



S9.5 - Legislation and relation to GMP+ FC scheme

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Guidelines Legislation

This document wants to provide support to GMP+ companies by explaining how the (EU) legislation should be applied in relation to GMP+ certification.

1. GMP+ requirements related to legislation

1.1. Guidance on compliance with legislation

Every company that is active in the feed industry must comply with the relevant feed safety legislation. The stakeholders of GMP+ International acknowledge the ultimate requirements that are set out in feed-related EU legislation.

The most important elements of those regulations are already incorporated in the GMP+ FC scheme and must therefore be respected by GMP+ certified companies. If national feed-related legislation are stricter than the GMP+ FSA certification requirements, the GMP+ certified companies must respect the requirements of those national legislation.

In all other cases (less strict or no national legislation) the GMP+ certified company must comply with the GMP+ requirements, regardless of where the company is located and which market it serves. It is thanks to this compliance level that a high level of feed safety assurance can be realized in all countries. This also ensures that a GMP+ FSA certificate has a high level of feed safety assurance all over the world.

It remains the responsibility of every GMP+ certified company to make sure that it complies with the relevant feed legislation.

A general summary of the EU legislation related to feed can be found in Appendix 1.



2. Incorporation of EU legislation in the GMP+ documents

2.1. TS 1.4 Forbidden Products and Fuels

EU legislation prohibits certain products for use as feed (or use (with) in the production of feed). These forbidden products are listed in TS 1.4 *Forbidden Products and Fuels*. These forbidden products, may NOT be used, by any GMP+ certified company.

You will find the applicable EU legislation in the table below in the column “legislation source”

Prohibited products	Legislation source
<ul style="list-style-type: none"> Animal proteins. 	Regulation (EC) no. 999/2001
<ul style="list-style-type: none"> Animal by-products; Catering waste and food leftovers. 	Regulation (EC) no. 1069/2009
<ul style="list-style-type: none"> Animal fats, derived from category 1 and 2 material (Appendix XIII, Chapter XI); Catering waste and food leftovers. 	Regulation (EC) no. 142/2011
<ul style="list-style-type: none"> Candida, protein products of the yeast; Faeces, urine; Packaging materials; Seeds and plant material treated with plant protection products; Skins treated with tanning extracts; Sludge from the processing of urban, domestic and industrial waste water; Urban waste, solid; Wood, treated with wood preservative. 	Regulation (EC) no. 767/2009



2.2. TS 1.5 Specific feed safety limits

The TS 1.5 document contains the feed safety limits that need to be respected by all GMP+ certified companies to determine whether a feed is safe to use or should be rejected. In most cases is EU legislation the source of the limits. But some limits are so called “GMP+ limits”. These limits are not based on EU Legislation but based on studies done for GMP+ International. The results of these studies can be found via ‘GMP+ Portal’.

Besides the limits in TS 1.5 it may be that stricter or additional limits have been included in national legislation, these should be respected as described in § 1.1.

Note: You will find the applicable EU legislation in the table below in the column “legislation source”

Contaminants	Legislation source
<ul style="list-style-type: none"> • Enterobacteriaceae; • Salmonella; • Insoluble impurities. 	Commission Regulation (EU) 142/2011
<ul style="list-style-type: none"> • Arsenic; • Cadmium; • Fluorine; • Lead; • Mercury; • Nitrite; • Melamine 	Directive 2002/32/EC Section I <i>INORGANIC CONTAMINANTS AND NITROGENOUS COMPOUNDS</i>
<ul style="list-style-type: none"> • Aflatoxin B1, • Rye ergot (<i>Claviceps purpurea</i>) 	Directive 2002/32/EC Section II <i>MYCOTOXINS</i>
<ul style="list-style-type: none"> • Free gossypol; • Hydrocyanic acid; • Theobromine; • vinyl thioxazolidone (5-vinyloxazolidine-2-thione); • Volatile mustard oil 	Directive 2002/32/EC Section III <i>INHERENT PLANT TOXINS</i>
<ul style="list-style-type: none"> • Aldrin; • Dieldrin; • Camphechlor (toxaphene) – sum of indicator congeners CHB 26, 50 and 62; • Chlordane (sum of cis- and transisomers and of oxychlordane, expressed as chlordane); • DDT (sum of DDT-, DDD- (or TDE-) and DDEisomers, expressed as DDT); • Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan); • Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin); • Heptachlor (sum of heptachlor and of heptachlor epoxide, expressed as heptachlor); • Hexachlorobenzene (HCB); • Hexachlorocyclohexane (HCH), - Alfa-isomer, - Beta-isomer, - Gamma-isomer (lindane) 	Directive 2002/32/EC Section IV <i>ORGANOCHLORINE COMPOUNDS (EXCEPT DIOXINS AND PCBs)</i>



<ul style="list-style-type: none"> • Dioxins [sum of polychlorinated dibenzo-paradioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005); , • Sum of dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo-paradioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors), 2005,; • Dioxin-like PCBs (sum of polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO- TEFs (toxic equivalency factors, 2005); • Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6) 	Directive 2002/32/EC Section V <i>DIOXINS AND PCBs</i>
<p>Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including;</p> <ul style="list-style-type: none"> • <i>Datura</i> sp., • <i>Crotalaria</i> spp., • Seeds and husks from <i>Ricinus communis</i> L., <i>Croton tiglium</i> L. and <i>Abrus precatorius</i> L. as well as their processed derivatives, separately or in combination • Unhusked beech mast — <i>Fagus sylvatica</i> L., • <i>Purghera</i> — <i>Jatropha curcas</i> L., • Seeds from <i>Ambrosia</i> spp., <p>Seeds from:</p> <ul style="list-style-type: none"> • Indian mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>integrifolia</i> (West.) Thell. — • Sareptian mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> • Chinese mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> var. <i>lutea</i> Batalin • Black mustard — <i>Brassica nigra</i> (L.) Koch • Ethiopian mustard — <i>Brassica carinata</i> A. Braun. 	Directive 2002/32/EC Section VI <i>HARMFUL BOTANICAL IMPURITIES</i>
<ul style="list-style-type: none"> • Prohibited Animal proteins (Restricted animal proteins). 	Regulation 999/2001, art. 7 and Annex IV
<ul style="list-style-type: none"> • DON (Deoxynivalenol); • Ochratoxin A; • Zearalenon; • Fumonisin B1 + B2; • T-2 and HT-2 toxin, Sum of. 	Commission Recommendation 2006/576/EC
<ul style="list-style-type: none"> • Pesticides. 	Regulation (EC) No 396/2005
<ul style="list-style-type: none"> • Radioactivity, Sum of Cs-134 and Cs-137. 	Commission Implementing Regulation (EU) No 2016/6 is amended by Commission Implementing Regulation (EU) No . 2017/2058 . (note: The new regulation does not concern adoption of new standards)



2.3. TS 1.7 Monitoring

Within the protocol for monitoring (TS 1.7) dioxin and dioxin-like PCBs in fats and oils EU legislation* is incorporated.

This means that the requirements of the protocol must be respected by all GMP+ certified companies.

** The requirements are based on EU-legislation, as laid down in Reg. (EU) No. 183/2005 (Appendix II) including the amendments regulated by Regulation (EU) No. 2015/1905.*

Commission Regulation (EC) No 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013.



Appendix 1: Overview European legislation related to the GMP+ FC scheme

Disclaimer: This overview is not complete but gives companies insight in most common EU legislation incorporated within the GMP+ FC scheme. For the complete overview and the latest version of EU legislation check the website eur-lex.europa.eu.

Nr. Legislation	Title Document
General	
Reg. (EC) No 178/2002	<p>General Food (& feed) law: 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.</p>
Reg. (EC) nr. 183/2005	<p>Feed Hygiene Regulation: Laying down requirements for feed hygiene.</p>
Reg. (EC) nr. 767/2009	<p>Feed Marketing Regulation: on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.</p>
Reg. (EC) nr. 152/2009	<p>Monitoring of feed: Laying down methods of sampling and analysis of feed.</p>
Animal feed	
Dir. 2002/32/EC	On undesirable substances in animal feed
Commission recommendation of 17/08/2006 2006/576/EC	On the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding.
Dir. 2008/38/EC	Establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes.
Council Reg. (Euratom) nr. 2016/52	Laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.
Reg. (EU) nr. 68/2013	Catalogue of feed materials
Reg. (EC) nr. 396/2005	On maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.



Nr. Legislation	Title Document
Commission Decision 2009/727/EC	On emergency measures applicable to crustaceans imported from India and intended for human consumption or animal feed.
Feed additives	
Reg. (EC) nr. 1831/2003	On additives for use in animal nutrition.
Register of Feed Additives	<p>The Commission has established acc. Article 17 the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorization Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.</p> <p>This register can be consulted via: http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm</p>
GMO	
Dir. 2001/18/EC	on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration.
Reg. (EC) nr. 1829/2003	On genetically modified food and feed.
Reg. (EC) nr. 1830/2003	Concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
Animal protein	
Reg. (EC) nr. 1069/2009	Laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).
Reg. 142/2011	Implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive.
Reg. (EC) Nr. 999/2001	Laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.
Salmonella and other zoonotic agents	
2003/99/EC	On the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC.

At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

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