



*GMP+ Feed Safety Assurance scheme*

## **General Regulations**

### **GMP+ A1**

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**EN**

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## History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 09-2010	Transfer of the document from PDV to GMP+ International	Entire document	01-01-2011

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# 1 Introduction

## 1.1 General

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) has been developed since 1992. It was managed from 1992 up until 2009 by the Product Board Animal Feed, The Hague, The Netherlands. Since 2010, this scheme is managed by GMP+ International.

It is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

The establishment and development of the scheme was primarily the result of demand from the subsequent links in the animal production chain for better control of feed safety. Another contributory factor was the damage caused by more and less serious contamination incidents.

In the initial phase the demand arose for better differentiation in an increasingly saturated European sales market for animal products. Since 1999, feed & food safety has been a top issue internationally both politically and commercially, because of serious incidents in the feed sector. Because of this, demonstrable assurance of feed safety has become a sales prerequisite.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper assurance of feed safety worldwide is a high priority. Companies must live up to their responsibilities and respond properly and convincingly to the needs of animal production. The GMP+ Feed Safety Assurance scheme is an aid to realise this.

## 1.2 Structure of the GMP+ Feed Safety Assurance scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. A description follows of these:

<b>A</b>		
General (framework) documents		These documents contain the requirements for participation in the certification scheme for companies and certification bodies (framework regulation, the use of logo's, etc.). This series also includes a general list of definitions and abbreviations.
<b>Document</b>	<b>Code</b>	<b>Name</b>
⇒ Standard	GMP+ Axx	e.g. GMP+ A1 <i>General regulations</i>

**B**  
Normative documents

These documents contain the international standards and additional country notes for use by companies with respect to the various feed products and production phases including cultivation and industrial production, treatment and processing, collection, trade, means of transport, storage and transshipment.

**C**  
Certification requirements

These documents contain the Rules of Certification including those for the approval of certification bodies and auditors, the frequency of audits, minimum audit time, assessment criteria, checklists, etc. There is also an explanation of how the supervision by certification bodies is implemented and of how GMP+ International supervises the certification process.

**D**  
Interpretations and accompanying texts

In addition to the above-mentioned normative documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidances with additional information.

All these documents are available through the website of GMP+ International ([www.gmpplus.org](http://www.gmpplus.org)).

The document in the present case is referred to as standard GMP+ A1 *General regulations* and is part of the GMP+ FSA scheme.

### 1.3 Scope and application of this standard

This standard contains the general regulations regarding certification procedure, public register, use of collective logo, duties of participants, and other general requirements. It is applicable to all other standards.

## 2 Terminology

In this General Regulations the definitions apply from the supplementary list of definitions (*GMP+ A2 Definitions and Abbreviations*) and the following terms have the following meanings:

GMP+ International	: GMP+ International B.V., situated in The Hague, The Netherlands (Chamber of Commerce registered under 27364542)
GMP+ FSA scheme	: The GMP+ Feed Safety Assurance scheme of GMP+ International
entrepreneur	: the natural or legal person irrespective of nationality, place of residence or establishment who operates a company as intended in <i>GMP+ A2 Definitions and Abbreviations</i>
participant	: The entrepreneur who has a valid GMP+ FSA certificate
certification criteria	: Assessment and certification criteria as stipulated in the GMP+ FSA scheme
GMP+ agreement	: A written agreement which is entered into between the company and the certification body and in which that which is determined by or by virtue of the GMP+ FSA scheme is declared to be applicable.
GMP+ certificate	: a document issued by the certification body which states that a company is certified for a particular business unit with effect from a particular moment in time under the GMP+ FSA scheme and in which the GMP+ standards and scopes specified which have been assessed and with which there is compliance
certification body	the organisation which is approved for certification based on the GMP+ FSA scheme by GMP+ International
business unit	any unit distinguishable by location or function where activities covered by a GMP+ scope are carried out.

### **3 Application for a GMP+ certificate**

- 3.1 A company which wishes to participate in the GMP+ FSA scheme may apply for a GMP+ certificate from a certification body.
- 3.2 Following an application as intended in the above section, the GMP+ agreement will be entered into in accordance with the certification criteria after which the audit as specified in section 4.1 will be carried out.

## 4 Certification procedure

- 4.1 The certification body will only issue a GMP+ certificate if:  
the result of an initial audit demonstrates, to the satisfaction of the certification body, that all activities in all business units for which a GMP+ standard applies, are in compliance with the GMP+ FSA scheme, and;  
all legally required registrations, approvals and licences are in place;  
a statement has been provided of the managerial relationships within the business, as well as the composition of any other businesses of which the business forms part.
- 4.2. If at one location several companies carry out activities covered by a GMP+ standard/scope, then each of them must hold a GMP+ certificate for these activities.
- 4.3. The GMP+ certificate shall be valid for a period of a maximum of three years (except when in the C3/C6 documents is mentioned different). The period of validity will be extended by a maximum of three years each time it expires unless:
  - a. the agreement between the participant cancels the GMP+ agreement before the expiry of the period of validity of the GMP+ certificate, or
  - b. the reassessment specified in section 4.4 results to a negative outcome, or
  - c. there has to be a measure is implemented as specified in section 9.
- 4.4 Prior to the extension of a GMP+ certificate, the certification body shall carry out a reassessment of continuing compliance with all the requirements of the GMP+ FSA scheme.

## 5 Public register

- 5.1 The certification body shall provide GMP+ International without delay with the name, address and registered office of any business to which they grant a GMP+ certificate, where necessary stating the business units involved as well as specifying the GMP+ standard(s) and additional terms referred to in article 5, third section. Also for each company a telephone number shall be recorded, so the company can be reached immediately in case of emergency (a '24/7'-number)
- 5.2 The certification body shall inform GMP+ International immediately in writing (through the company database) within one month of any change to the information specified in the first section.
- 5.3 The certification body shall inform GMP+ International in writing within 24 hours of the names, addresses and registered offices of businesses whose certificate of approval has been subject a sanction. GMP+ International is empowered to actively inform interested parties accordingly.
- 5.4 GMP+ International shall record the information specified in the sections above in a public register.

## 6 Use of designations and collective logo

- 6.1 The participant is entitled to use the joint logo “GMP+ Feed Safety Assurance”:
  - a. on or near the company unit for which the GMP+ certificate has been given
  - b. on or near products originating in the business unit specified under a. above, provided that trade, storage or transshipment, chartering, transport, processing or treatment or production of those products has been carried out in accordance with the applicable GMP+ standards
  - c. on documents issued by the company as intended under section a.
- 6.2 Anyone using the joint logo is required to report any misuse he becomes aware of to his certification body who in turn will report the infringement to GMP+ International.
- 6.3 Without prejudice to the authority of GMP+ International, each certification body is independently authorised to bring a claim against any person who, without proper entitlement, makes use of a joint logo or any of the associated symbols.
- 6.4 Every user of the joint GMP+ FSA logo is authorised to enter into a joint action or to intervene in a legal action as described in section 6.2.
- 6.5 It is not allowed to make an own logo with references to de GMP+ FSA logo or GMP+ International logo only the own company colours may be used.

## 7 Certification Bodies

- 7.1 An application for approval as a certification body should be submitted to GMP+ International in writing.
- 7.2 GMP+ International, taking account of the rules advised by the International Expert Committee, shall set down the procedure and requirements for approval of a certification body.
- 7.3 Following submission of a fully-completed application form and all the required documents, GMP+ International will make an assessment within a period of at least four weeks and at most six weeks or whether the certification body complies with the requirements specified in the second section.
- 7.4 Approval of a certification body will be granted by GMP+ International in a mutual agreement with a maximum period of duration of four years.
- 7.5 Upon approval, the certification body will enjoy the non-exclusive entitlement to grant GMP+ FSA certificates to businesses in the animal feed sector, under the requirements specified in the agreement mentioned in section 7.4.
- 7.6 The names, addresses and registered offices of the approved certification bodies will be recorded by GMP+ International in a public register.
- 7.7 In the event of changes to its name, address or registered office, or in the event of closure, the certification body is required to inform GMP+ International accordingly one month in advance.
- 7.8 A certification body submitting an application for approval as specified in section 7.1 shall be liable to pay a fee to GMP+ International. Approved certification bodies shall be liable to pay an annual licence fee to GMP+ International, consisting of a fixed amount for each certification body and an amount for each participant certified by the certification body.
- 7.9 A certification body will, when assessing companies and during the auditing of participants, pay strict attention to that which is determined in or by virtue of the GMP+ FSA scheme.
- 7.10 GMP+ International will be authorised to supervise compliance of the certification bodies with the requirements mentioned to in section 7.9 as well at the certification body's office as well as at the certified location.
- 7.11 GMP+ International will pay strict attention in the assessment of certification bodies to that which is determined in the GMP+ FSA scheme.
- 7.12 If the certification body does not meet the requirements of the GMP+ FSA scheme, then GMP+ International may:
  - a. not extend the approval, or
  - b. suspend approval for a period of a maximum of three months, or
  - c. withdraw approval possibly after suspension and make this decision known by decree.

As a consequence of withdrawal the certification body will be excluded for a period of one year from participation in the GMP+ FSA scheme.

- 7.13 During a suspension the suspended certification body should ensure that its tasks are taken over by another certification body.
- 7.14 GMP+ International may subject a certification body to a binding instruction with respect to:
  - a. the submit of a claim against a company which misuses a joint logo as specified in section 6
  - b. the implementation of measures and sanctions.

## 8 Obligations of participants

- 8.1 The participant is obliged to comply with the requirements contained in or arising from the GMP+ FSA scheme and the GMP+ agreement.
- 8.2 The participant is obliged to cooperate fully in auditing and supervision as specified in section 7.
- 8.3 In the event of amendments to the GMP+ FSA scheme participants shall comply with the amended requirements within a period of one year after its publication, unless GMP+ International prescribes a shorter period for urgent reasons.
- 8.4 If the approval of the certification body by whom the participant has been issued a GMP+ certificate is withdrawn, then the participant is obliged within three months to enter into an agreement with another approved certification body. This certification body should within 3 months after closing the agreement carry out an initial audit.

## 9 Measures and sanctions

- 9.1 If the certification body as a result of an audit as specified in section 7 or in some other way establishes that a participant does not comply in fully or partly with what is determined in or by virtue of the GMP+ FSA scheme or the GMP+ agreement, then measures will be taken or sanctions applied to the participant by the certification body.
- 9.2 With respect to the application of measures or sanctions by the certification body, what is determined in or by virtue of the GMP+ FSA scheme will apply.
- 9.3 Applied measures or sanctions may, possibly on request, be reported by or on behalf of the certification body to governmental inspection authorities according tot applicable statutory provisions.
- 9.4 The measures mentioned in the previous sections may consist of:
- a compliance audit; this is an audit check on specific relevant instructions where non-conformities were observed in a previous audit. This is charged to the participant;
  - a repeat audit; this is an audit check aimed at all the instructions in the GMP+ FSA scheme and is charged to the participant;
  - the subjection of the participant to stricter checks during a period of a maximum of a year at the expense of the participant.
- 9.5 The sanctions mentioned in the previous sections may consist of:
- suspension of the GMP+ certificate for a period of a maximum of three months;
  - withdrawal, possibly after suspension, of the GMP+ certificate;
  - publication by GMP+ International of the observed infringement and the measure or sanction applied at the expense of and specifying the name of the infringing participant.
- 9.6 When the sanction in section 9.5, sub b is applied, the participant will be excluded for one year from participation in the GMP+ FSA scheme.
- 9.7 Contrary to that which is determined in section 9.6, exclusion of a participant for a longer period of time is possible if previous non-conformities show that the participant is not quality-minded.
- 9.8 Where it is justified in the judgement of GMP+ International and on the advice of the International Expert Committee, the exclusion set out in the previous sections may also be applied to any other business over which decisive control is obtained or exercised in any way, whether directly or otherwise, by:
- the excluded participant,
  - a legal entity exercising decisive control in any way, whether directly or otherwise, on the excluded business, currently or has done so during the period of certification, or
  - a natural person exercising decisive control in any way, whether directly or otherwise, on the excluded business, currently or during the period of certification.

9.9 Findings on the basis of audits and supervision as specified in section 8.2 may, whether or not on request, be reported by GMP+ International or the certification body to agencies which are tasked by or on behalf of the governmental authorities with the implementation of statutory provisions.

## 10 Arbitration

- 10.1 The disputes procedure published as GMP+ A4 *Disputes Procedure* shall be applicable in disputes between certification bodies and participants regarding the exercise by the certification body of its powers by virtue of the applicable stipulations of the GMP+ FSA scheme, as a supplement to the certification body's own disputes procedure.
- 10.2 The disputes procedure published as GMP+ A4 *Disputes Procedure* is also applicable in the event of disputes of a participant and GMP+ International.

## 11 Temporary provisions

- 11.1 GMP+ International may in exceptional situations or in the event of an emergency situation related to those subjects which are regulated in the GMP+ FSA scheme, draw up short-term additional provisions by way of an executive decree.
- 11.2 The participants are obliged to comply with and/or implement the temporary additional provisions referred to in section 11.1.
- 11.3 GMP+ International may:
  - a. in a case which is eligible provide full or partial exemption to what is determined in or by virtue of the GMP+ FSA scheme and associate such an exemption with requirements or conditions whereby in the event of non-compliance, late compliance or incomplete compliance, the exemption in question will be considered to have been retracted, and/or
  - b. withdraw an exemption which has been given.