GMP+ Feed Certification scheme

BA

Module: Feed Safety Assurance

GMP+ BA5
Minimum Requirements EWS

5

Version: 1st of March 2017

EN

GMP+ International
info@gmpplus.org
www.gmpplus.org

Feed for Food

History of the document

Revision no. - Date of approval	Amendment	Concerns	Final implementation date
0.0 / 09-2010	Previous versions can be found in History		01-01-2011
0.1 / 09-2011			01-01-2012
0.2 / 2012			01-03-2013
1.0 / 06-2014	Editorial changes: All editorial changes are put together in a factsheet	Entire Document	01-08-2014
	A thorough editorial amendment Introduction of obligation of notification of exceeding of maximum permitted levels in all cases when it concerns GMP+ certified feed. The EWS notification form has been redesigned.	Entire document	01-08-2014
1.1 / 06-2014	Rename of GMP+ BA1 *Specific Feed Safety Limits*	Entire document	01-01-2015
1.2 / 09-2016	Modified items : - stricter EWS notification obligation - notification within 12 hours - renewed decision tree - simplified notification form - roles EWS identified and clarified - confidentiality of information	Entire document	01-03-2017

Editorial note:
All changes in this version of the document are made visible. This is how you can recognize:
- New text
- ~~Old text~~
The changes must be implemented by the participant latest at the final implementation date.

INDEX

1 Introduction

1.1 General

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 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 module, such as requirements for the feed safety management system, HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

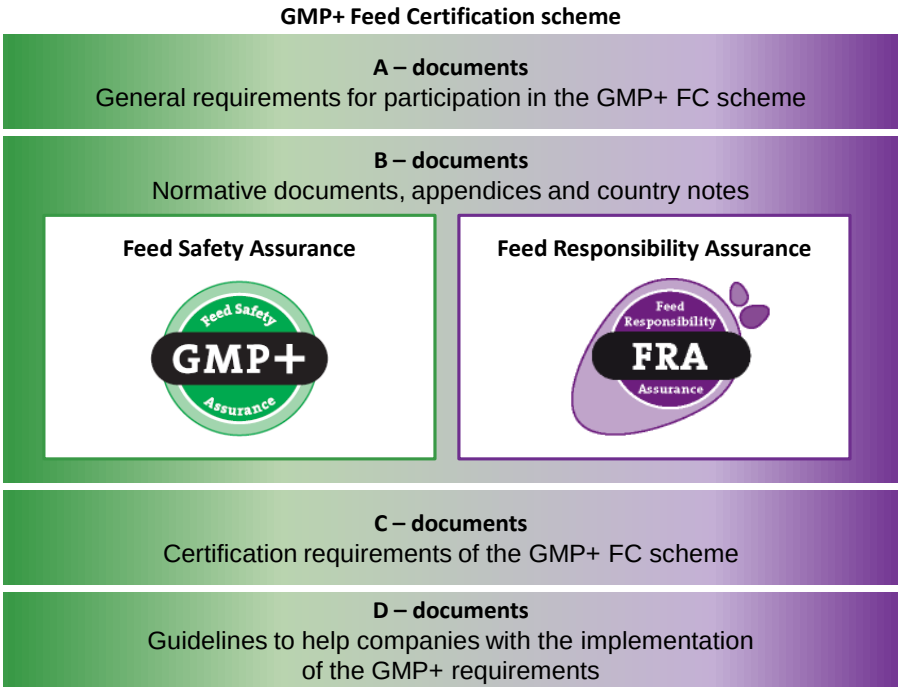
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance.

Together with the GMP+ partners, GMP+ International transparently sets clear requirements to guarantee feed safety & responsibility. Certification bodies are able to carry out GMP+ certification independently.

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.

1.2 Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series.The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:



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

This document is referred to as GMP+ BA5 *Minimum Requirements EWS* and is part of the GMP+ FSA module.

2 Early Warning System

The objective of an Early Warning and Response System (EWS) is the early detection and notification of irregularities regarding feed safety in (raw materials for use in) feed and to allow rapid response and communication throughout the animal feed 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) feed safety assurance of the GMP+ Feed Safety Assurance module of the GMP+ Feed Certification scheme.

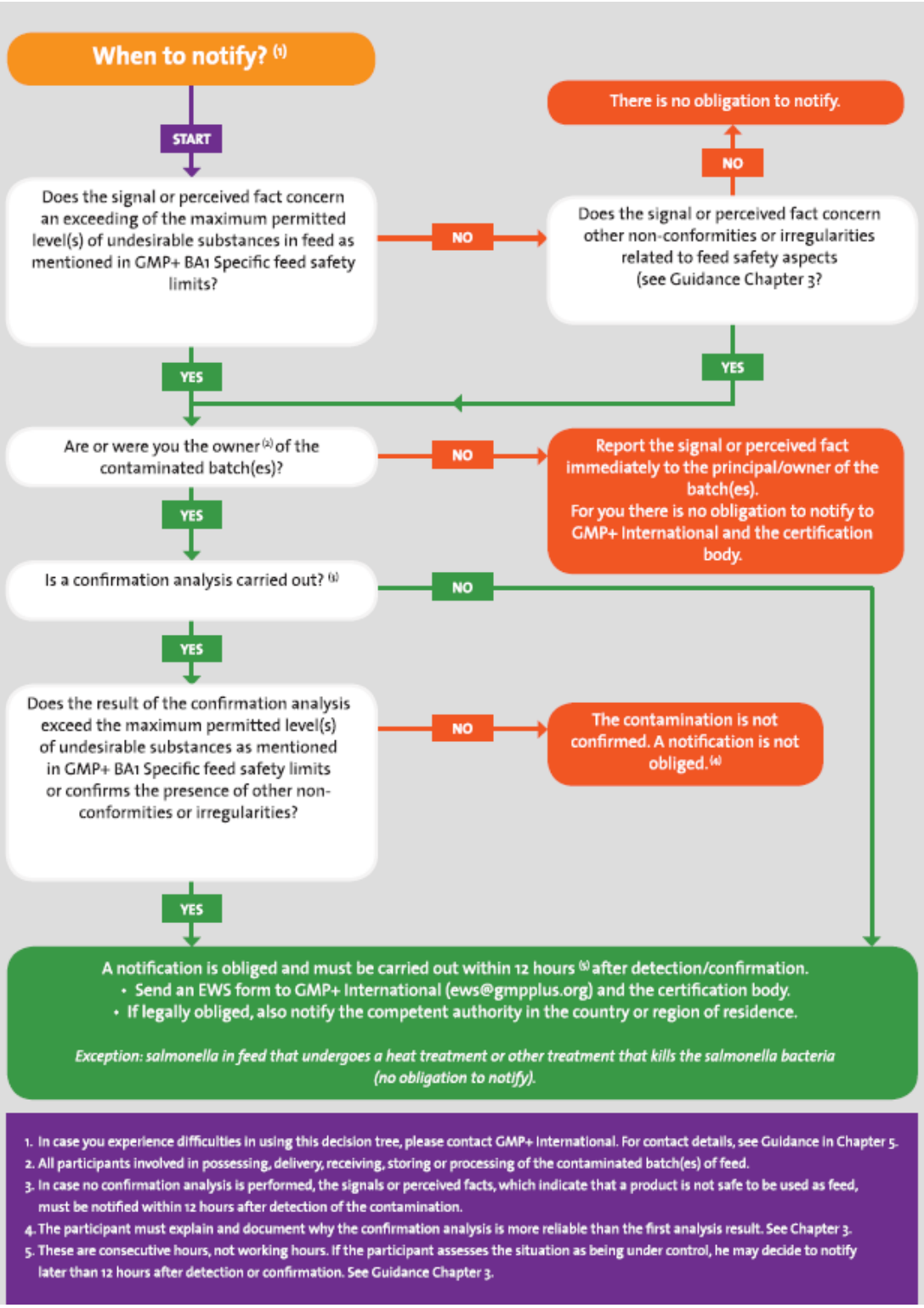
Various GMP+ B standards state that a participant must draw up a documented procedure for the timely (and early) warning and handling of signals or perceived facts which indicate that ~~the safety of~~ a product is not ~~in compliance with the legal product standards or with the product standards laid down in GMP+ BA1 *Specific Feed Safety Limits*.~~ safe to be used as feed. These signals or perceived ~~exceeding of the permitted level(s)~~ facts will be assessed ~~on this basis~~ and, if desired, control measures will be taken to prevent or to control the hazard.

A participant needs to notify GMP+ International and the certification body in accordance with this GMP+ BA5 *Minimum Requirements EWS*. The participant can use the decision tree in Figure 1 to determine when to notify.

Damage control is a shared responsibility. But each involved relation does have its own role:

- The primary focus of the certified company is to trace back and forward the origin and destination of contaminated batches, to inform involved suppliers, customers, GMP+ International and the certification body, to identify the source of contamination and investigate the cause of contamination and take corrective actions.
- GMP+ International assesses EWS notifications and, if it is necessary, alerts GMP+ FSA participants about the occurrence of a contamination in the market.
- The primary focus of the certification body is to monitor the application of the appropriate actions and measures by the involved feed company.

Figure 1 Decision tree EWS notification



If it is a legal obligation, the participant needs also to notify the ~~non-conformity~~ signal or perceived fact to the competent authority in the country or region of residence. In each case the participant should fill in the *EWS Notification Form* (Annex ~~2~~ 1 or the digital form on the GMP+ Portal) or otherwise use the notification form prescribed by the competent authority in question.

3 ~~What~~ When to notify?

~~In the following cases, the~~ The participant is obliged to notify GMP+ International and the certification body in case of signals or perceived facts that a feed has a negative effect on the feed – and/or food safety, such as:

a. an exceeding of the maximum permitted level(s) of undesirable substances in feed as mentioned in legislation or/and GMP+ BA1 *Specific feed safety limits*, irrespective of the measurement uncertainty, or
b. other non-conformities or irregularities related to feed safety aspects (others than complaints), not controlled by the participant, which could have consequences for other companies.

Guidance

Obligation to notify

A participant is obliged to notify GMP+ International and the certification body only when the non-conforming feed is included in the scope of his GMP+ certificate. If the non-conformity found concerns non-GMP+ feed, there is no obligation to notify. However, it may be interesting for GMP+ International to receive such information.

Measurement uncertainty

When a notification is made to GMP+ International on the basis of laboratory result then no account should be taken of the measurement uncertainty.

Informing customers

In case the non-conforming feed has been delivered to customers, the participant should inform those customers.

Examples of non-conformities or irregularities as mentioned under b:

a. Matters directly observable in the product (color, odor - for example a strong odor 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. Signals or suspicions of increasing levels of undesirable substances in certain region.
d. Abnormal illness/death of animals.
e. Unusual or inexplicable occurrences.

~~In the following cases, the participant may notify GMP+ International and the certification body:~~

~~b. other non-conformities or irregularities related to feed safety aspects (others than complaints), not controlled by the participant, which could have consequences for other companies.~~

~~*Guidance*~~

~~*A participant is obliged to notify GMP+ International and the certification body only when the non-conforming feed is included in the scope of his GMP+ certificate. If the non-conformity found concerns non-GMP+ feed, there is no obligation to notify. However, it may be interesting for GMP+ International to receive such information.*~~

~~*Guidance*~~
~~*Examples of non-conformities or irregularities as mentioned under b:*~~
~~*a. Matters directly observable in the product (color, odor - for example a strong odor 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. Signals or suspicions of increasing levels of undesirable substances in certain region.*~~
~~*d. Abnormal illness/death of animals.*~~
~~*e. Unusual or inexplicable occurrences.*~~

~~When to notify?~~

In case of signals or perceived facts that a feed has a negative effect on the feed – and/or food safety as mentioned ~~before~~, the notification must be carried out within 12 hours after confirmation of the contamination. In case the contra-analysis does not confirm the contamination, the participant must explain why the contra-analysis is more reliable than the first analysis result. This explanation must be documented.

In case no confirmation analysis is performed, the notification must be carried out within 12 hours after detection of the contamination.

It is the responsibility of each participant to assess whether the situation is under control or not. The assessment must be motivated and documented.

Guidance
Damage control is a shared responsibility, but in the end it is the responsibility of each individual participant to put this into practice.
Notifying within 12 hours after detection or confirmation becomes more important when the situation is not under control, meaning:
a) the contaminated batch in question is not fully blocked and/or recalled, and
b) the traceability is not clear.

If the participant assesses the situation as being under control, he may decide to notify later than 12 hours after detection or confirmation.

~~All other perceived non-conformities and irregularities as mentioned before shall be notified as soon as possible.~~

~~*Guidance*~~
~~*When a notification 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)*~~

~~*Based on this assessment, the participant decides whether the analyses obtained are useful for drawing conclusions regarding conformity of the product.*~~

4 Who should notify?

All participants involved in possessing, delivery, receiving, storing or processing of contaminated batches of feed are obliged to notify according to this document. This also includes intermediate ~~the~~ (paper) traders.

In the event of irregularities in the feed at a participant which provides service to third parties (laboratories, storage and transshipment companies, freight brokers and transport companies), this will be immediately reported to the owner of the feed as well as to the competent authority, if it is a legal obligation.

5 How to notify?

The participant should fill in the EWS Notification Form (Annex 1 ~~2~~ or the digital form on the GMP+ Portal) to make sure that every relevant part of information is included in the notification.

Guidance
The timely and complete notification of ~~exceedance of the maximum permitted level(s) of undesirable substances in feed~~ *signals or perceived facts that a feed has a negative effect on the feed – and/or food safety is of great importance. In practice, it may sometimes be difficult to fill out the EWS Notification Form completely at the first notification because not all necessary details are available. The first notification should in that case contain at least the details that are indispensable for a proper first assessment of the incident. Subsequently, the participant must supplement and submit the missing details* ~~*as soon as possible.*~~ *directly after receipt.*

A Word version of this form is also published on the GMP+ International Portal. The participant has to send the completed form to GMP+ International, the certification body (and the competent authority if applicable) by email ~~or fax~~ or digitally via the GMP+ Portal. In case of urgency a 24/7 phone number is available.

Guidance
Please use the EWS Notification Form for making a notification of signals or perceived facts that a feed has a negative effect on the feed – and/or food safety.

EWS notification point GMP+ International:

During ordinary business hours (in the Netherlands):
GMP+ International
Tel. + 31 (0)70 307 41 20
~~Fax. + 31 (0)70 307 41 30~~
Mob. ~~+31 (0)6 53 83 31 90~~ + 31 (0)6 46 07 60 36
Mail: ews@gmpplus.org

Outside ordinary business hours (available 24/7):
~~Contact person: Mr. J. den Hartog~~
Mob. ~~+31 (0)6 53 83 31 90~~ + 31 (0)6 46 07 60 36 and
Mail: ews@gmpplus.org

~~**EWS team**~~
~~Mrs. L. D. Alpaca Carnero (Project Manager)~~
~~Mrs. D. Brkulic (Project Advisor)~~
~~Mr. J. van der Kloet (Project Coordinator)~~

6 Assessment of the notification

~~GMP+ International will handle the data confidentially taking into account legal obligations for all parties involved. No business-specific information will be provided to third parties without the permission of the notifying participant~~.

The notification will be assessed by ~~the~~ GMP+ International and discussed, if necessary, anonymously with external experts.

After assessing the notification, the next outcomes are possible:

a. Publication of an EWS warning
   If the situation is urgent and not (completely) under control, an EWS warning will be published on the GMP+ International website. This alerts other participants to take appropriate measures in order to prevent and/or control the hazard.
   Also, an EWS warning will be published if the situation is under control, but it is useful to inform the other participants about what risks can occur. With this information, the other participants can take measures in their own process.

b. No publication
   The situation is under control and there is no need for informing the other participants ~~(when the situation is based on an incident)~~.

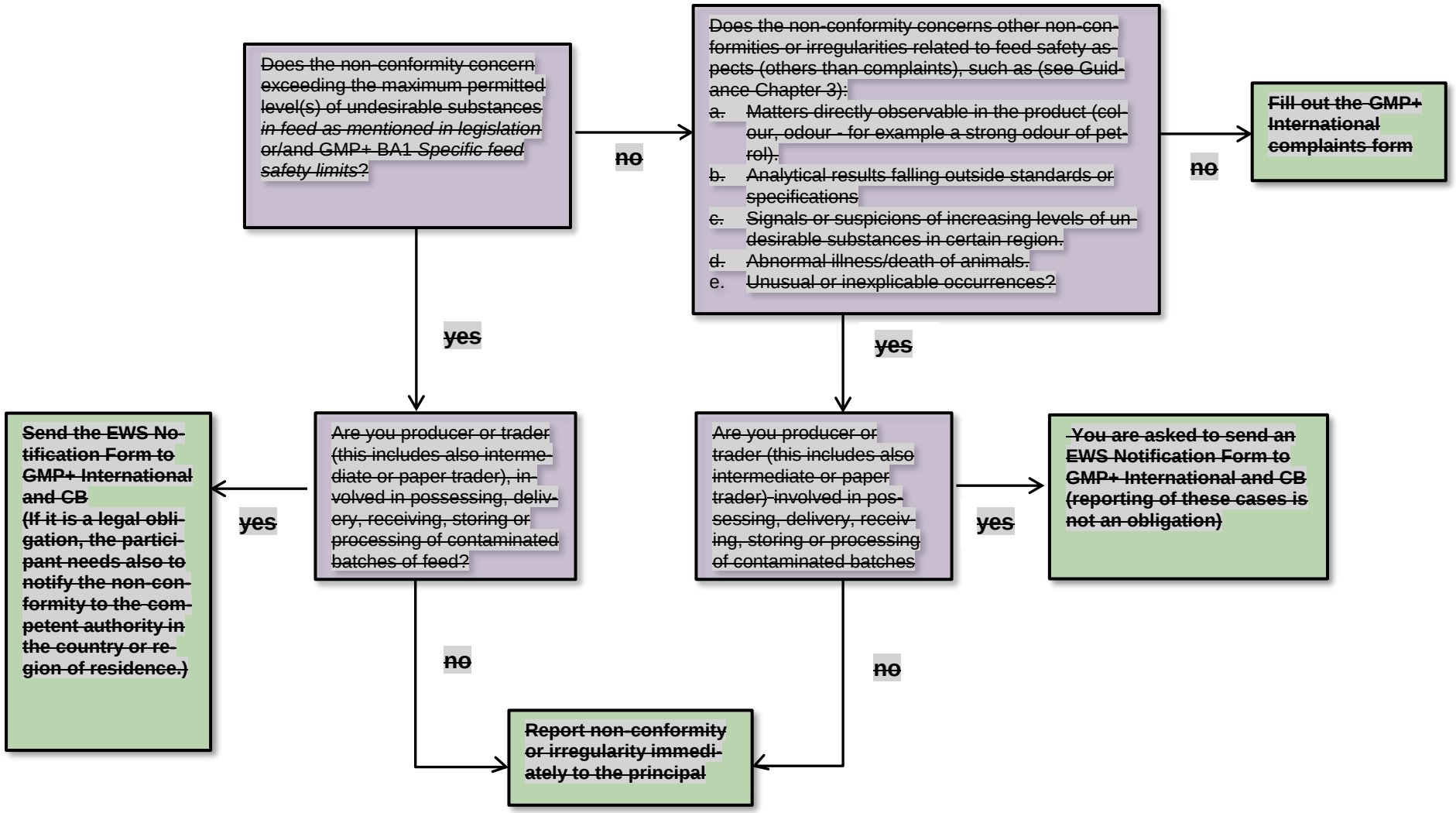
The notifying participant will be informed about the outcome of the assessment. In the case of publication, the notifying participant will also receive a draft of the message for approval, before publishing.

7 Confidentiality of information

GMP+ International shall not disclose any confidential information regarding a company (or certification body) to third parties, unless:

a. companies, covered by a quality assurance system other than the GMP+ FSA module, are involved in an incident, and GMP+ International has an interchangeability agreement with that system and that system has a similar privacy policy, then GMP+ International will communicate relevant information regarding the incident to the system concerned.
b. a breach of statutory requirements is detected on the basis of audits or EWS notifications, then GMP+ International is entitled (see GMP+ A1, section 9.7) to report these findings to the concerned certification body as well as to the competent authority.

ANNEX 1: Decision tree



ANNEX ~~2~~ 1: EWS Notification Form GMP+ Feed Safety Assurance

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. Input is required for grey shaded fields, if applicable.

Guidance
The timely and complete notification of ~~exceedance of the maximum permitted level(s) of undesirable substances in *feed*~~ *signals or perceived facts that a feed has a negative effect on the feed – and/or food safety is of great importance. In practice, it may sometimes be difficult to fill out the EWS Notification Form completely at the first notification because not all necessary details are available. The first notification should in that case contain at least the details that are indispensable for a proper first assessment of the incident. Subsequently, the participant must supplement and submit the missing details* ~~*as soon as possible.*~~ *directly after receipt.*

Your report form must be sent to:

a. **GMP+ International(see GMP+ BA5)**
b. **The concerned competent authority in your country / region (in case of legal requirement).**
c. **The certification body responsible for the GMP+ FSA certification.**

1)	**Email address of GMP+ International:**	ews@gmpplus.org
2)	**Email address of competent authority (in country or region of residence)**	
3)	**Email address of certification body (certifying GMP+FSA module):**	

	GENERAL INFORMATION	
4)	**Date and time of the notification*:***	
5)	**Reported by (name of person in charge):**	
	COMPANY AND CONTACT INFORMATION	
6)	**Company name:**	
7)	**Street + no.:**	
8)	**Postal code + city:**	
9)	**Country:**	
10)	**GMP+ number:**	
11)	**-Company salutatory approval number/ registration number (EU Reg. 183/2005)*(EU market)*: -Approval number EU Reg. 1069/2009 (animal by-products) (if applicable):**	
12)	**Name of contact person:**	
13)	**Telephone number of contact person:**	

14)	**Telephone number of contact person outside office hours:**	
15)	**Telephone number of a second contact person outside office hours:**	
16)	**E-mail address contact person:**	
	RISK (NATURE OF IRREGULARITY/POTENTIAL RISK)	
17)	**Hazard(s) observed:**	
18)	**Possible cause (confirmed/suspected):**	
19)	**(Probable) cause date:**	
20)	**Date of finding the irregularity:**	
21)	**Was a risk assessment related to the specific situation performed? (yes/no) Conclusion of risk analysis: Serious risk (yes/no)**	
22)	**Motivation:**	
23)	**Impact on animal health (yes/no)**	
24)	**Symptoms:**	
	SAMPLING AND ANALYSIS	
25)	**Date of sampling:**	
26)	**Sampling information/place:**	
27)	**Analysis performed: (yes/no) If yes, you can attach the Certificate of Analysis**	
28)	**Date of product analysis:**	
29)	**Laboratory data that performed analysis (name, address, country):**	
30)	**Analytical results and outcome of analysis:**	
31)	**Relevant legislation (EU/national/other standard):**	
32)	**Maximum permitted level:**	
	PRODUCT (INFORMATION ON THE PRODUCT AND INVOLVED PRODUCT BATCH)	
33)	**Product name:**	
34)	**Brand name/trade name:**	
35)	**Product category:(choose from:) -compound feed -feed additive -feed material -feed pre-mixture -pet food -other**	
36)	**In case of feed material: Number in Catalogue of feed materials (Regulation 68/2013)*(EU market):***	
37)	**Product aspect (packaging type, (bulk/packed product, describe packaging units):**	
38)	**Product is intended for which animal species? (if applicable)**	
39)	**Identification of the batch: (batch code)**	

40)	**Total net weight/volume of the batch:**	
41)	**Use-by date of the batch:**	
42)	**Temperature (if applicable):**	
43)	**Distribution status of the batch (where is the reported batch at this time?): (see also chapter Distribution of the product/batch)**	
44)	**Is the batch part of a larger unit (yes/no): If yes, is it known how large the unit is and what the location of the remaining products is?**	
	ORIGIN AND SUPPLIER OF THE PRODUCT	
45)	**Country of origin of the goods:**	
46)	**If origin of product differs from reporting company: data of producer, trader or importer: (below): (choose from:) -producer -manufacturer -exporter -trader/broker -transporter -importer -storage -other:....**	
47)	**Is the producer your direct supplier? (Yes/no)**	
48)	**Company name of supplier (1):**	
49)	**Street + number:**	
50)	**Country:**	
51)	**Postal code + city:**	
52)	**GMP+ number (if relevant), or: -not certified -certified according to certification scheme other than GMP+ FSA (name of scheme):**	
53)	**-Company statutory approval number/ registration number (EU Reg. 183/2005)*(EU market)*: -Approval number EU Reg. 1069/2009 (animal by-products) (if applicable):**	
54)	**Name of contact person of supplier:**	
55)	**Telephone number of contact person:**	
56)	**Telephone number of contact person outside office hours:**	
57)	**Telephone number of a second contact person outside office hours:**	
58)	**Email address contact person:**	
	DISTRIBUTION OF THE PRODUCT/BATCH	
59)	**Is the contaminated product (already) placed on the market? Yes/no**	
60)	**Products distributed in your own country: Yes/no**	

	If yes: Annex Distribution list/List of recipients with names, locations and quantities		
61)	**Products at end user (livestock farmer): Yes/no If yes: Quantities**		
62)	**Products distributed in EU member states: Yes/no If yes: Distribution list/List of recipients with names and quantities**		
63)	**Products distributed outside EU: Yes/no If yes: Annex Distribution list/List of recipients with names and quantities**		
	CORRECTIVE MEASURES AND INFORMED PARTIES		
64)	**Is the product/batch blocked? Yes/no**		
65)	**Has the product already been recalled? Yes/no If yes: quantities**		
66)	**Has the product already been destroyed? Yes/no If yes: quantities**		
67)	**Have the customers already been informed? Yes / No If yes: Annex Distribution list/List of recipients, per country**		
68)	**Has the supplier already been informed? Yes/no**		
69)	**Other chain partners or authorities informed? Yes/no If yes: who?**		
70)	**Other measures taken:**		
71)	**Compulsory measures? (by competent authorities) Yes/no If yes, which?**		
72)	**Measures to be taken in the near future:**		
	ATTACHED DOCUMENTS (PLEASE ENCLOSE THE FOLLOWING DOCUMENTS IF THESE ARE AVAILABLE)		
		Enclosed (yes/no)	**Can be made available to 3rd parties (yes/no)**
73)	**Analytical report(s)**		
74)	**Distribution list/List of recipients/List of recipients**		
75)	**Contracts/Delivery documents/bills**		
76)	**Transport- and shipping documents**		
77)	**Risk assessment of the EWS case or situation**		
78)	**Product/batch documents like labels and pictures**		
79)	**Phytosanitary certificate**		

80)	**CVED/CED (Common Veterinary Entry document/Common Entry Document) if Regulation (EU) 669/2009 is relevant**		
81)	**Other**		
	OTHER INFORMATION		
82)	**What other information concerning the irregularity/potential risk is relevant?**		
	DATE AND SIGNATURE		
83)	**Date:** **Signature:** **Name:**		

~~Fax + 31 (0)70 307 41 30~~
~~Mail ews@gmpplus.org~~