

Borderline Working Group

Regulatory Framework and Jurisprudence (case-law)

Version 3 dd 15 June 2017

LEGISLATION

Biocides

General information:

https://ec.europa.eu/health/biocides/biocidal_products_en

<https://echa.europa.eu/regulations/biocidal-products-regulation>

Regulation 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2012:167:SOM:EN:HTML>

Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, as amended

Consolidated version: [http://www.fsai.ie/uploadedFiles/Consol_Reg853_2004\(1\).pdf](http://www.fsai.ie/uploadedFiles/Consol_Reg853_2004(1).pdf)

Teat dips in Annex II, under II. B.1.(e)

Article 3(3) Biocidal Products Regulation decisions

<https://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

Active substances authorised for biocidal products

<https://echa.europa.eu/fr/information-on-chemicals/biocidal-active-substances>

Veterinary Medicinal Products

General information:

http://ec.europa.eu/health/veterinary-use_en

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended

Consolidated version:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0082:20090807:EN:PDF>

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF>

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 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

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF>

Food, Feed Additives, Medicated Feed

General information

http://ec.europa.eu/food/food/foodlaw/index_en.htm

https://ec.europa.eu/food/safety/animal-feed/feed-additives_en

https://ec.europa.eu/food/safety/animal-feed/medicated-feed_en

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT>

General Food Law

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1831:EN:NOT>

Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0167:EN:HTML>

Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:229:0001:01:EN:HTML>

Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0038:en:NOT>

Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials

<http://eur->

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0025:0065:en:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:159:0025:0065:en:PDF)

Community register for feed additives

https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-eu-reg-comm_register_feed_additives_1831-03.pdf

Miscellaneous

Commission Recommendation of 14.01.2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products

<http://eur->

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:011:0075:0079:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:011:0075:0079:EN:PDF)

JURISPRUDENCE, CASE-LAW FROM THE EUROPEAN COURT OF JUSTICE

Non exhaustive list of European Court of Justice Judgements concerning the Definition of Medicinal Products

Case C-227/82

Judgment of the Court (Fifth Chamber) of 30 November 1983. - Criminal proceedings against Leendert van Bennekom. - Reference for a preliminary ruling: Arrondissementsrechtbank Amsterdam - Netherlands. - Concept of "Medicinal products" - "Medicinal preparations".

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61982CJ0227:EN:HTML>

Case C-112/89

Judgment of the Court (Fifth Chamber) of 16 April 1991.
Upjohn Company and Upjohn NV v Farzoo Inc. and J. Kortmann. Reference for a preliminary ruling: Hoge Raad - Netherlands.
Concepts of "medicinal product" and "cosmetic product".

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61989CJ0112>

Case C-369/88

Judgment of the Court (Fifth Chamber) of 21 March 1991.
Criminal proceedings against Jean-Marie Delattre. Reference for a preliminary ruling: Tribunal de grande instance de Nice - France.
Interpretation of Articles 30 and 36 of the EEC Treaty - Concepts of "disease" or "illness" and "medicinal product" - Pharmacists' monopoly of the right to sell certain products.

<http://curia.europa.eu/juris/showPdf.jsf?jsessionid=9ea7d0f130de25fe888f104d447bb0318a0fd48a0a1b.e34KaxiLc3eOc40LaxqMbN4Ob3aTe0?text=&docid=96404&pagen dex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=493434>

Case C-60/89

Judgment of the Court (Fifth Chamber) of 21 March 1991.
Criminal proceedings against Jean Monteil and Daniel Samanni. Reference for a preliminary ruling: Cour d'appel d'Aix-en-Provence - France.
Interpretation of Articles 30 and 36 of the EEC Treaty - Concepts of "disease" or "illness" and "medicinal products" - Pharmacists' monopoly of the right to sell certain products.

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61989CJ0060>

Case C-290/90

Judgment of the Court of 20 May 1992. Commission of the European Communities v Federal Republic of Germany.
Interpretation of Articles 30 and 36 of the EEC Treaty - Eye lotions - Concept of "medicinal product" - Cosmetic products.

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61990CJ0290>

Case C-387/99

Judgment of the Court (Sixth Chamber) of 29 April 2004.
Commission of the European Communities v Federal Republic of Germany.
Failure of a Member State to fulfil obligations - Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC) - Directive 65/65/EEC – Food preparations containing three times more vitamins than the recommended daily amount - Preparations lawfully marketed as food supplements in the Member State of exportation - Preparations classified as medicinal products in the Member State of importation - "Medicinal product" - Obstacle - Justification - Public health - Proportionality - Admissibility of the application.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61999CJ0387:EN:HTML>

Case C-150/00

Judgment of the Court (Sixth Chamber) of 29 April 2004.

Commission of the European Communities v Republic of Austria.

(Failure of a Member State to fulfil obligations – Articles 28 and 30 EC – Directive 65/65/EEC – Food preparations containing vitamins A, D or K or minerals in the chromate group or containing more than the daily amount of other vitamins or minerals – Preparations lawfully marketed as food supplements in the Member State of exportation – Preparations classified as medicinal products in the Member State of importation – ‘Medicinal product’ – Obstacle – Justification – Public health – Proportionality)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62000CJ0150:EN:HTML>

Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03

Judgment of the Court (First Chamber) of 9 June 2005. HLH Warenvertriebs GmbH and Orthica BV against Bundesrepublik Deutschland. Reference for a preliminary ruling: Oberverwaltungsgericht für das Land Nordrhein-Westfalen - Germany.

Free movement of goods - Distinction between medicinal products and food additives - Product marketed as a food additive in the Member State of origin but treated as a medicinal product in the Member State of import – Marketing authorisation.

<http://curia.europa.eu/juris/showPdf.jsf?docid=58348&pageIndex=0&doclang=EN&mode=doc&dir=&occ=first&part=1&cid=705150>

Case 88/07

Judgement of the Court (First Chamber) 5 March 2009. Commission of the European Communities against Kingdom of Spain.

Articles 28 EC and 30 EC – Free movement of goods – Directive 2001/83/EC – Products based on medicinal herbs – Products classified as medicinal products – Products lawfully produced or marketed as food supplements or dietary products in other Member States – Meaning of ‘medicinal product’ – Marketing authorisation – Restriction – Justification – Public health – Consumer protection – Proportionality – Decision No 3052/95/EC – Procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62007CJ0088:EN:HTML>

Case 140/07

Judgement of the Court (First Chamber) 30 April 2009. Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg. Reference for a preliminary ruling: Bundesverwaltungsgericht - Germany.

Directive 2001/83/EC – Articles 1(2) and 2(2) – Concept of ‘medicinal product by function’ – Product in respect of which it has not been established that it is a medicinal product by function – Account taken of the content in active substances

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62007CJ0140:EN:HTML>

Case C-319/05

Judgment of the Court (First Chamber) of 15 November 2007. European Commission against Federal Republic of Germany.

Failure of a Member State to fulfil its obligations - Article 28 EC and Article 30 EC - Directive 2001/83/EC - Garlic preparation in capsule form - Preparation legally marketed as a food supplement in a number of Member States - Preparation classified as a medicinal product in the Member State of importation - Definition of ‘medicinal product’ - Obstacle - Justification - Public health - Proportionality.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62005J0319:EN:HTML>

Case 27/08

Judgement of the Court (First Chamber) 15 January 2009. Hecht-Pharma GmbH against Staatliches Gewerbeaufsichtsamt Lüneburg.

Reference for a preliminary ruling: Bundesverwaltungsgericht - Germany.

Directive 2001/83/EC – Article 1(2)(b) – Concept of ‘medicinal product by function’ – Dosage of the product – Normal conditions of use – Risk to health – Ability to restore, correct or modify physiological functions in human beings

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62008J0027:EN:HTML>

Case C-308/11

Judgment of the Court (Fifth Chamber) of 6 September 2012. Chemische Fabrik Kreussler & Co. GmbH v Sunstar Deutschland GmbH. Reference for a preliminary ruling: Oberlandesgericht Frankfurt am Main - Germany. Directive 2001/83/EC – Medicinal products for human use - Article 1(2)(b) - Meaning of ‘medicinal product by function’ - Definition of the term ‘pharmacological action’.

<http://curia.europa.eu/juris/document/document.jsf?jsessionid=9ea7d0f130d57a9196d7a02c4fa8b79fa4c399846457.e34KaxiLc3eQc40LaxqMbN4Oa3qLe0?text=&docid=126438&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=3459590>

Joined cases C-358/13 and C-181/14.

Judgment of the Court (Fourth Chamber) of 10 July 2014. Criminal proceedings against Markus D. (C-358/13) and G. (C-181/14). References for a preliminary ruling: Bundesgerichtshof - Germany. Medicinal products for human use - Directive 2001/83/EC - Scope - Interpretation of the concept of ‘medicinal product’ - Scope of the criterion based on the capacity to modify physiological functions - Herb and cannabinoid-based products.

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62013CJ0358>

NATIONAL GUIDANCE DOCUMENTS

Belgium

http://www.fagg-afmps.be/en/veterinary_use/particular_products/grey_area/

Koninklijk besluit tot vaststelling van de samenstelling en de werking van de Gemengde Commissie en tot uitvoering van artikel 1, § 2, van de wet van 25 maart 1964 op de geneesmiddelen.

Arrêté royal portant fixation de la composition et du fonctionnement de la Commission mixte et portant exécution de l'article 1er, § 2, de la loi du 25 mars 1964 sur les médicaments

Royal Decree determining the composition and functioning of the mixed committee.

28.10.2008, available in Dutch & French

Decision tree, available in English

Indicatieve lijst van beweringen die niet beschouwd worden als een beschrijving van therapeutische of profylactische eigenschappen.

Liste indicative d'allégations considérées comme ne décrivant pas des propriétés curatives ou préventives.

Indicative list of statements which are not regarded as a description of therapeutic or prophylactic properties.

19.10.2010, available in Dutch & French

Toelichting m.b.t. de borderline biocide / diergeneesmiddel.

Explications relatives au cas borderline biocide / médicament vétérinaire.

Explanatory notes regarding the borderline biocide / veterinary medicinal product.

17.10.2010, available in Dutch & French

Czech Republic

Act No. 166/1999 Coll., on veterinary care and amending certain related laws, as amended by Act No. 308/2011 Coll.

<http://uskvbl.cz/cs/registrace-a-schvalovani/schvalovani-vp>

Information document regarding the non-medicinal veterinary products, available in Czech.

<http://www.uskvbl.cz/cs/registrace-a-schvalovani/schvalovani-vp/pokyny-a-informace/informace-a-upozornni>

Hungary

Decree of the Minister of Agriculture and Rural Development No. 33/2010 (IV.7.) FVM Decree on the amendment of FVM Decree No 128/2009 (X.6.) on medicinal products for veterinary use.

http://www.complex.hu/jr/gen/hjegy_doc.cgi?docid=A0900128.FVM

<http://www.vm.gov.hu/main.php?folderID=957&articleID=15703&ctag=articlist&iid=1>

The second decree a joint decree of three ministers: 38/2003. (VII.7.) on the conditions of manufacturing and distribution of biocidal products Minister of Health, Social Affairs and Family Protection, Minister of Agriculture and Rural Development, Minister of Environmental Protection and Water.

https://www.antsz.hu/en/biocide/transitional_period

According to the decree of: a biocid termékek előállításának és forgalomba hozatalának feltételeiről szóló 38/2003. ESzCsM-FVM-KvVM együttes rendelet

Ireland

Guide to the definition of an animal remedy and classification process.

<http://www.hpra.ie/homepage/veterinary/regulatory-information/additional-activities>

04.03.2009

United Kingdom

Veterinary Medicines Guidance Note N°1, Controls of Veterinary Medicines

www.vmd.defra.gov.uk

July 2011

Sweden

The Swedish Medicines Act (1992:859) contains the fundamental regulations concerning the handling of medicinal products in Sweden. For classification 1992:859, 1§.

Frequently asked questions and answers about product classification

<http://www.lakemedelsverket.se/english/overview/Legislation/Frequently-asked-questions-and-answers-about-product-classification/>

Estonia

National regulation:

The Conditions and Procedure for Classifying a Substance or Product as a Medicinal Product

Passed 13.04.2005 Annex 59

RTL 2005, 45, 629

<https://www.riigiteataja.ee/en/eli/508102014008/consolide>

State Agency of Medicines is responsible of classifying a substance or product as a medicinal product.

Contact details: maaratlused@ravimiamet.ee, phone +372 737 4140.

The Veterinary and Food Board (VFB) is responsible for food, feed and supplements

Contact details: vet@vet.agri.ee, phone +372 605 1710.

Medical devices fall within the remit of the Health Board. Contact details:

mso@terviseamet.ee

The Health Board is responsible for biocides as well.