia</i> spp. And preparations thereof	Annex IV	Reg. 1568/98
<i>Arnicae montana</i>	Annex II	Reg. 2728/99
<i>Arnicae radix</i>	Annex II	Reg. 2728/99
<i>Artemisia abrotanum</i>	Annex II	Reg. 2728/99
Ascorbic acid	Annex II (E-number 300)	Reg. 2034/96
Asparagine	Annex II	Reg. 1931/99
Aspartic acid	Annex II	Reg. 1931/99
<i>Atropa belladonna</i>	Annex II	Reg. 889/99
Atropine	Annex II	Reg. 1943/99
Avilamycin	Annex I	Reg. 1064/2007
Azagly-nafarelin	Annex II	Reg. 1530/2002
Azamethiphos	Annex II	Regs 1140/96 ; 1836/97 ; 1931/99
Azaperone	Annex I	Regs 675/92; 1798/96;1858/98
Bacitracin (bovine meat)	Annex II	Reg. 2686/98
Bacitracin (bovine milk and rabbits)	Annex I	Regs 953/99; 1478/2001; 544/2003
<i>Balsamum peruvianum</i>	Annex II	Reg. 1916/98
Baquiloprim	Annex I	Regs 1433/96; 1838/97
Barium selenate	Annex II	Reg. 2757/99
Beclomethasone dipropionate	Annex II	Reg. 2232/04
<i>Bellis perennis</i>	Annex II	Reg. 2728/99
Bentonite	Annex II (E-number 558)	Reg. 2034/96
Benzalkonium chloride	Annex II	Reg. 1191/98
Benzetimide hydrochloride	No recommendation	
Benzocaine	Annex II	Reg. 1569/98; 868/2002
Benzoic acid	Annex II (E-number 210)	Reg. 2034/96
Benzyl alcohol	Annex II	Reg. 1442/95
Benzyl benzoate	Annex II	Reg. 2796/95
Benzylideneacetone	No recommendation	
Benzylpenicillin	Annex I	Reg. 675/92
Benzyl-p-hydroxybenzoate	Annex II	Reg. 2796/95
<i>Berberis vulgaris</i>	No recommendation	
Betaine	Annex II	Reg. 121/98
Betaine glucuronate	Annex II	Reg. 2393/99
Betamethasone	Annex I	Reg. 2593/99
Biotin	Annex II	Reg. 997/99

Substance	Status	Regulation amending Annex of Regulation 2377/90
Bismuth subcarbonate	Annex II	Reg. 1838/97
Bismuth subgallate	Annex II	Reg. 1838/97
Bismuth subnitrate	Annex II	Regs 1838/97; 1286/2000
Bismuth subsalicylate	Annex II	Reg. 1838/97
Bituminosulfonates, ammonium and sodium salts	Annex II	Regs 2393/99; 712/2005
<i>Boldo folium</i>	Annex II	Reg. 1931/99
Boric acid and borates	Annex II	Reg. 2034/96
Bovine somatotropins	Annex II proposal – Rejected by the Commission	
Bromhexine	Annex II	Reg. 997/99
Bromide, sodium salt	Annex II	Reg. 1837/97
Bronopol	Annex II	Regs 2686/98; 2162/2001
Brotizolam	Annex II	Reg. 1102/95
<i>Bryonia</i>	No recommendation	
Buserelin	Annex II	Reg. 282/96
Butafosfan	Annex II	Regs 2728/99; 2391/2000
Butane [n-Butane]	Annex II	Reg. 1147/96
Butanilcaine	No recommendation	
Butanol [n-Butanol]	Annex II	Reg. 1442/95
Butorphanol tartrate	Annex II	Reg. 1076/98
Butyl 4-hydroxybenzoate	Annex II	Reg. 1433/96
Butylated hydroxyanisole	Annex II (E-number 320)	Reg. 2034/96
Butylated hydroxytoluene	Annex II (E-number 321)	Reg. 2034/96
Butylscopolaminium bromide	Annex II	Reg. 1958/98
Caffeine	Annex II	Reg. 282/96
Calcium acetate	Annex II	Reg. 1102/95
Calcium alginate	Annex II (E-number 404)	Reg. 2034/96
Calcium aspartate	Annex II	Reg. 1286/2000
Calcium benzoate	Annex II	Reg. 1102/95
Calcium borogluconate	Annex II	Reg. 2796/95
Calcium carbonate	Annex II	Reg. 1102/95
Calcium chloride	Annex II	Reg. 1102/95
Calcium citrate	Annex II	Reg. 2796/95
Calcium glucoheptonate	Annex II	Reg. 2686/98
Calcium gluconate	Annex II	Reg. 1102/95
Calcium gluconoglucoheptonate	Annex II	Reg. 2686/98
Calcium gluconolactate	Annex II	Reg. 2686/98
Calcium glutamate	Annex II	Reg. 2686/98
Calcium glycerophosphate	Annex II	Reg. 2908/2000
Calcium hydroxide	Annex II	Reg. 1102/95
Calcium hypophosphite	Annex II	Reg. 1102/95
Calcium maleate	Annex II	Reg. 1102/95
Calcium oxide	Annex II	Reg. 1102/95
Calcium pantothenate	Annex II	Reg. 2162/2001
Calcium phosphate	Annex II	Reg. 1102/95
Calcium polyphosphates	Annex II	Reg. 1102/95
Calcium propionate	Annex II	Reg. 1102/95
Calcium silicate	Annex II	Reg. 1102/95
Calcium stearate	Annex II	Reg. 1102/95
Calcium sulphate	Annex II	Reg. 1102/95

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Calendula officinalis</i>	Annex II	Reg. 2728/99
<i>Calendulae flos</i>	Annex II	Reg. 2593/99
Camphor	Annex II	Reg. 2796/95
<i>Camphora</i>	Annex II	Reg. 2728/99
<i>Capsici fructus</i>	Annex II	Reg. 2385/99
Carazolol	Annex I	Regs 675/92; 1442/95; 953/99; 1960/2000
Carbasalate calcium	Annex II	Regs 750/2001; 1029/2003
Carbetocin	Annex II	Reg. 1433/96
Carboxymethylcellulose	Annex II (E-number 466)	Reg. 2034/96
Cardamom extract	Annex II	Reg. 2796/95
<i>Cardiospermum halicacabum</i>	Annex II	Reg. 2728/99
<i>Carlinae radix</i>	Annex II	Reg. 1931/99
Carnitine	Annex II	Reg. 1931/99
Carprofen	Annex I	Regs 1311/96; 613/98; 1931/99; 869/2005
Carprofen	Annex II	Reg. 869/2005
<i>Carvi aetheroleum</i>	Annex II	Reg. 2560/98
<i>Caryophylli aetheroleum</i>	Annex II	Reg. 2560/98
Cefacetrile (bovine meat)	Annex II	Reg. 804/99
Cefacetrile (bovine milk)	Annex I	Regs 804/99; 807/2001; 2126/2001
Cefalexin	Annex I	Reg. 2728/99
Cefalonium (bovine meat)	Annex II	Reg. 2728/99
Cefalonium (bovine milk)	Annex I	Reg. 1931/99; 1322/2001; 61/2003
Cefapirin	Annex I	Regs 270/97; 804/99; 1553/2001
Cefazolin (bovine, ovine and caprine meat)	Annex II	Regs 270/97 ; 121/98
Cefazolin (bovine, ovine and caprine milk)	Annex I	Regs 270/97; 121/98
Cefoperazone (bovine meat)	Annex II	Reg. 1943/99
Cefoperazone (bovine milk)	Annex I	Regs 1943/99; 807/2001
Cefquinome (bovine, porcine, Equidae)	Annex I	Regs 895/93; 282/96; 954/99; 1931/99; 2145/2003
Ceftiofur	Annex I	Regs 1837/97; 804/99, 1752/2002; 1231/2006
Cefuroxim	No recommendation	
<i>Centellae asiaticae extractum</i>	Annex II	Reg. 804/99
Cetostearyl alcohol	Annex II	Reg. 2686/98
Cetrimide	Annex II	Reg. 1742/96
<i>Chelidonii herba</i>	No recommendation	
<i>Chelidonium majus</i>	No recommendation	
Chloramphenicol	Annex IV	Regs 675/92; 1430/94
Chlorhexidine	Annex II	Reg. 17/97
Chlormadinone acetate	Annex I	Reg. 2584/2001
Chlorocresol	Annex II	Reg. 1742/96
Chloroform	Annex IV	Reg. 270/97
Chlorphenamine	Annex II	Reg. 2393/99
Chlorpromazine	Annex IV	Reg. 17/97
Chlortetracycline	Annex I	Regs. 3426/93; 281/96
Choline	Annex II	Reg. 1931/99
<i>Chrysanthemi cinerarifolii flos</i>	Annex II	Reg. 1568/98
Chymotrypsin	Annex II	Reg. 1931/99

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Cimicifugae racemosae rhizoma</i>	Annex II	Reg. 2593/99
<i>Cinchonae cortex</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
<i>Cinnamomi cassiae aetheroleum</i>	Annex II	Reg. 2560/98
<i>Cinnamomi cassiae cortex</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
<i>Cinnamomi ceylanici aetheroleum</i>	Annex II	Reg. 2560/98
<i>Cinnamomi ceylanici cortex</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
<i>Citri aetheroleum</i>	Annex II	Reg. 2560/98
Citric acid	Annex II (E-number 330)	Reg. 2034/96
<i>Citronellae aetheroleum</i>	Annex II	Reg. 2560/98
Citrulline	Annex II	Reg. 1931/99
Clavulanic acid	Annex I	Regs 749/97; 1943/99; 1553/2001
Clazuril	Annex II	Reg. 1916/98
Clenbuterol	Annex I	Regs 1312/96; 2391/2000
Cloprostenol	Annex II	Regs 1838/97; 2232/2004
Cloprostenol [R, RS-Cloprostenol]	Annex II	Regs 1838/97; 2232/2004
Clorsulon	Annex I	Regs 1147/96; 1942/99
Closantel	Annex I	Reg. 2901/93
Cloxacillin	Annex I	Reg. 675/92
Cobalt carbonate	Annex II	Reg. 1916/98
Cobalt dichloride	Annex II	Reg. 1916/98
Cobalt gluconate	Annex II	Reg. 1916/98
Cobalt oxide	Annex II	Reg. 1916/98
Cobalt sulphate	Annex II	Reg. 1916/98
Cobalt trioxide	Annex II	Reg. 1916/98
Coco alkyl dimethyl betaines	Annex II	Reg. 1916/98
Colchicine	Annex IV	Reg. 1311/96
Colistin	Annex I	Regs 282/96; 2338/2000; 1181/2002
<i>Collinsonia canadensis</i>	No recommendation	
<i>Condurango cortex</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
<i>Convallaria majalis</i>	Annex II	Reg. 998/99
Copper chloride	Annex II	Reg. 2560/98
Copper gluconate	Annex II	Reg. 2560/98
Copper heptanoate	Annex II	Reg. 2560/98
Copper methionate	Annex II	Reg. 2560/98
Copper oxide	Annex II	Reg. 2560/98
Copper sulphate	Annex II	Reg. 2560/98
<i>Coriandri aetheroleum</i>	Annex II	Reg. 2560/98
Corticotrophin	Annex II	Reg. 1191/98
Coumafos	Annex I	Regs 1931/99; 1478/2001
<i>Crataegus</i>	Annex II	Reg. 2728/99
<i>Cupressi aetheroleums</i>	Annex II	Reg. 1931/99
Cyfluthrin	Annex I	Reg. 1958/98; 807/2001; 542/2008
Cyhalothrin	Annex I	Reg. 807/2001
Cymiazole	Annex III (01.07.2001) – Expired	Regs 2017/96; 1931/99
Cypermethrin	Annex I	Regs 954/99 ; 77/2002; 869/2002; 1029/2003; 1490/03; 1646/2004

Substance	Status	Regulation amending Annex of Regulation 2377/90
Cyromazine	Annex I	Regs 2593/99; 1478/2001
Cysteine	Annex II	Reg. 1931/99
Cytidine	Annex II	Reg. 1931/99
Danofloxacin	Annex I	Regs 1442/95; 1837/97; 121/98; 1942/99; 953/99; 1942/99; 1181/2002
Dapsone	Annex IV	Regs 675/92; 3426/93
Decoquinate	Annex II	Regs 282/96; 2338/2000
Deltamethrin	Annex I	Regs 1942/99; 1960/2000; 1815/2001; 2162/2001; 1646/2004
Deltamethrin (chicken)	Annex III (01.07.2003) - Expired	Regs 1942/99; 1815/2001
Dembrexine	Annex II	Reg. 2010/96
Denaverine hydrochloride	Annex II	Reg. 1191/98
Deslorelin acetate	Annex II	Reg. 1530/2002
Detomidine	Annex II	Reg. 1102/95
Dexamethasone	Annex I	Regs 1441/95; 749/97; 1837/97; 1646/2004
Dexpanthenol	Annex II	Reg. 869/2002
Diazinon	Annex I	Reg. 1442/95
Diclazuril	Annex II	Regs 2010/96; 1101/2004
Diclofenac	Annex I	Regs. 324/2004; 582/2009
Dicloxacillin	Annex I	Reg. 675/92
Dicopper oxide	Annex II	Reg. 2560/98
Dicyclanil	Annex I	Regs 2393/99; 1960/2000; 2391/2000
Diethyl phthalate	Annex II	Reg. 1311/96
Diethyl sebacate	Annex II	Reg. 2796/95
Diethylene glycol monoethyl ether	Annex II	Regs. 2728/98; 205/2006
Difloxacin	Annex I	Regs 1311/96; 749/97; 997/99; 2908/2000; 1181/2002
Diflubenzuron	Annex I	Regs 997/99; 2593/99
Dihydrostreptomycin	Annex I	Regs 1140/96; 1960/2000; 1530/2002; 6/2006, 703/2007
Diiodo-L-tyrosine [3,5-Diiodo-L-tyrosine]	Annex II	Reg. 2757/99
Dimanganese trioxide	Annex II	Reg. 2692/98
Dimethicone	Annex II	Reg. 2796/95
Dimethyl acetamide	Annex II	Reg. 2796/95
Dimethyl phthalate	Annex II	Reg. 1311/96
Dimethyl sulfoxide	Annex II	Reg. 2796/95
Dimetridazole	Annex IV	Regs 675/92 ; 3426/93 ; 1798/95
Dinoprost	Annex II	Reg. 1569/98
Dinoprost tromethamine	Annex II	Reg. 1442/95
Dinoprostone	Annex II	Reg. 61/2008
Diphenhydramine (di)hydrochloride	No recommendation	
Diprophylline	Annex II	Reg. 1916/98
Dodecylgallate	Annex II (E-number 312)	Reg. 2034/96
Doramectin	Annex I	Regs 1430/94; 270/97; 1836/97; 2728/99; 1478/2001; 1831/2006
Doxapram	Annex II	Reg. 1931/99
Doxycycline	Annex I	Regs 17/97; 1000/98
D-Phe ⁶ -luteinizing hormone releasing	Annex II	Reg. 716/97

Substance	Status	Regulation amending Annex of Regulation 2377/90
hormone		
<i>Drosera</i>	No recommendation	
<i>Echinacea</i>	Annex II	Reg. 2728/99
<i>Echinacea purpurea</i>	Annex II	Reg. 1568/98
Emamectin	Annex I	Regs 1931/99; 1490/2003
Enilconazole	Annex II	Reg. 804/99
Enrofloxacin	Annex I	Regs 2901/93; 2728/98; 2593/99; 1181/2002
Ephedrine (hydrochloride)	No recommendation	
Epinephrine	Annex II	Reg. 2796/95
Eprinomectin	Annex I	Regs 17/97; 1934/99
Ergometrine maleate	Annex II	Reg. 2593/99
Erythromycin	Annex I	Regs 1442/95, 2338/2000; 1181/2002
Etamiphylline camsylate	Annex II	Reg. 2010/96
Etamsylate	Annex II	Reg. 804/99
Ethanol	Annex II	Reg. 1442/95
Ethyl lactate	Annex II	Reg. 1311/96
Ethyl oleate	Annex II	Reg. 2796/95
Ethyl-1, 3-hexanediol [2-Ethyl-1, 3-hexanediol]	No recommendation	
Ethylenediaminetetraacetic acid and salts (EDTA)	Annex II	Reg. 2796/95
Ethyl-p-hydroxybenzoate	Annex II (E-number 214)	Reg. 2034/96
Etilefrine hydrochloride	Annex II proposal – Rejected by the Commission	
Etiproston tromethamine	Annex II	Reg. 2901/93
<i>Eucalypti aetheroleum</i>	Annex II	Reg. 2728/98
Eucalyptol	Annex II	Reg. 2796/95
<i>Eucalyptus globulus</i>	Annex II	Reg. 2728/99
<i>Euphrasia officinalis</i>	Annex II	Reg. 2728/99
Fatty acids	Annex II (E-number 570)	Reg. 2034/96
Febantel	Annex I	Regs. 675/92; 1441/95; 1837/97; 1646/2004
Fenbendazole	Annex I	Regs 675/92; 1441/95; 1837/97; 1646/2004
Fenpipramide hydrochloride	Annex II	Reg 1942/99
Fenvalerate	Annex I	Regs 1937/2002; 1875/2004 ; 1805/2006
Fertirelin acetate	Annex II	Reg. 3425/93
Firocoxib	Annex I	Regs 1729/2006; 1323/2007
Florfenicol	Annex I	Regs 2703/94; 613/98; 1942/99; 2385/99; 1322/2001; 1181/2002
Fluazuron	Annex I I	Regs 1518/2005; 1451/2006
Flubendazole	Annex I	Regs 895/93; 1798/96; 1000/98; 2385/99; 1055/2006
Flugestone acetate	Annex I	Regs 2584/2001; 665/2003; 739/2003; 1911/2005
Flumequine	Annex I	Regs. 17/97; 2728/99; 2338/2000; 1181/2002;
Flumethrin (bovine, ovine)	Annex I	Regs 2686/98; 2391/2000
Flumethrin (honey)	Annex II	Reg. 2686/98
Flunixin	Annex I	Reg. 2728/99; 2908/2000

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Foeniculi aetheroleum</i>	Annex II	Reg. 2560/98
Folic acid	Annex II	Reg. 121/98
Follicle Stimulating Hormone (natural FSH from all species and their synthetic analogues)	Annex II	Reg. 2796/95
Formaldehyde	Annex II	Reg. 2796/95
Formic acid	Annex II	Reg. 2796/95
<i>Frangulae cortex</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
Fumagillin	No recommendation	
Furazolidone	Annex IV	Regs 2901/93; 1442/95
Furosemide	Annex II	Reg. 2728/99
Gamithromycin	Annex I	Regs. 203/2008; 581/2009
Gentamicin	Annex I	Regs 1140/96; 1960/2000; 868/2002
<i>Gentianae radix</i> , standardised extracts and preparations thereof	Annex II	Reg. 2338/2000
<i>Ginkgo biloba</i>	Annex II	Reg. 2728/99
<i>Ginseng</i>	Annex II	Reg. 2728/99; 287/2007
Glutamic acid	Annex II	Reg. 1931/99
Glutamine	Annex II	Reg. 1931/99
Glutaraldehyde	Annex II	Reg. 2796/95
Glycerol	Annex II (E-number 422)	Reg. 2034/96
Glycerol formal	Annex II	Reg. 17/97
Glycine	Annex II	Reg. 1931/99
Gonadotrophin releasing hormone	Annex II	Reg. 2703/94
Guaiacol	Annex II	Reg. 2796/95
Guanosine	Annex II	Reg. 1931/99
Halofuginone	Annex I	Regs 997/99; 2908/2000
<i>Hamamelis virginiana</i>	Annex II	Regs 1568/98; 2728/99
<i>Harpagophytum procumbens</i>	Annex II	Reg. 2728/99
<i>Harunga madagascariensis</i> (1:100)	Annex II	Reg. 1942/99
Heparin and salts	Annex II	Reg. 2796/95
Heptaminol	Annex II	Reg. 1311/96
Hesperidin	Annex II	Reg. 17/97
Hesperidin methyl chalcone	Annex II	Reg. 17/97
Hexetidin	Annex II	Reg. 1916/9
<i>Hippocastini semen</i>	Annex II	Reg. 2385/99
Histidine	Annex II	Reg. 1931/99
Human Chorionic Gonadotrophin (natural HCG and its synthetic analogues)	Annex II	Regs 1102/95 ; 2796/95
Human menopausal urinary gonadotrophin	Annex II	Reg. 3425/93
Humic acid and its sodium salt	Annex II	Reg. 2393/99
Hyaluronic acid	Annex II	Reg. 1931/99
Hydrochloric acid	Annex II	Reg. 1442/95
Hydrochlorothiazide	Annex II	Reg. 1942/99
Hydrocortisone	Annex II	Reg. 1917/98
Hydrogen peroxide	Annex II	Regs 895/93 ; 1433/96
Hydroxyethylsalicylate	Annex II	Reg. 1752/2002
Hydroxyquinoline [8-Hydroxyquinoline]	Annex II	Reg. 2728/98

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Hyperici oleum</i>	Annex II	Reg. 2728/98
<i>Hypericum perforatum</i>	Annex II	Reg. 2728/99
Imidocarb	Annex I	Regs 953/99; 2162/2001; 2145/2003
Inosine	Annex II	Reg. 1931/99
Inositol	Annex II	Reg. 1931/99
Iodine and iodine inorganic compounds including: – Sodium and potassium – iodide – Sodium and potassium – iodate – Iodophors	Annex II	Reg. 955/94
Iodine organic compounds – Iodoform – Polyvinylpyrrolidine – iodine	Annex II	Reg. 955/94
Iron ammonium citrate	Annex II	Reg. 2796/95
Iron dextran	Annex II	Reg. 2796/95
Iron dichloride	Annex II	Reg. 1916/98
Iron fumarate	Annex II	Reg 485/2009
Iron glucoheptonate	Annex II	Reg. 2796/95
Iron gluconate	Annex II (E-number 579)	Reg. 2034/96
Iron sulphate	Annex II	Reg. 1916/98
Isobutane	Annex II	Reg. 1147/96
Isoflupredone	No recommendation	
Isoflurane	Annex II	Reg. 426/98
Isoleucine	Annex II	Reg. 1931/99
Isopropanol	Annex II	Reg. 2796/95
Isoxsuprine	Annex II	Reg. 748/97
Ivermectin	Annex I	Regs 675/92; 2901/93; 716/97; 2728/98; 869/2005
<i>Jecoris oleum</i>	Annex II	Reg. 2593/99
Josamycin	No recommendation for final MRLs	Regs 282/96; 953/99; 2338/2000
<i>Juniperi fructus</i>	Annex II	Reg. 2385/99
Kanamycin	Annex I	Regs 1931/99; 2162/2001; 324/2004
Ketamine	Annex II	Reg. 1191/98
Ketanserin tartrate	Annex II	Reg. 3425/93
Ketoprofen	Annex II	Regs 282/96 ; 1742/96
<i>Lachnanthes tinctoria</i>	Annex II	Reg. 2728/99
Lactic acid	Annex II	Reg. 995/94
Lanolin	Annex II	Reg. 2796/95
Lasalocid sodium	Annex I	Regs 712/2005; 1055/2006; 1353/2007
<i>Lauri folium aetheroleum</i>	Annex II	Reg. 2385/99
<i>Lauri fructus</i>	Annex II	Reg. 2385/99
<i>Lavandola aetheroleum</i>	Annex II	Reg. 1931/99
Lecirelin	Annex II	Reg. 1442/95
Lectin (extracted from red kidney beans)	Annex II	Reg. 542/2008
<i>Lespedeza capita</i>	Annex II	Reg. 2686/98
Leucine	Annex II	Reg. 1931/99
Levamisole	Annex I	Regs 675/92; 3059/94
Levomethadon	Annex II	Reg. 1942/99
Levothyroxine	Annex II	Reg. 2757/99

Substance	Status	Regulation amending Annex of Regulation 2377/90
Lidocaine hydrochloride	Annex II	Reg. 2728/99
Lincomycin	Annex I	Regs 804/99; 807/2001; 1181/2002
Linear alkyl benzene sulphonic acids	Annex II	Reg. 807/2001; 75/2005
<i>Lini oleum</i>	Annex II	Reg. 121/98
<i>Lobaria pulmonaria</i>	Annex II	Reg. 2728/99
Lobeline	Annex II	Reg. 1742/96
<i>Lophophytum leandri</i>	No recommendation	
Luprostiol	Annex II	Reg. 1838/97
Luteinizing Hormone (natural LH from all species and their synthetic analogues)	Annex II	Reg. 2796/95
Lysine	Annex II	Reg. 1931/99
Magnesium	Annex II	Reg. 1147/96
Magnesium acetate	Annex II	Reg. 1147/96
Magnesium aluminium silicate	Annex II	Reg. 1147/96
Magnesium asparate	Annex II	Reg. 1147/96
Magnesium carbonate	Annex II	Reg. 1147/96
Magnesium chloride	Annex II	Reg. 2796/95
Magnesium citrate	Annex II	Reg. 1147/96
Magnesium gluconate	Annex II	Reg. 2796/95
Magnesium glutamate	Annex II	Reg. 1147/96
Magnesium glycerophosphate	Annex II	Reg. 1147/96
Magnesium hydroxide	Annex II	Reg. 1147/96
Magnesium hypophosphite	Annex II	Reg. 2796/95
Magnesium orotate	Annex II	Reg. 1147/96
Magnesium oxide	Annex II	Reg. 1147/96
Magnesium phosphate	Annex II	Reg. 1147/96
Magnesium stearate	Annex II	Reg. 1147/96
Magnesium sulphate	Annex II	Reg. 1147/96
Magnesium trisilicate	Annex II	Reg. 1147/96
<i>Majorana herba</i>	Annex II	Reg. 2686/98
Malic acid	Annex II	Reg. 1442/95
Manganese carbonate	Annex II	Reg. 2692/98
Manganese chloride	Annex II	Reg. 2692/98
Manganese gluconate	Annex II	Reg. 2692/98
Manganese glycerophosphate	Annex II	Reg. 2692/98
Manganese oxide	Annex II	Reg. 2692/98
Manganese pidolate	Annex II	Reg. 2692/98
Manganese ribonucleate	Annex II	Reg. 2692/98
Manganese sulphate	Annex II	Reg. 2692/98
Mannitol	Annex II	Reg. 2796/95
Marbofloxacin	Annex I	Regs 2017/96; 1568/98; 2338/2000
<i>Matricaria recutita</i>	Annex II	Reg. 1286/2000
<i>Matricariae flos [Chamomilla]</i>	Annex II	Reg. 1958/98
Mebendazole	Annex I	Regs 2728/99; 1680/2001
Mecillinam	Annex II	Reg. 2728/98
Meclofenamic acid	No recommendation	
<i>Medicago sativa</i>	Annex II	Reg. 2686/98
Medroxyprogesterone acetate	Annex II	Reg. 270/97
Melatonin	Annex II	Reg. 955/94
<i>Melissae aetheroleum</i>	Annex II	Reg. 804/99

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Melissae folium</i>	Annex II	Reg. 1958/98
Meloxicam	Annex I	Regs 1569/98; 2393/99; 1274/2001; 1530/2002; 1805/2006
Menadione [Vitamin K3]	Annex II	Reg. 2686/98
Menbutone	Annex II	Reg. 17/97
<i>Menthae arventis aetheroleum</i>	Annex II	Reg. 2162/2001
<i>Menthae piperitae aetheroleum</i>	Annex II	Reg. 2560/98
Menthol	Annex II	Reg. 1311/96
Mepivacaine	Annex II	Reg. 2593/99
Mercaptamine hydrochloride	Annex II	Reg. 997/99
Metamizole	Annex I	Reg. 2728/99; 1322/2001; 2011/2003
Metesculetol sodium	No recommendation	
Methionine	Annex II	Reg. 1931/99
Methyl nicotinate	Annex II	Reg. 2728/98
Methyl salicylate	Annex II	Reg. 1286/2000
Methylbenzoate	Annex II	Reg. 2796/95
Methyl-p-hydroxybenzoate	Annex II (E-number 218)	Reg. 2034/96
Methylprednisolone	Annex I	Regs 1286/2000; 77/2002
Methyl-pyrrolidone [1-Methyl-pyrrolidone]	Annex II	Reg. 804/99
Metrifonate	No recommendation	
Metronidazol	Annex IV	Reg. 613/98
<i>Millefolii herba</i>	Annex II	Reg. 1958/98
Mineral hydrocarbons, low to high viscosity including microcrystalline waxes, approximately C10-C60; aliphatic, branched aliphatic and salicyclic compounds	Annex II	Reg. 2804/95
Monensin	Annex I	Reg 1353/2007
Monepantel	Annex I and Annex III	Reg 478/2009
Monothioglycerol	Annex II	Reg. 2796/95
Montanide	Annex II	Reg. 2796/95
Morantel	Annex I -	Reg. 997/99; 1322/2001; 1851/2004; 1356/2005
Moxidectin	Annex I	Regs 2703/94; 748/97; 613/98; 1942/99; 1553/2001; 75/2005
Myglyol	Annex II	Reg. 2796/95
<i>Myristicae aetheroleum</i>	Annex II	Reg. 2560/98
Nafcillin	Annex I	Regs 1850/97; 804/99; 807/2001; 546/2004
Natamycin	Annex II	Reg. 1568/98
Neomycin (including framycetin)	Annex I	Regs 1140/96; 1960/2000; 1181/2002
Neostigmine	Annex II	Reg. 716/97
Netobimin	Annex I	Regs 1102/95; 1837/97; 807/2001
<i>Niauli aetheroleum</i>	No recommendation	
Nickel gluconate	Annex II	Reg. 2686/98
Nickel sulphate	Annex II	Reg. 2686/98
Nicoboxil	Annex II	Reg. 2728/98
Nitrofurans (except furazolidone)	Annex IV	Reg. 2901/93
Nitroxynil	Annex I	Reg. 997/99
Nonivamide	Annex II	Reg. 2728/98

Substance	Status	Regulation amending Annex of Regulation 2377/90
Norgestomet	Annex I	Regs 665/2003; 1299/2005
Novobiocin (bovine meat)	Annex II	Reg. 2593/99
Novobiocin (bovine milk)	Annex I	Reg. 2593/99
<i>Oenanthe aquatica</i>	No recommendation	
Oestradiol-17 β	Annex II	Reg. 3059/94
<i>Okoubaka aubrevillei</i>	Annex II	Reg. 2728/99
Oleyloleat	Annex II	Reg. 2686/98
Omeprazole	Annex II	Reg. 1937/2002
<i>Opium tincture</i>	No recommendation	
Orgotein	Annex II	Reg. 2796/95
Ornithine	Annex II	Reg. 1931/99
Orotic acid	Annex II	Reg. 1931/99
Oxacillin	Annex I	Reg. 675/92
Oxalic acid	Annex II	Reg. 546/2004
Oxfendazole	Annex I	Regs 675/92; 1441/95; 1837/97; 1646/2004
Oxibendazole	Annex I	Regs 895/93; 1798/96; 1000/98
Oxidation products of <i>terebinthinae oleum</i>	Annex II	Reg. 1916/98
Oxolinic acid	Annex I	Regs 804/99; 807/2001; 739/2003; 546/2004; 1356/2005
Oxyclozanide	Annex I	Regs 997/99; 2338/2000; 1181/2002; 1646/2004
Oxytetracycline	Annex I	Regs 3426/93; 281/96
Oxytocin	Annex II	Reg. 1441/95
Pancreatin	Annex II	Reg. 1742/96
Papain	Annex II	Reg. 1147/96
Papaverine	Annex II	Reg. 1147/96
Paracetamol	Annex II	Reg. 2393/99
Parconazole	Annex II	Reg. 953/99
Paromomycin (Aminosidine)	Annex I	Regs 2017/96; 2338/2000; 1181/2002
Patent Blue V	Annex II (E-number 131)	Reg. 2034/96
Pectin	Annex II (E-number 440)	Reg. 2034/96
Peforelin	Annex II	Reg. 1451/2006
Penethamate	Annex I	Regs 1311/96; 2034/96; 121/98; 2757/99; 1148/2005
Pentoxyverine	No recommendation	
Pepsin	Annex II	Reg. 1931/99
Peracetic acid	Annex II	Reg. 1433/96
Permethrin	Annex I	Reg. 1295/2000; 807/2001; 61/2003
Phenazone	No recommendation	
Phenol	Annex II	Reg. 1147/96
Phenoxymethyl penicillin	Annex I	Regs 1286/2000; 1299/2005
Phenylalanine	Annex II	Reg. 1931/99
Phenylbutazone	No recommendation	
Phloroglucinol	Annex II	Reg. 1311/96
Phosmet	No recommendation	
Phosphoric acid	Annex II (E-number 338)	Reg. 2034/96

Substance	Status	Regulation amending Annex of Regulation 2377/90
Phoxim	Annex I	Regs 2385/99; 2391/2000; 807/2001; 1299/2005
<i>Phytolacca americana</i>	Annex II	Reg. 2757/99
Phytomenadione [Vitamin K1]	Annex II	Reg. 2686/98
<i>Piceae turiones recentes extractum</i>	Annex II	Reg. 6/2006
Piperazine (porcine, chicken eggs)	Annex I	Regs 2593/99; 1478/2001; 868/2002
Piperazine dihydrochloride (chicken meat)	Annex II	Reg. 2593/99
Piperonyl butoxide	Annex II	Reg. 1931/99
Pirlimycin	Annex I	Regs 953/99; 2338/2000
Polaxalene	Annex II	Reg. 2796/95
Policresulene	Annex II	Reg. 1147/96
Poloxamer	Annex II	Reg. 2796/95
Polyethylene glycol stearates with 8-40 oxyethylene units	Annex II	Reg. 1916/98
Polyethylene glycol-15-hydroxystearate	Annex II	Reg. 1916/98
Polyethylene glycol-7-glycerol-cocoate	Annex II	Reg. 1916/98
Polyethylene glycols (molecular weight ranging from 200 to 10.000)	Annex II	Reg. 1147/96
Polymixin B sulphate	No recommendation	
Polyoxyethylene sorbitan monolaurate (polysorbate 20)	Annex II (E-number 432)	Reg. 2034/96
Polyoxyethylene sorbitan monooleate	Annex II (E-number 433)	Regs. 2034/96; 205/2006
Polyoxyethylene sorbitan trioleate	Annex II	Reg. 1231/2006
Polyoxyethylene sorbitan monopalmitate (polysorbate 40)	Annex II (E-number 434)	Reg. 2034/96
Polyoxyethylene sorbitan monostearate (polysorbate 60)	Annex II (E-number 435)	Reg. 2034/96
Polyoxyethylene sorbitan tristearate (polysorbate 65)	Annex II (E-number 436)	Reg. 2034/96
Polyoxyl castor oil with 30 to 40 oxyethylene units	Annex II	Reg. 2593/99
Polyoxyl hydrogenated castor oil with 40 to 60 oxyethylene units (Fatty acid polyethylene glycol ester)	Annex II	Reg. 2593/99
Polysulphated glycosaminoglycan	Annex II	Reg. 2034/96
Polyvinylpyrrolidone	Annex II (E-number 1201)	Reg. 2034/96
<i>Populeum ointment</i>	No recommendation	
Potassium acetate	Annex II (E-number 261)	Reg. 2034/96
Potassium alginate	Annex II (E-number 402)	Reg. 2034/96
Potassium bromide	Annex II	Reg. 1931/99
Potassium carbonates	Annex II (E-number 500)	Reg. 2034/96
Potassium chloride	Annex II (E-number 508)	Reg. 2034/96
Potassium citrates	Annex II (E-number 332)	Reg. 2034/96
Potassium DL-aspartate	Annex II	Reg. 613/98
Potassium glucuronate	Annex II	Reg. 613/98
Potassium glycerophosphate	Annex II	Reg. 613/98
Potassium metabisulphite	Annex II (E-number 224)	Reg. 2034/96
Potassium nitrate	Annex II	Reg. 613/98
Potassium phosphates	Annex II (E-number 340)	Reg. 2034/96
Potassium selenate	Annex II	Reg. 1000/98
Praziquantel	Annex II	Regs 748/97; 1076/98; 997/99

Substance	Status	Regulation amending Annex of Regulation 2377/90
Prednisolone	Annex I	Reg. 2535/2000
Pregnant Mare Serum Gonadotrophin	Annex II	Reg. 3059/94
Prethcamide	Annex II	Reg. 1916/98
Procaine	Annex II	Reg. 1076/98
Progesterone	Annex II	Reg. 1837/2003
Proline	Annex II	Reg. 1931/99
Propane	Annex II	Reg. 1147/96
Propetamphos	Annex III (01.01.2001) – Expired	Reg. 2728/99
Propylene glycol	Annex II	Reg. 270/97
Propyleneglycol alginate (Propane-1,2-diol alginate)	Annex II (E-number 405)	Reg. 2034/96
Propyl-p-hydroxybenzoate	Annex II (E-number 216)	Reg. 2034/96
<i>Prunus laurocerasus</i>	Annex II	Reg. 2728/99
<i>Pulsatilla pratensis</i>	No recommendation	
Pyrantel embonate	Annex II	Reg. 997/99
<i>Pyrethrum extract</i>	Annex II	Reg. 1568/98
Pyrrolidone [2-Pyrrolidone]	Annex II	Reg. 2686/98
Quatresin	Annex II	Reg. 17/97
<i>Quercus cortex</i>	Annex II	Reg. 1958/98
Quillaia saponins	Annex II	Reg. 1433/96
Rafoxanide	Annex I	Regs 2728/99; 1478/2001
Ramifenazone	No recommendation	
<i>Rhamni purshiani cortex</i>	No recommendation	
<i>Rhei radix</i>	Annex II	Reg. 1286/2000
<i>Ricini oleum</i>	Annex II	Reg. 1916/98
Rifaximin (bovine milk)	Annex I	Regs 2034/96; 1191/98
Rifaximin (meat)	Annex II	Regs 2034/96; 2560/98
Romifidine	Annex II	Reg. 1102/95
Ronidazole	Annex IV	Regs 675/92; 3426/93
<i>Rosmarini aetheroleum</i>	Annex II	Reg. 2560/98
<i>Rosmarini folium</i>	Annex II	Reg. 1958/98
Roxarsone	No recommendation	
<i>Ruscus aculeatus</i>	Annex II	Reg. 2385/99
<i>Ruta graveolens</i>	Annex II	Reg. 2385/99
Salicylic acid	Annex II	Reg. 1286/2000
<i>Salviae folium</i>	Annex II	Reg. 1958/98
<i>Sambuci flos</i>	Annex II	Reg. 1958/98
Sarafloxacin	Annex I	Regs 1441/95; 1850/97; 1568/98
<i>Secalis cornuti extractum</i>	No recommendation	
<i>Selenicerus grandiflorus</i>	Annex II	Reg. 1942/99
<i>Serenoa repens</i>	Annex II	Reg. 2728/99
Serine	Annex II	Reg. 1931/99
Serotonin	Annex II	Reg. 2796/95
Silicon dioxide	Annex II (E-number 551)	Reg. 2034/96
<i>Silybum marianum</i>	Annex II	Reg. 2728/99
<i>Sinapis semen</i>	Annex II	Reg. 2686/98
Sodium 2-methyl-2-phenoxypropanoate	Annex II	Reg. 2728/98
Sodium acetate	Annex II (E-number 262)	Reg. 2034/96
Sodium acetylsalicylate	Annex II	Regs 750/2001; 1029/2003
Sodium alginate	Annex II (E-number 401)	Reg. 2034/96

Substance	Status	Regulation amending Annex of Regulation 2377/90
Sodium benzyl 4-hydroxybenzoate	Annex II	Reg. 1433/96
Sodium bicarbonate	Annex II (E-number 500)	Reg. 2034/96
Sodium boroformiate	Annex II	Reg. 2338/2000
Sodium butyl 4-hydroxybenzoate	Annex II	Reg. 1433/96
Sodium cetostearyl sulphate	Annex II	Reg. 2686/98
Sodium chloride	Annex II	Reg. 2796/95
Sodium chlorite	Annex II	Reg. 955/94
Sodium chromoglycate	Annex II	Reg. 2796/95
Sodium citrates	Annex II (E-number 331)	Reg. 2034/96
Sodium cyclamate	Annex II (E-number 952)	Reg. 2034/96
Sodium dichloroisocyanurate	Annex II	Reg. 1442/95
Sodium dioctylsulfosuccinate	Annex II	Reg. 2796/95
Sodium ethyl-p-hydroxybenzoate	Annex II (E-number 215)	Reg. 2034/96
Sodium formaldehydesulphoxylate	Annex II	Reg. 2796/95
Sodium gluconate	Annex II (E-number 576)	Reg. 2034/96
Sodium glycerophosphate	Annex II	Reg. 997/99
Sodium hypophosphite	Annex II	Reg. 2686/98
Sodium lactate	Annex II (E-number 325)	Reg. 2034/96
Sodium laurylsulphate	Annex II	Reg. 2796/95
Sodium methyl-p-hydroxybenzoate	Annex II (E-number 219)	Reg. 2034/96
Sodium nitrite	Annex II	Reg. 1451/2006
Sodium phosphates	Annex II (E-number 339)	Reg. 2034/96
Sodium propionate	Annex II	Reg. 2338/2000
Sodium propyl-p-hydroxybenzoate	Annex II (E-number 217)	Reg. 2034/96
Sodium pyrosulphite	Annex II	Reg. 2796/95
Sodium salicylate	Annex II	Regs 1286/2000; 1875/2004
Sodium selenate	Annex II	Reg. 1000/98
Sodium selenite	Annex II	Reg. 1000/98
Sodium stearate	Annex II	Reg. 2796/95
Sodium thiosulphate	Annex II	Reg. 2796/95
<i>Solidago virgaurea</i>	Annex II	Reg. 2728/99
Somatosalm	Annex II	Reg. 211/97
Sorbic acid	Annex II (E-number 200)	Reg. 2034/96
Sorbitan monolaurate	Annex II (E-number 493)	Reg. 2034/96
Sorbitan monooleate	Annex II (E-number 494)	Reg. 2034/96
Sorbitan monopalmitate	Annex II (E-number 495)	Reg. 2034/96
Sorbitan monostearate	Annex II (E-number 491)	Reg. 2034/96
Sorbitan sesquioleate	Annex II	Reg. 2232/2004
Sorbitan tristearate	Annex II (E-number 492)	Reg. 2034/96
Spectinomycin (bovine, porcine, chicken)	Annex I	Regs 3059/94; 1568/98; 2728/99; 1960/2000; 869/2002; 1181/2002
Spiramycin	Annex I	Regs 675/92; 1442/95
Streptomycin	Annex I	Regs 1140/96; 1530/2002, 703/2007
<i>Strychni semen</i> [Nux vomica]	Annex II	Regs 2385/99; 1960/2000
Strychnine	Annex II	Reg. 804/99
Sulfoguaiacol	Annex II	Reg. 1931/99
Sulfonamide group	Annex I	Regs 675/92; 3426/93; 281/96
Sulphur	Annex II	Regs 895/93; 544/2003
Suxibuzone	No recommendation	
<i>Symphyti radix</i>	Annex II	Reg. 1931/99

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Syzygium cumini</i>	Annex II	Reg. 2728/99
Tanninum	Annex II	Reg. 1568/98
Tartaric acid [L-tartaric acid] and mono- and di-basic salt of sodium, potassium and calcium	Annex II	Reg. 1442/95
Tau-fluvalinate	Annex II	Reg. 2034/96
Teflubenzuron	Annex I	Regs 426/98; 1931/99
<i>Terebinthinae aetheroleum rectificatum</i>	Annex II	Reg. 1916/98
<i>Terebinthinae laricina</i>	Annex II	Reg. 1916/98
Terpin hydrate	Annex II	Reg. 1916/98
Tetracaine	Annex II	Reg. 1569/98
Tetracycline	Annex I	Regs . 3426/93; 281/96
Theobromine	Annex II	Reg. 282/96
Theophylline	Annex II	Reg. 282/96
Thiabendazole	Annex I	Regs 3093/92; 1311/96; 1000/98; 1646/2004
Thiamphenicol	Annex I	Regs 895/93; 1798/96; 1000/98; 804/99; 1299/2005; 1805/2006
Thiamylal	Annex II	Reg. 749/2001
Thiomersal	Annex II	Reg. 749/97
Thiopental sodium	Annex II	Reg. 749/2001
Thiotic acid	Annex II	Reg. 1931/99
Threonine	Annex II	Reg. 1931/99
<i>Thuja occidentalis</i>	Annex II	Reg. 1942/99
<i>Thymi aetheroleum</i>	Annex II	Reg. 2560/98
Thymidine	Annex II	Reg. 1931/99
Thymol	Annex II	Reg. 1742/96
Tiamulin	Annex I	Regs 2728/99; 2338/2000; 807/2001
Tiaprost	Annex II	Reg. 998/99
<i>Tiliae flos</i>	Annex II	Reg. 1958/98
Tilmicosin	Annex I	Regs 955/94; 1102/95; 1917/98; 2338/2000; 2391/2000; 1274/2001; 1181/2002
Tiludronic acid, disodium salt	Annex II	Regs. 1478/2001; 485/2009
Timerfonate	Annex II	Reg. 749/97
Toldimphos	Annex II	Reg. 1295/2000
Tolfenamic acid	Annex I	Reg. 1838/97
Toltrazuril	Annex I	Regs 1916/98; 2593/99; 2908/2000; 2232/2004; 205/2006
Tosylchloramide sodium	Annex II	Regs 2393/99; 1680/2001 ; 6/2006
Tragacanth	Annex II	Reg. 2796/95
Tricaine methane sulphonate	Annex II	Reg. 1942/99
Trichlormethiazide	Annex II	Regs 1942/99; 61/2003
Triclabendazole	Annex I	Regs 895/93; 1441/95; 426/98, 1729/06
Trimethoprim	Annex I	Regs 675/92; 281/96; 121/98; 1181/2002
Trimethylphloroglucinol	Annex II	Reg. 1311/96
Trypsin	Annex II	Reg. 1931/99
Tryptophan	Annex II	Reg. 1931/99
Tulathromycin	Annex I	Regs 1937/2002; 1101/2004

Substance	Status	Regulation amending Annex of Regulation 2377/90
<i>Turnera diffusa</i>	Annex II	Reg. 2728/99
Tylosin	Annex I	Regs 3093/92; 1442/95; 1838/97; 1960/2000; 1181/2002
Tylvalosin (formerly acetylisovaleryltylosin)	Annex I	Regs 1286/2000 ; 77/2002; 75/2005; 1518/2005; 1353/2007
Tyrosin	Annex II	Reg. 1931/99
Urea	Annex II	Reg. 2796/95
<i>Urginea maritima</i>	Annex II	Reg. 2757/99
Uridine	Annex II	Reg. 1931/99
<i>Urticae herba</i>	Annex II	Reg. 1958/98
Valine	Annex II	Reg. 1931/99
Valnemulin	Annex I	Reg. 2560/98
Vedaprofen	Annex I	Regs 1147/96; 749/97
Vegetable carbon	Annex II (E-number 153)	Reg. 2034/96
Vetrabutine hydrochloride	Annex II	Reg. 1931/99
<i>Viburnum opulus</i>	No recommendation	
<i>Viburnum prunifolium</i>	No recommendation	
Vincamine	Annex II	Reg. 1942/99
<i>Virola sebifera</i> (1:100)	Annex II	Reg. 1942/99
<i>Viscum album</i>	Annex II	Reg. 2728/99
Vitamin A	Annex II	Reg. 1879/2001
Vitamin B1	Annex II	Reg. 997/99
Vitamin B12	Annex II	Reg. 997/99
Vitamin B2	Annex II	Reg. 997/99
Vitamin B3	Annex II	Reg. 997/99
Vitamin B5	Annex II	Reg. 997/99
Vitamin B6	Annex II	Reg. 997/99
Vitamin D	Annex II	Reg. 1917/98
Vitamin E	Annex II	Reg. 997/99
Wool alcohols	Annex II	Reg. 2686/98
Xylazine hydrochloride	Annex II	Regs 2593/99; 1752/2002
Zinc acetate	Annex II	Reg. 17/97
Zinc aspartate	Annex II	Reg. 1286/2000
Zinc chloride	Annex II	Reg. 17/97
Zinc gluconate	Annex II	Reg. 17/97
Zinc oleate	Annex II	Reg. 17/97
Zinc oxide	Annex II	Reg. 2796/95
Zinc stearate	Annex II	Reg. 17/97
Zinc sulphate	Annex II	Reg. 2796/95