



GMP+ Certification Guidance for FSSC 22000 certified organizations

GMP+ D 5.2

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GMP+ Feed Certification scheme



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1. Introduction

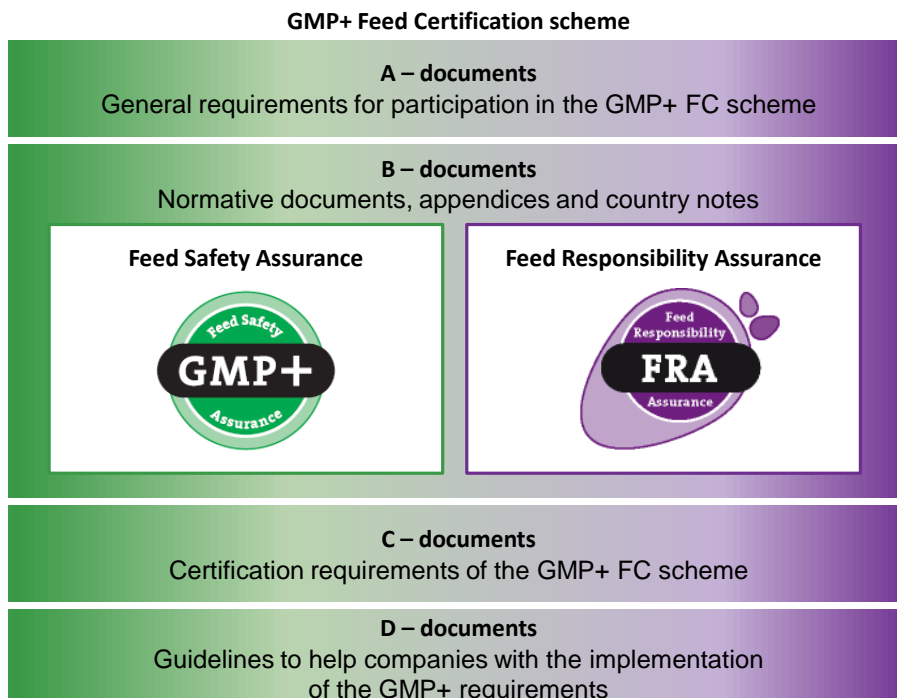
The FSSC 22000 certified organizations produce food by-products that can be used in the feed industry as an ingredient for the production of feed. This is why FSSC 22000 and GMP+ International have chosen to create an option, that provides FSSC 22000 certified food producing organizations, which produce by-products for feed, an easy access to all feed markets. This option is focused on getting 2 certificates (FSSC 22000 for food production and GMP+FSA for the food by-products), as the result of one combined audit.

This document is referred to as GMP+ D5.2 *Guidance for combined GMP+ FSA and FSSC 22000 certification*.

1.1. Introduction GMP+ Feed Safety Assurance

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).



GMP+ Feed Safety Assurance is a complete module with standards for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, for traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification Bodies are able to carry out GMP+ certification independently.

More information can be found on [the website](#) of GMP+ International.

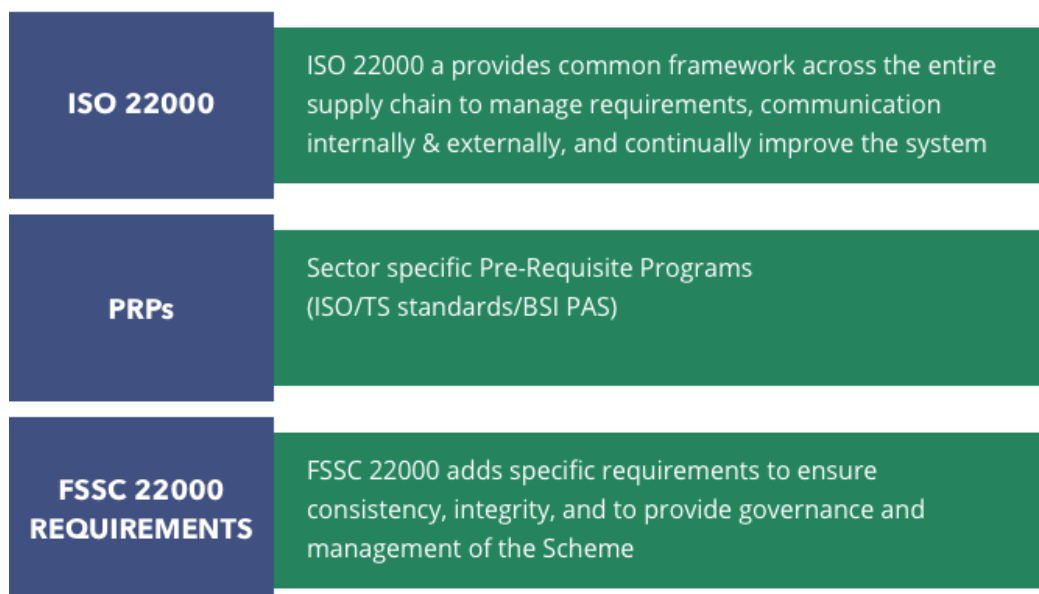
1.2. Introduction FSSC 22000

The FSSC 22000 Food Safety System Certification provides a framework for effectively managing food safety and quality responsibilities. FSSC 22000 demonstrates an organizations has a robust and effective food safety management system (FSMS) in place to meet the requirements of regulators, food business clients and consumers.

The FSSC 22000 Scheme is managed by Foundation FSSC 22000 and governed by an independent Board of Stakeholders which consists of representatives from several sectors in the food industry. The Global Food Safety Initiative (GFSI) has given full recognition to the FSSC 22000 Scheme since 2010 demonstrating meeting the highest standards globally leading to international food industry acceptance.

The FSSC 22000 Scheme consists of three components: ISO 22000, sector specific Pre-Requisite Programs (PRPs) and FSSC 22000 Additional Requirements. Besides these three components there is a FSSC 22000-Quality option based on the additional requirements of a full ISO 9001 quality management system audit.

The FSSC 22000 Scheme has 3 required components



More information can be found on [the website](#) of FSSC 22000.

2. Certification Guidance

2.1. Scope

This document describes which requirements from the GMP+ Feed Certification scheme need to be implemented, in addition to the FSSC 22000 scheme requirements, in order to obtain full GMP+ FSA certification.

Many of the requirements for both GMP+ FSA and FSSC 22000 certification are similar. Think of management system requirements, PRP's and other control measures. Of course, one should keep in mind that the focus for operating all these controls, procedures and programs is different: FSSC 22000 focuses on controlling food safety and GMP+ focuses on controlling feed safety. This document guides organizations towards the specific GMP+ elements that need to be implemented on top of the existing food safety management system.



As most food organizations produce next to food products also feed ingredients (by-products of food production), the GMP+ standard B2 'Production of Feed Ingredients' has been used as the reference standard.

The content of this document is created by GMP+ International to give guidance to

- an organization to implement a GMP+ feed safety management system next to a food safety management system as required by FSSC 22000.
- a Certification Body to apply the certification rules from both schemes during one audit and certification procedure.

2.2. Structure of the document

This certification guidance shows per topic in a table which information is stated in the FSSC 22000 scheme requirements. In case the standard GMP+ B2 contains requirements that are not covered by the FSSC 22000 scheme, this is shown in the second part of the table.

Scheme	Requirement
	<p>The auditable FSSC scheme requirements for food manufacturing are covered by the following standards:</p> <ul style="list-style-type: none"> - ISO 22000:2018 Food safety management system requirements - ISO/TS 22002-1:2009 Sector specific prerequisite programs (PRP) requirements - FSSC 22000 Additional requirements (see Part 2, section 2.5)
	<p>This specific requirement is not included in FSSC 22000 certification and must therefore be implemented additionally in order to obtain GMP+ certification.</p>

2.3. Disclaimer

This document does not replace the relevant documents from both schemes but should be considered as a supporting tool to identify the relevant additional requirements in one scheme (GMP+) to obtain certification for the both schemes (FSSC 22000 and GMP+).

It is the responsibility of the individual organization and the Certification Body to assure that there is compliance with all the relevant requirements from both schemes. In no way can GMP+ International nor FSSC 22000 be held liable for the use of the information provided in this document.



3. Guidance for the organization

3.1. General

An organization wishing to become certified under both certification schemes must demonstrably comply with the requirements laid down in both the FSSC 22000 scheme and the GMP+ Feed Certification scheme. The organization must be able to demonstrate that there is compliance with the conditions of each individual standard.

Regarding the conditions, there are some differences between both schemes. This chapter describes the additional GMP+ requirements which an FSSC 22000 certified organization must implement to obtain GMP+ certification.

3.2. Feed Safety Management System

Scheme	Requirement
	<p>The ISO22000:2018 standard specifies requirements for any organization in the food chain that implements a management system that handles food, feed or packaging products. Therefore the requirements in the ISO22000:2018 standard focuses on <u>food</u>, <u>feed</u> and <u>packaging</u> safety.</p>
	<p>As GMP+ FSA certification is intended for assuring <u>feed</u> safety only, the requirements are on some topics more detailed and focused on activities to assure the safety of the feed.</p> <p>Therefore organizations certified for FSSC 22000 interested in obtaining GMP+ FSA certification must focus specifically on the following items as laid down in GMP+ B2:</p> <ul style="list-style-type: none"> • Scope of the Feed Safety Management System – the participant must include feed in the food safety management system. Feed cannot be considered as waste but is part of the products delivered to customers and should therefore have the same attention in the FSMS as food. • Management must determine what resources are required to realize safe feed and ensure that these resources are also available. • The participant must also describe all other activities and/or products which are not feed related. The participant must ensure that these activities do not have a negative influence on the safety of the feed ingredients. • Feed product specifications must be agreed between the participant and the purchaser and confirmed in the contract. The participant must ensure that all feed ingredients supplied meet the agreed specifications. The sale of feed products must be clearly recorded. • All activities related to the production of the feed ingredients, including activities which are outsourced must comply with GMP+ BA10 <i>Minimum Requirements for Purchasing</i>.



3.3. Feed Safety Limits

Feed safety limits are used in the HACCP analysis and defined if a product is safe to use as feed.

Scheme	Requirement
	<p>The ISO22000:2018 standard requires compliance with applicable legislative and regulatory requirements for all food, feed and packaging products covered by the scope of the organization's FSMS.</p>
	<p>The GMP+ B2 standard requires compliance with applicable EU legislation. All EU feed safety limits are included in GMP+ BA1 <i>Specific feed safety limits</i>. To have a level playing field all over the world, all certified organizations are required to comply with the feed safety limits in GMP+ BA1, also if the organization is not located in Europe. Only if national legislation has defined more stricter limits, of course these limits must be respected.</p> <p>Note that for a few specific feed products, additional GMP+ feed safety limits are included in the GMP+ BA1. These feed safety limits do not originate from EU legislation but are agreed upon by the market.</p> <p>Therefore organizations certified for FSSC 22000 interested in obtaining GMP+ FSA certification, must comply with all relevant feed safety limits in GMP+ BA1 <i>Specific feed safety limits</i>.</p>



3.4. Negative list

Negative list refers to a list of products that are not allowed to be used as feed.



Scheme	Requirement
	<p>The ISO22000:2018 standard requires compliance with applicable legislative and regulatory requirements for all food, feed and packaging products covered by the scope of the organization's FSMS.</p>
	<p>The GMP+ B2 standard requires compliance to applicable EU legislation. Just like the feed safety limits, this is regulated via copying the EU list of forbidden feed products in a special Appendix, (GMP+ BA3). All products that are not allowed to be used as feed according the EU legislation are included in GMP+ BA3 <i>Negative list</i>.</p> <p>Additionally, some products are included on the GMP+ negative list. These forbidden products do not originate from EU legislation but are agreed upon by the market. Lastly, a negative list for fuels, not allowed for direct drying of feed, is included.</p> <p>Therefore organizations certified for FSSC 22000 interested in obtaining GMP+ FSA certification, must comply with GMP+ BA3 Negative list, even if they are not located in Europe.</p>

3.5. FSP product list

The FSP product list is used in GMP+ FSA certification as a 'positive list of feed materials'. Only feed materials that are included in this list may be produced, traded or used under GMP+ certification.



Scheme	Requirement
	<p>The ISO22000:2018 standard requires compliance with applicable legislative and regulatory requirements for all food, feed and packaging products covered by the scope of the organization's FSMS. This means that all used feed materials must be allowed by law.</p>
	<p>The GMP+ B2 <i>Production of Feed Ingredients</i> standard requires, on top of compliance with legislation, inclusion of all produced / sold feed materials in the Feed Support Products (FSP) Product list. Inclusion on this list can be achieved by an approved risk assessment. This generic risk assessment is, before inclusion in the FSP product list, assessed by a team of experts and approved once considered safe to be used in feed. Organizations can use the risk assessment for their hazard analysis. More information for the inclusion of a feed material in the FSP list can be found on our website via this link.</p> <p>FSSC 22000 certified organizations which want to be GMP+ certified must comply with this requirement. When a product is missing in the FSP Product list, inclusion can be requested via the website of GMP+ International.</p> <p>As there are many feed materials already included in the FSP product list, most feed materials which FSSC 22000 organizations produce are probably already included.</p>

3.6. Documentation and data



Scheme	Requirement
	<p>The ISO22000:2018 standard requires that documented information of external origin determined by the organization to be necessary for the planning and operation of the FSMS shall be identified, as appropriate, and controlled.</p>
	<p>The GMP+ B2 standard also requires the organizations to retain the documents at least three years unless a longer storage period is required according the applicable feed legislation or other regulations.</p>

3.7. Purchasing requirements

Both certification schemes include purchasing requirements to ensure a good selection of suppliers of processes, products and/or services.

Scheme	Requirement
	The ISO22000:2018 standard requires that the organization shall establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers of processes, products and/or services.
	<p>The GMP+ certification scheme has a very strong chain approach and requires GMP+ (or equivalent) certification of suppliers of feed products and services for which a scope is included in the GMP+ certification scheme.</p> <p>All relevant purchase requirements can be found in the GMP+ D3.5 via this link.</p> <p>GMP+ International requires certified organizations to use GMP+ B11 registered laboratories for analyzing critical contaminants as aflatoxin B1, dioxins/dioxin-like PCBs/ non-dioxin-like PCBs and heavy metals.</p>

3.8. Positive declaration and use of logo

Scheme	Requirement
	<p>The ISO22000:2018 standard requires that organizations shall maintain documented information concerning the characteristics of end products to the extent needed to conduct the hazard analysis, including information on labelling relating to food safety and/or instructions for handling, preparation and intended use.</p> <p>The FSSC 22000 Additional requirements specify that:</p> <ul style="list-style-type: none"> Organizations shall ensure that the finished products are labelled according all applicable statutory and regulatory requirements in the country of intended sale. Certified organizations and Certification Bodies shall use the FSSC 22000 logo only for marketing activities such as organization's printed matter, website and other promotional material. The certified organization is not allowed to use the FSSC 22000 logo, any statement or make reference to its certified status on a product, its labelling, its packaging (primary, secondary or any other form) or in any other manner that implies FSSC 22000 approves a product, process or service.
	The GMP+ B2 <i>Production of Feed Ingredients</i> standard also requires legal compliance, but additionally requires a positive declaration about GMP+ products. This is to confirm the client that the product is covered within their GMP+ certification.



FSSC 22000 certified organizations that want to be GMP+ certified must comply with the labelling requirements as stated in GMP+ BA6 *Minimum Requirements Labelling & Delivery*.

The GMP+ certified organizations are entitled to display the Logo's and/or Trademarks as follows:



- a. on or near the Business Location or transport vehicle of the certified organizations;
- b. on documents issued by the certified organizations, but only in case the delivered products are produced under the scope of the GMP+ certificate;
- c. on the website of the certified organizations;
- d. it is not allowed to use the GMP+ Feed Safety Assurance module (GMP+ FSA) Logo on or nearby GMP+ certified (produced) products.

3.9 Early Warning and Response System and recall

The objective of an Early Warning and Response System (EWS) is the early detection and notification of irregularities regarding safety in feed products and to allow rapid response and communication throughout the feed production chain, with the aim of preventing or limiting the harmful consequences for humans, animals and the environment.

Scheme	Requirement
	<p>The ISO22000:2018 standard requires the organization to notify relevant parties (e.g. customers, consumers, statutory and regulatory authorities) and to initiate a withdrawal/recall if products that have left the control of the organization are subsequently determined to be unsafe.</p>
	<p>The GMP+ B2 <i>Production of Feed Ingredients</i> requires notification to relevant parties (the national authorities, customers, suppliers and CBs). Besides this, in some cases an organization also needs to notify GMP+ International.</p> <p>The requirements regarding the EWS procedure are included in GMP+ BA5 <i>Minimum requirements EWS</i>.</p> <p>Organizations certified for both certification schemes, must comply with the EWS procedure according to GMP+ BA5 <i>Minimum requirements EWS</i>.</p> <p>Once a year the organizations must carry out a recall simulation. It is possible for an organization to do one recall simulation, if the product is intended for food and feed. Otherwise two simulations are obliged.</p>

3.10. Sampling and analysis

Scheme	Requirement
	<p>The ISO22000:2018 standard does not require an organization to maintain a representative sample of each incoming material for an appropriate period of time unless stipulated by statutory, regulatory or customer requirements.</p>
	<p>Sampling requirements: The GMP+ B2 <i>Production of Feed Ingredients</i> requires within the framework of traceability samples must be taken from incoming and/or outgoing feed.</p> <p>Analysis requirements: A certified organization must comply with the requirements which are applicable on their product:</p> <ul style="list-style-type: none"> - GMP+ BA4 paragraph 2.2; <i>Specific requirement for monitoring of fats and oils as regards dioxin and dioxin like PCB's.</i> - GMP+ BA4 paragraph 2.3; <i>Protocol Monitoring Aflatoxin B1.</i> - GMP+ BA7 <i>Specific requirements for by-products from the Oil & Fat Industry</i> <p>If the producer is based in the EU and registered as an EU food operator and the by-products come out of a process, covered by the EU food registration, this Appendix does not apply. In that case the regular scheme requirements are applicable.</p> <p>Otherwise the organization should comply with the requirements in the BA7.</p>

4. Guidance for the Certification Body / auditor

4.1. General



A Certification Body wishing to certify an organization under both certification schemes must demonstrably comply with the certification requirements, as laid down in both the FSSC 22000 and the GMP+ Feed Certification scheme.

Regarding the certification requirements, there are some differences between both schemes. These differences are:



- Acceptation procedure
- Competences for auditors
- Examination Regulation
- Audits
- Multisite certification
- Temporary acceptance
- Compliance assessment of Certification Bodies

Before issuing a FSSC 22000 and/or a GMP+ certificate the Certification Body must be able to demonstrate that the certification requirements of each individual scheme are met. Where requirements are similar, they can be combined.



4.2. Acceptance procedure

Scheme	Requirement
	<p>The CB should submit a completed application form to be provided with a provisional license agreement. After a period of 1 year, the CB shall have achieved accreditation for the FSSC 22000 Scheme scopes with one of the recognized ABs. If successful, the license will become a full one for the licensed scopes.</p>
	<p>GMP+ International executes an acceptance procedure consisting of:</p> <ul style="list-style-type: none"> - Documentation assessment - Acceptation audit <p>After successful completing the acceptance procedure, a license agreement will be granted.</p>



4.3. Competences for auditors

Scheme	Requirement
	The FSSC 22000 audit team must meet the competence requirements set out by the Foundation in section 3 of Part 4. In Annex C of ISO/TS 22003:2013, the food safety management system competence for all CB functions are described. These are competences related to auditing any organization in the food chain that handles food, feed and/or packaging.
	GMP+ International requires that the Certification Bodies must ensure that all GMP+ auditors, inspectors, technical/material experts, technical reviewers and personnel involved in certification activities demonstrably comply with the applicable requirements as stated in GMP+ C10 Annex 2. These are competences related to auditing feed organizations.



4.4. Examination regulation

Scheme	Requirement
	FSSC 22000 requires that all auditors must complete the GFSI exam within the timeframe given by the Foundation. For new auditors this must be completed prior to qualification as a FSSC 22000 auditor.
	The GMP+ Feed Certification scheme requires all auditors who carry out GMP+ audits to pass the GMP+ examination.



4.5. Audits

Scheme	Requirement
	FSSC 22000 has three types of nonconformities during an audit, a minor, major and critical nonconformity. A minor nonconformity is issued when the situation does not affect the capability of the management system to achieve the intended results. A major nonconformity is issued when the situation does affect the capability of the management system to achieve the intended results. A critical nonconformity is issued when there is a failure in the system with direct food safety impact and no appropriate action by the organization is observed or when legality and/or certification integrity are at stake.
	GMP+ International has three types of nonconformities during an audit. A minor nonconformity is given to any nonconformity which does not adversely affect the safety of a product. A major is given to any nonconformity other than critical, which may result in failure for health or safety and which cannot be completely eliminated by rework or reduced to a minor nonconformity. A Critical nonconformity is given when any nonconformity which results in hazardous or unsafe products for humans and animals. This will at least result in stricter supervision audits and/or suspension and/or withdrawal of the organization's certificate.

4.6. Temporary acceptance for the organization

Scheme	Requirement
	FSSC 22000 has no temporary acceptance in the scheme requirements. Certificates will be issued for a maximum period of three years.
	GMP+ International grants a temporary acceptance for a maximum period of four months. Certificates will be issued for a maximum period of three years.

4.7. Compliance assessment of Certification Bodies

Scheme	Requirement
	FSSC 22000 requires that the Certification Bodies must hold a valid ISO/IEC 17021-1: 2015 accreditation including ISO/TS 22003:2013 for the Scheme and applicable food chain categories in which it supplies its FSSC 22000 certification services. FSSC 22000 accepted Certification Bodies will be audited annually by the Accreditation Bodies involved. Next to this, the FSSC Integrity Program also undertakes CB office assessments and desk reviews of all information related to final audit reports and certificates.
	<p>Outside The Netherlands: GMP+ International requires that the Certification Bodies comply with the requirements of ISO/IEC17065 and/or ISO/IEC17021 (latest version) + ISO/TS22003 (latest version).</p> <p>GMP+ accepted Certification Bodies will be audited annually by the Accreditation Body involved. GMP+ International performs compliance assessments. These compliance assessments include a certification body/critical location office audit and/or witness audit and/or parallel audit.</p> <hr/> <p>Inside The Netherlands: GMP+ International performs compliance assessments on its Certification Bodies. These compliance assessments include a Certification Body/critical location office audit and/or witness audit and/or parallel audit.</p>



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