

GMP+ Feed Safety Assurance scheme

Minimum Requirements EWS

BA

GMP+ BA5

5

EN

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History of the document

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0.0 / 09-2010	Transfer of the document from PDV to GMP+ International and some restructuring.	Entire document	01-01-2011
	Expansion report requirement.	Section 6	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 whole animal 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:

A
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
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.

These documents are divided in several subgroups, with a code and a name

Document	Code	Name
⇒ Standard	GMP+ Bxx	
⇒ Appendix	GMP+ BAxx	e.g. GMP+ BA5 <i>Minimum Requirements EWS</i>
⇒ Country Note	GMP+ BCNxx	

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 standard documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidelines with additional information.

All these documents are available through the website of GMP+ International (www.gmpplus.org).

The document in the present case is referred to as appendix GMP+ BA05 *Minimum Requirements EWS* and is part of the GMP+ FSA scheme. It has a structure of its own.

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B segment of the GMP+ FSA scheme. If there is a reference to such an GMP+ BAxx-appendix, then it applies within the framework of this standard. GMP+ BAxx-appendices are indicated as such.

Next to this, also reference to a number of other appendices may be made. These appendices are in that case only part of this document, and are attached to it. To indicate them, only the word 'appendix' is used.

2 Early Warning System

The objective of an Early Warning and Response System (EWS) is the early detection and reporting of irregularities in (raw materials for use in) animal feeds¹ and to allow rapid response and communication throughout the animal food production chain, with the aim of preventing or limiting the harmful consequences for man, animals and the environment.

EWS is therefore an addition to (preventive) quality assurance of the GMP+ Feed Safety Assurance Scheme.

Various GMP+ standards state that a participant must draw up a documented procedure for the timely (and early) warning and handling of signals which indicate that the safety of a product is not in accordance with the legal standards or with the standards laid down in GMP+ BA1 *Product Standards* and which may lead to damage to the customers in the chain. These signals will be assessed on this basis and, if desired, control measures will be taken to prevent or to control the hazard.

If there is a potential hazard which can not be controlled by the participant in question and which may also cause damage to others then the participant is obliged to inform GMP+ International. This should be done in accordance with this appendix GMP+ BA5 *Minimum requirements EWS*.

3 What to report?

All non-conformities concerning legal/GMP+ standards (See BA1 *Product Standards*) should be reported, but also other GMP+ related violations.

Examples of reports:

- a. Matters directly observable in the product (colour, odour - for example a strong odour of petrol).
- b. Analytical results falling outside standards or specifications (exceeding agreed action limits, standards or tolerances, or extremely high values in the absence of standards).
- c. Abnormal illness/death of animals.
- d. Rejected consignments of goods.
- e. Unusual or inexplicable occurrences.

4 When to report?

The reporting party decides whether or not the observation needs to be reported to the EWS Reporting Point.

¹ Definition animal feed in accordance with the statutory legislation

Where a non-conformity can not be rectified internally by means of (control) measures, or where the consequences threaten to pass beyond the bounds of the business, the non-conformity must be reported directly to the EWS Reporting Point.

GMP+ International also requests a report if the non-conformity can be fixed or controlled by the party involved. This is the case when information on the non-conformity found, can be beneficial for other GMP+ certified companies. If you have information on feed safety issues on, for example, a feed material from a certain origin, you can inform GMP+ International so all GMP+ certified companies can be alerted on that issue. You will be informed on these types of information as well if any non-conformities occur at other GMP+ members. If the non-conformity found is specific for your own production method / location, there is no need to inform GMP+ International.

To help you decide whether or not you need to report, you can use the decision tree in appendix 1.

Reporting on the basis of analysis results

When a report is made to GMP+ International on the basis of laboratory result (for example a standard infringement) then account should be taken of:

- a. Measuring inaccuracies
- b. The analysis methods to be used for confirmation (preferably on the basis of well-known, accepted methods)
- c. repeatability / reproducibility (for example in the event of fluorine determinations in molasses this is moderate)

5 Who should report?

A number of organisations may report within the framework of the EWS, for example GMP+ certified feed companies and laboratories. Sector organisations, live-stock holders, arable farmers, inspection agencies, dairy, meat and egg processors, the foodstuffs industry and, for example, veterinarians and agricultural consultants may also make reports.

6 How to report?

When it is decided to make the report then the reporter must provide as much information as possible about the signal to the EWS Reporting Point. The reporter should fill out the Observation Reporting Form (appendix 2) to make sure that every part of information is included in the report.

You can fill out the form by hand, but preferably digitally. A Word version of this form is also published on the GMP+ International website.

Once you've filled out the form, you can send it to the Central EWS reporting centre GMP+ International. If you have any analysis supporting your report, please send them along.

Central EWS reporting centre GMP+ International:
GMP+ International

During ordinary business hours (in the Netherlands):

Contact person: Mr J. den Hartog or Mrs S. de Bruin
Tel. + 31 (0)70 3708670
Fax. + 31 (0)70 3708671
Mob. +31 (0)6 53833190
Mail: ews@gmpplus.org

Outside ordinary business hours (available 24/7):

Contact person: Mr J. den Hartog
Mob. +31 6 53833190
Private + 31 180 436224
Mail: ews@gmpplus.org

EWS team

Mr J. den Hartog (Managing Director of GMP+ International)
Mrs S. de Bruin (Coordinator EWS of GMP+ International)

NOTE:

An EWS report to GMP+ International does not substitute a report to the local authorities. If the non-conformity is a legal non-conformity, you will also need to report to the authorities in your country.

7 What will be done with the report?

GMP+ International is obliged to handle the data in confidence:

- a. All reports will be treated in confidence. No business-specific information will be provided to third parties without the permission of the reporting body.
- b. GMP+ International will allocate an anonymous serial number to the report so that the report may be discussed anonymously (where possible).
- c. GMP+ International will issue no information to third parties in the form of an EWS report without prior consultation with the relevant EWS team for the feed sector, the reporter and any third parties involved.
- d. The information provided will be available only to GMP+ International and the EWS team for the feed sector.
- e. The EWS registers are accessible only to GMP+ International. Third parties will only have access with the permission of the managing director of the GMP+ International.

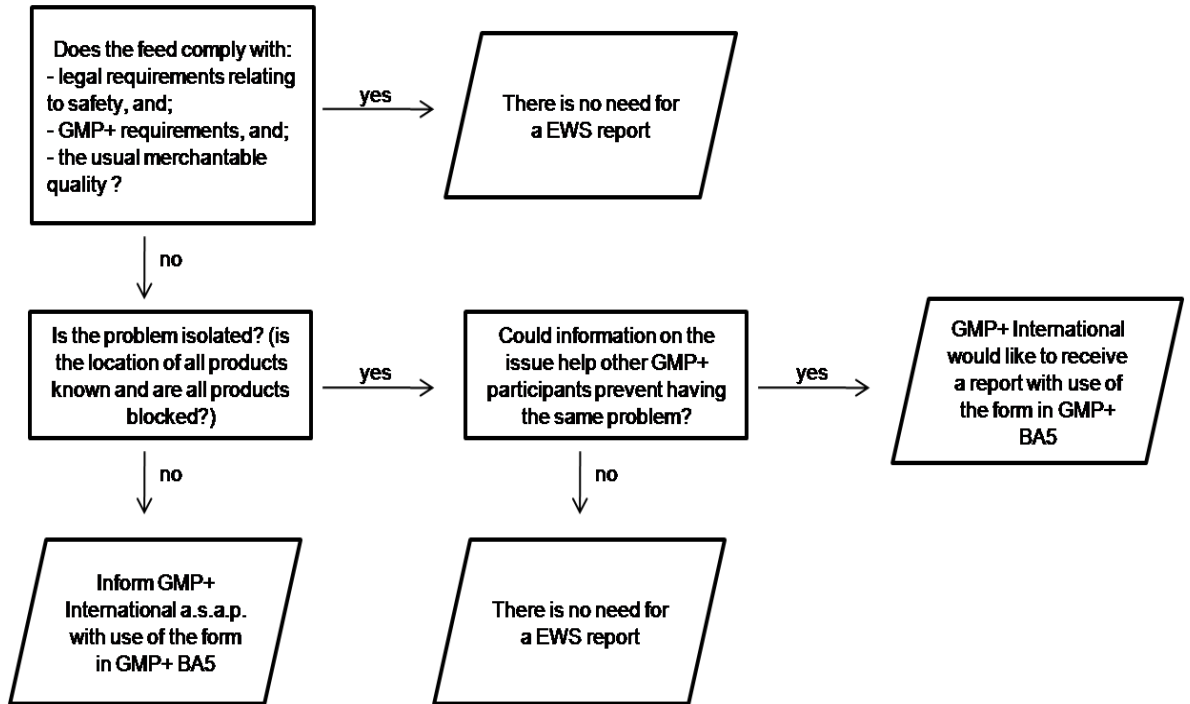
The report will be assessed by the GMP+ International EWS Internal feed team, and discussed if necessary within the feed sector with the EWS team for the feed sector.

After assessing the report, there are three possible outcomes:

- a. EWS alert – if the situation is urgent and not (completely) under control, a EWS message will be published on the GMP+ International website. This warns all GMP+ certified companies to take appropriate measures.
- b. General report within the framework of the EWS procedure – if the situation is under control, but it is useful to inform the other GMP+ members about what happened. With this information, the other GMP+ members can take measures in their own process.
- c. No publication – the situation is under control and there is no need for informing the GMP+ certified companies (when the situation is based on an incident).

The reporting party will be informed of the outcome of the assessment. In the case of a or b, the reporting party will also receive a draft on the message for approval.

APPENDIX 1: Decision tree



Appendix 2: OBSERVATION REPORTING FORM

Observation Report Form		No.:
Date and time of the observation:	
Reported by: (contact person, organisation)	Code: (anonymous)
Telephone nr:	
E-mail address:	
Nature of report:	<p>.....</p> <p>.....</p> <p>.....</p> <ul style="list-style-type: none"> • What does the observation refer to? • What has been observed, and what is the context of the problem? • What is the (probable) cause date? • What products or raw materials are involved? • What anomalies, contaminants or hazards have been observed? • Has there been an analysis (screening or confirmation) • By whom? (accredited lab.) • How was the sample taken? • Which analysis method was used? (bundle method) • What is the possible cause, is this confirmed or only suspected? • What other information is available? 	
Origin of the goods: / Explanation relating to supplier of the goods:	<p>.....</p> <p>.....</p> <ul style="list-style-type: none"> • What is the origin of the goods? • In the case of sea transport: Is the name of the vessel known? If so, which? • Quantity/size of the batch involved? • Is the batch part of a larger unit and if so is it known how big this is and where the other products are? • Where is the reported batch at this time? 	
Products or raw materials already been delivered or blocked	<p>.....</p> <p>.....</p> <p>(Information required to implement isolation of the relevant links in the supply chain)</p>	
What measures have already been taken?	<p>Measure 1:.....</p> <p>.....</p> <p>Measure 2:.....</p> <p>.....</p>	

Inform those involved.	Have the customers already been informed? Yes / No These are:
	Has the supplier already been informed? Yes / No This is
What measures have been taken by the reporter in the short term?	Measure 1:..... Measure 2:.....
Agreed follow-up action: (Any follow-up action agreed between the reporter and the staff-member at the reporting centre; when (after what period) will the reporter be called back?)
Has there been discussion with others? If so, with whom?
Date: Signature:

Fax + 31 (0)70 3708671
Mail ews@gmpplus.org