



# 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"> <li>Animal proteins.</li> </ul>	Regulation (EC) no. 999/2001
<ul style="list-style-type: none"> <li>Animal by-products;</li> <li>Catering waste and food leftovers.</li> </ul>	Regulation (EC) no. 1069/2009
<ul style="list-style-type: none"> <li>Animal fats, derived from category 1 and 2 material (Appendix XIII, Chapter XI);</li> <li>Catering waste and food leftovers.</li> </ul>	Regulation (EC) no. 142/2011
<ul style="list-style-type: none"> <li>Candida, protein products of the yeast;</li> <li>Faeces, urine;</li> <li>Packaging materials;</li> <li>Seeds and plant material treated with plant protection products;</li> <li>Skins treated with tanning extracts;</li> <li>Sludge from the processing of urban, domestic and industrial waste water;</li> <li>Urban waste, solid;</li> <li>Wood, treated with wood preservative.</li> </ul>	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"> <li>• Enterobacteriaceae;</li> <li>• Salmonella;</li> <li>• Insoluble impurities.</li> </ul>	Commission Regulation (EU) 142/2011
<ul style="list-style-type: none"> <li>• Arsenic;</li> <li>• Cadmium;</li> <li>• Fluorine;</li> <li>• Lead;</li> <li>• Mercury;</li> <li>• Nitrite;</li> <li>• Melamine</li> </ul>	Directive 2002/32/EC Section I <i>INORGANIC CONTAMINANTS AND NITROGENOUS COMPOUNDS</i>
<ul style="list-style-type: none"> <li>• Aflatoxin B1,</li> <li>• Rye ergot (<i>Claviceps purpurea</i>)</li> </ul>	Directive 2002/32/EC Section II <i>MYCOTOXINS</i>
<ul style="list-style-type: none"> <li>• Free gossypol;</li> <li>• Hydrocyanic acid;</li> <li>• Theobromine;</li> <li>• vinyl thioxazolidone (5-vinyloxazolidine-2-thione);</li> <li>• Volatile mustard oil</li> </ul>	Directive 2002/32/EC Section III <i>INHERENT PLANT TOXINS</i>
<ul style="list-style-type: none"> <li>• Aldrin;</li> <li>• Dieldrin;</li> <li>• Camphechlor (toxaphene) – sum of indicator congeners CHB 26, 50 and 62;</li> <li>• Chlordane (sum of cis- and transisomers and of oxychlordane, expressed as chlordane);</li> <li>• DDT (sum of DDT-, DDD- (or TDE-) and DDEisomers, expressed as DDT);</li> <li>• Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan);</li> <li>• Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin);</li> <li>• Heptachlor (sum of heptachlor and of heptachlor epoxide, expressed as heptachlor);</li> <li>• Hexachlorobenzene (HCB);</li> <li>• Hexachlorocyclohexane (HCH), - Alfa-isomer, - Beta-isomer, - Gamma-isomer (lindane)</li> </ul>	Directive 2002/32/EC Section IV <i>ORGANOCHLORINE COMPOUNDS (EXCEPT DIOXINS AND PCBs)</i>



<ul style="list-style-type: none"> <li>• 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); ,</li> <li>• 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,;</li> <li>• Dioxin-like PCBs (sum of polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO- TEFs (toxic equivalency factors, 2005);</li> <li>• Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6)</li> </ul>	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"> <li>• <i>Datura</i> sp.,</li> <li>• <i>Crotalaria</i> spp.,</li> <li>• 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</li> <li>• Unhusked beech mast — <i>Fagus sylvatica</i> L.,</li> <li>• <i>Purghera</i> — <i>Jatropha curcas</i> L.,</li> <li>• Seeds from <i>Ambrosia</i> spp.,</li> </ul> <p>Seeds from:</p> <ul style="list-style-type: none"> <li>• Indian mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>integrifolia</i> (West.) Thell. —</li> <li>• Sareptian mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i></li> <li>• Chinese mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> var. <i>lutea</i> Batalin</li> <li>• Black mustard — <i>Brassica nigra</i> (L.) Koch</li> <li>• Ethiopian mustard — <i>Brassica carinata</i> A. Braun.</li> </ul>	Directive 2002/32/EC Section VI <i>HARMFUL BOTANICAL IMPURITIES</i>
<ul style="list-style-type: none"> <li>• Prohibited Animal proteins (Restricted animal proteins).</li> </ul>	Regulation 999/2001, art. 7 and Annex IV
<ul style="list-style-type: none"> <li>• DON (Deoxynivalenol);</li> <li>• Ochratoxin A;</li> <li>• Zearalenon;</li> <li>• Fumonisin B1 + B2;</li> <li>• T-2 and HT-2 toxin, Sum of.</li> </ul>	Commission Recommendation 2006/576/EC
<ul style="list-style-type: none"> <li>• Pesticides.</li> </ul>	Regulation (EC) No 396/2005
<ul style="list-style-type: none"> <li>• Radioactivity, Sum of Cs-134 and Cs-137.</li> </ul>	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](http://eur-lex.europa.eu).

Nr. Legislation	Title Document
<b>General</b>	
Reg. (EC) No 178/2002	<p><b>General Food (&amp; feed) law:</b> 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><b>Feed Hygiene Regulation:</b> Laying down requirements for feed hygiene.</p>
Reg. (EC) nr. 767/2009	<p><b>Feed Marketing Regulation:</b> 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><b>Monitoring of feed:</b> Laying down methods of sampling and analysis of feed.</p>
<b>Animal feed</b>	
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.
<b>Feed additives</b>	
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: <a href="https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en">https://ec.europa.eu/food/safety/animal-feed/feed-additives/eu-register_en</a></p>
<b>GMO</b>	
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.
<b>Animal protein</b>	
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.
<b>Salmonella and other zoonotic agents</b>	
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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