GMP+ International

FAQ GMP+ BA5 (EWS)

GMP+ D 3.11

Version EN: 1 march 2017

GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

TABLE OF CONTENTS

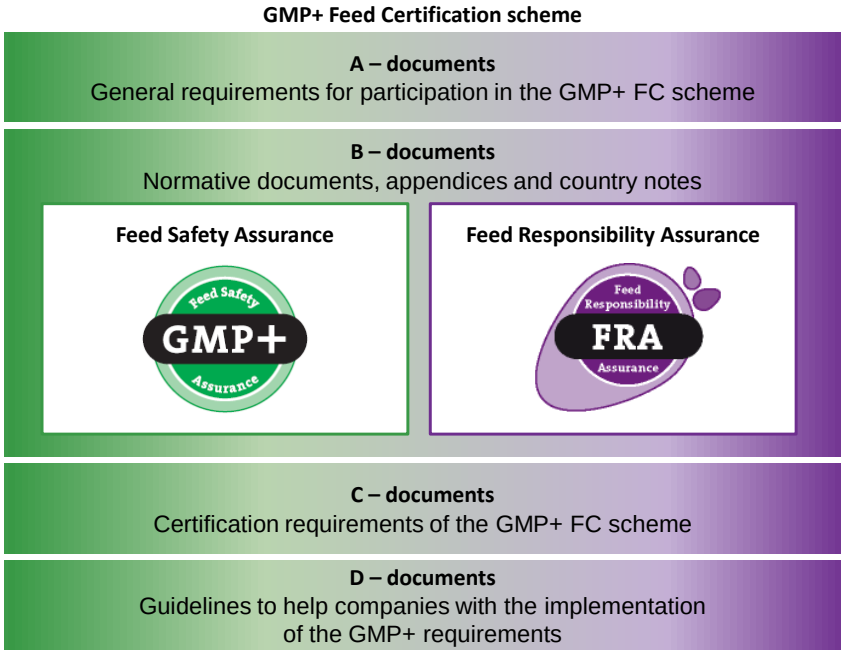
1 Introduction

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.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

The certification scheme consists of various standard documents, subdivided into an A, B and C section.

In addition, there are so-called D-documents. These are not normative documents. D-documents are intended as additional information or explanation about the scheme documents.



This FAQ was drawn up based on the GMP+ BA5 document *Minimum requirements EWS*. The BA5 document contains the requirements for the early detection and notification of irregularities regarding the safety of (raw materials for use in) feed and allowing for fast response and communication throughout the production chain of feed, with the purpose of preventing or limiting harmful consequences for people, animals and the environment.

If your question is not in the list, you can always contact GMP+ International via the contact page on the GMP+ website. Where necessary, this FAQ can be supplemented.

2 Early Warning Systeem (EWS)

2.1 Why an Early Warning System (EWS) within the GMP+ Feed Safety Certification module?

Feed companies must identify every part of their production process that is essential for feed safety. As soon as they have done this, they must make sure that adequate control and enforcement mechanisms are applied and must continuously update and evaluate this security process.

In the end, feed safety is humans work. Things can always go wrong. In that case, the Early Warning System (EWS) forms an important safety net to limit the extent or to reduce a (potential) problem at an early stage with the help of adequate measures.

The purpose of EWS is to report irregularities regarding feed safety and to allow for a fast response and fast communication about (new) hazards and risks throughout the complete feed production chain for feed, with the purpose of preventing or limiting the harmful consequences for humans, animals and the environment.

3 What to notify

3.1 What must I notify?

All observations and signals that feed is unsafe or forms a risk for subsequent links in the feed or food chain, whether or not based on legal and / or GMP+ limits must be notified.

3.2 Why is there an exception for Salmonella?

Salmonella in feed is fairly simple to eliminate. If feed is subjected to a heat treatment or another treatment that (demonstrably) eliminates the salmonella bacteria, there is a conforming product and an EWS notification to GMP+ International and the certification body is not required.

3.3 I submitted an EWS notification to GMP+ International and my certification body. Do I need to do anything else?

Yes, see chapter 2 in GMP+ BA5 *Minimum requirements EWS*.
If legally required, you must also notify the incident to the competent authority of the country in which you are located.

In addition to notifying, you must also retrieve the origin and destination of unsafe batches, block them or have them blocked, inform the suppliers and customers involved, identify the cause of contamination and take corrective measures.

4 When to notify

4.1 When must I submit an EWS notification?

You must submit a notification within 12 hours after confirmation of the contamination, or, if you have no confirmation analysis carried out, within 12 hours after detection of the contamination.

This period of 12 hours are consecutive hours and take effect on the moment you learn of the contamination. This can, for instance, be when you receive the analysis certificate or a phone call from the laboratory that carried out the analysis or from your supplier.

Participants must act responsibly in notifying GMP+ International and the certification body. Notifying within 12 hours after detection or confirmation becomes more important when the situation is not under control (meaning the contaminated batch is not fully blocked and/or recalled and/or the traceability is not clear). It is up to each participant to assess whether the situation is under control and to demonstrate this. Your GMP+ auditor should check on this in a reasonable matter and decide if a differentiation of the 12 hours is acceptable.

4.2 What is meant by a confirmation analysis?

A confirmation analysis is a second analysis (also referred to as: counter analysis) of the same sample in which previously a too high level of an undesirable substance was detected. You can carry out a confirmation analysis to be sure whether or not there is contamination.

The result of the confirmation analysis, in principle, replaces the result of the first analysis. See 4.4 for the requirement associated with this.

A different laboratory than the one that carried out the first analysis can carry out the confirmation analysis.

4.3 Am I required to carry out a confirmation analysis?

No, you are not required to carry out a confirmation analysis. You are free in your decision on whether or not to have a confirmation analysis carried out. Please also see 4.1, When must I submit an EWS notification?

No deadline has been set within which you must carry out a confirmation analysis. This is your own responsibility.

4.4 The result of my 1st analysis is positive (above the maximum permitted limit) and the result of the confirmation analysis is negative (below the maximum permitted limit). Do I have to submit an EWS notification?

No, in this case, an EWS notification is not required, provided that you can motivate why the result of the confirmation analysis is more reliable than the result of the first analysis. If you have no motivation and cannot explain the difference between the two analysis results, you will have to submit an EWS notification. After all, it means that there is a situation in which you are not sure whether or not the product you are marketing is a safe product. The product could pose a risk for the safety of people, animals or the environment.

4.5 What if the analysis result, after deduction of the measurement uncertainty, falls under the maximum permitted limit? Do I have to submit an EWS notification then?

Yes. In the determination of whether or not you must submit a notification, you must assume the measured analysis result. You cannot deduct the measuring uncertainty.

Feed companies have the care duty of delivering safe products (General Food Regulation 178/2002). If the measurement uncertainty were to be deducted from the measured value, measures (such as notifying, blocking product, informing customers etc, also see the answer to question 3.3) would only be taken when it is certain the product does not meet the requirements. To prevent any damage in the chain, it is very important for measures to be taken even if it isn't 100% sure that the feed is unsafe.

You cannot sell any products that exceed the maximum permitted limit and you are responsible in determining whether or not a notification is necessary.

4.6 As trading company, I sometimes deliver non-GMP+ assured feed. Must I inform GMP+ International if this feed is unsafe?

No, you are only required to inform GMP+ International and the certification body (and competent authority) when the non-conforming product is part of the scope of your GMP+ certificate. You are not required to inform GMP+ International about unsafe non-GMP+ assured feed. However, it can be interesting for GMP+ International to receive such information about the feed market.

5 Who notifies

5.1 Who must notify?

All participants that have or had a contaminated batch of feed in their possession or that are involved in the delivery, receipt, storage or processing of a contaminated batch of feed are required to submit a notification in accordance with the requirements in the GMP+ BA5 document. These are GMP+ certified producers and traders in feed (including pet food).

5.2 I am producer of, only, pet feed. Does the EWS notification obligation also apply to me?

Yes. Although the GMP+ B8 standard does not refer to GMP+ BA5 *Minimum requirements EWS,* GMP+ A1, art 8.1 imposes this obligation on all GMP+ participants. This means that the EWS notification obligation also applies to producers and trading companies of pet food. This is logical, since ingredients processed in pet food can also end up in feed for professionally kept food producing animals.

5.3 Do I have to inform my certification body or will GMP+ International do this?

As GMP+ participant, you are responsible for informing your certification body. GMP+ International does not take this responsibility off your hands.

6 How to notify

6.1 How to submit an EWS notification?

You can submit an EWS notification by filling out and submitting the EWS notification form. There are two notification forms: a paper version and a digital (abridged) notification form. The paper form is available in Annex 1 of GMP+ BA5 or here on the GMP+ Portal. The digital notification form is available here. You can send the filled-out paper form to ews@gmpplus.org.

6.2 What should the notification contain in any case?

In any case, the first report must contain the minimum, indispensable, information that allow for the first assessment of the incident. This includes at least information about:
- the notifying company: GMP+ registration number, contact information
- the contaminated product
- the contamination
- the location where the product is situated
- the supplier(s) and buyer(s) involved

6.3 Instead of the EWS notification form, can I also use the notification form of the competent authority to inform GMP+ International and the certification body?

Yes, you can. In that case, you don't have to fill out an EWS notification form. See chapter 2 in GMP+ BA5 *Minimum requirements EWS*.

7 Assessment of the notification

7.1 What does GMP+ International do with my EWS notification?

GMP+ International receives, registers, assesses and evaluates EWS notifications and where possible, alerts GMP+ participants to a feed safety issue in the market.

Central questions in the assessments of whether or not the situation is under control:

- Is the contaminated batch fully identified (traced)?
- Is the contaminated batch fully blocked or is it being recalled?

When the situation is urgent and not (completely) under control, an EWS warning will be published on the GMP+ International website and participants will be alerted by means of a newsletter, specifying the product involved (generic name), the undesirable substance(s) and detected level(s) reported, as well as the country of origin. **Details of the company involved are never published.**

These warnings help participants take appropriate measures for prevention of controlling hazards. When the situation is under control, an EWS warning can also be published to inform participants of possible risks or good practices. With this information, the companies can take appropriate measures.

GMP+ International will not publish EWS warnings if the situation is under control, the feed safety is not being compromised and the notification does not provide relevant information that can be useful to other participants.

EWS notifications form a source of inspiration for GMP+ International to emphasize potential risks in its communication and it can lead to improvements of the GMP+ FSA module (the Aflatoxin B1 protocol is an example of this), Feed Support Products (for instance quick scans and adjustment of risk assessments), the certification and conformity requirements, risk communication and other activities.

7.2 When can I expect a response of GMP+ International to my notification?

Within 12 hours after receipt of your notification, GMP+ International will assess your notification and contact you (by phone or e-mail). You will then be informed about the outcome of the assessment. If publication of an EWS warning is in order, (see question 7.1), this publication shall always first be communicated with the notifying body before publication.

8 Confidentiality

8.1 What information falls under ‘confidential information’?

All information that could be traced back to the GMP+ participant(s) involved in the incident. For instance the GMP+ registration number, the company name and the name of the seagoing vessels involved in the incident will not be communicated.

GMP+ International
Braillelaan 9
2289 CL Rijswijk
The Netherlands
t. +31 (0)70 – 307 41 20 (Office)
+31 (0)70 – 307 41 44 (Help Desk)
e. info@gmpplus.org