



Guidelines Recall

GMP+ D 2.3

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GMP+ Feed Certification scheme



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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 quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

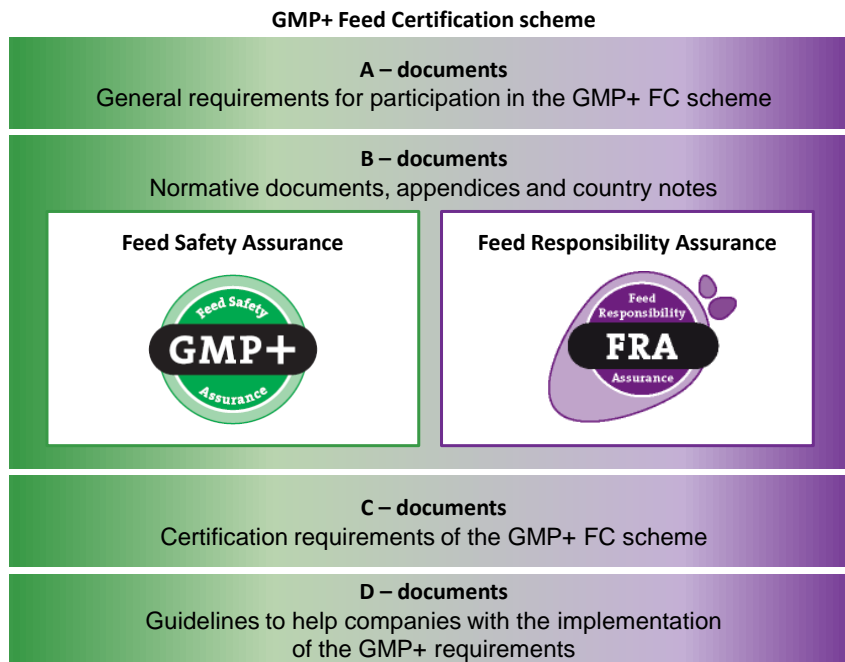
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) 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 through the website of GMP+ International (www.gmpplus.org).

The document in the present case is referred to as GMP+ D2.3 *Guideline for Recall..*

This document was previously published as a standard document under the GMP + certification scheme 2006. The choice of words and the tone may be compulsory, but the document should be read as a guideline.

2 Introduction Recall

Various GMP+ standards require that the participant should establish a documented recall procedure which complies with the requirements set in this D-document.

Every GMP+ certified participant is obliged to have its recall policy available so that it can, if desired, be used as the basis for carrying out a recall.

Among other things this means that the participant draws up, establishes and implements a recall procedure (the recall plan). The recall plan must ensure that it can be used in every possible situation and this applies to the most unfavourable situation as well as less serious situations.

A proper traceability system (the tracking & tracing system) is indispensable for performing a recall action. Based on the GMP+ Feed Certification scheme, specific guidelines for traceability for the different company categories have been established for the animal feed sector: Refer to GMP+ D2.4 *Guideline for Traceability of the GMP+ FC scheme*.

The participant has to draw up, in advance, the recall criteria, when a recall should be implemented and what type of publicity a recall receives. Several departments of the participating organisation, such as purchasing, production, marketing and sales, quality assurance, research and development, and public relations are involved in the setting up of a detailed recall plan. Naturally, this is related to the size of the participating organisation.

A recall plan should be recorded in writing and be aimed at implementing a recall action that is effective (fast and complete) and efficient (costs of a recall versus the damage involved in not implementing the recall).

3 Contents of the Recall plan

A recall plan contains the following components:

1. Foreword by the general manager
2. Flow chart of a recall action
3. Reasons for a recall action
4. Responsibilities and powers of the recall coordinator and the recall team
5. Criteria for starting and ending a recall
6. Planning and establishing procedures for an effective and fast recall action. (This is only possible if a proper traceability system is operational.)
7. Emergency measures
8. Information for employees
9. External information, clients, parties in the chain, product board(s), certification bodies, branch organisations, government, media, other persons concerned
10. Sample texts for press releases, advertisements, warnings, letters
11. Follow-up lists, lists of contact persons, media lists, lists of external experts
12. Registration of data and experiences

- 13. Reporting and evaluation
- 14. After-care

The nature and size of a recall plan depends on the size and complexity of the company.

3.1 Foreword

In the foreword the general manager indicates that a recall action takes precedence over all other organisation activities and that in a recall action all possible organisational resources are available to the recall team. A recall is important for the reduction of consequential damage to the participating company and its clients as well as to retain trust in the organisation.

3.2 Flow chart

See the appendix to this document.

3.3 Reasons for a recall action

The first and most important reason for a recall is to prevent that clients and others experience damages of a product delivered by the participant through picking up or removing the dangerous and faulty product. Therefore the primary goal is the “prevention of damage, accidents or dangerous situations”.

The second reason for a recall action is to satisfy the product standards with regard to safety and essential requirements of the GMP+ Feed Certification scheme (for instance the insufficient risk assessment of the product, insufficient conditions for the transportation of the product, the purchasing of raw materials and other ingredients from non GMP+ worthy companies by the company concerned or by its supplier, etc.).

The third reason for a recall action is to protect the image of the product and the company and to prevent sales losses.

Within the scope of the GMP+ Fed Certification scheme a participant is always obliged to start a recall, in case the shortcomings may (possibly) lead to an infringement of legal standards for animal products of the contaminants involved.

3.4 Responsibilities and powers of the recall coordinator and the recall team

There is usually a single leader of a recall team who is usually the recall coordinator, who has been appointed and who is qualified for the job. The team is comprised of staff members of the different areas in the company (sections/ departments) such as purchasing, production, quality management, sales, technical service, marketing, finance, administration/client management, legal services, research and development, and public relations.

The recall coordinator draws up the recall plan and trains the employees. He is in charge of a recall action.

The actual decision to proceed with a recall action is made by the board of directors, who also carries the final responsibility for the recall action.

The recall coordinator puts together the team and appoints a secretary, who takes the minutes. Besides that the coordinator can involve external experts in the recall action.

The tasks of the recall team are:

- To determine which products are involved, the quantity of the product, where they are stored, delivered etc. If an adequately functioning tracking & tracing system is present this data will be available very quickly.
- Announcing the recall action (internally and externally incl. producers, certification bodies, branch organisations, government and so on).
- To set up a procedure for quick and efficient information availability and to direct the recall.
- Drawing up a cost control report

For these tasks administrative employees are added to the team with regard to Internet messages, fax, telephone, correspondence and so on.

- Testing of the quality of the performance of the correcting measures.
- Check the quantities of the recalled product versus the quantity to be recalled.
- Determine the reimbursement or the replacement product.
- Analyse the reactions of the clients and other persons concerned.
- Analyse the side effects of the recall on the image of the company with regard to clients, parties in the chain, government, media, and social organisations.
- Analysis of the effects of the recall within the organisation.
- Make sure that the recalled products arrive at their correct destination (return flow, technical destination, destruction, etc.)

3.5 Criteria for starting a recall

See 3.3 and 3.4.

3.6 Planning and establishment of procedures for an effective and fast recall action,

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3.7 Information for employees

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3.8 External information, clients, parties in the chain, product boards, branch organisations, government, media, other persons concerned

See 3.4

3.9 Sample texts for press releases, advertisements, warnings, letters

Sample texts of announcements, press releases, advertisements, warnings and letters have been entered in the appendices of the recall plan. Besides that it contains instructions for telephone operators, advice on how to deal with the media and so on.

3.10 Follow-up lists, lists of contact persons, media lists, lists of external experts

In the appendices of the recall plan should be stated who the recall coordinator is, who his deputy is, who the members of the recall team and their replacements are, their telephone numbers, fax numbers, e-mail addresses and so on.

Besides internal advisors also external advisors can be involved in the beginning of the recall action as well as in the following execution of the recall action, for instance toxicologists, lawyers, experts in the field of information (public relations) etc.

The names, addresses, telephone and fax numbers, and e-mail addresses have been reported in the appendices of the recall plan.

All components of the recall plan are numbered and given to the persons concerned. It should be supervised that all changes to the recall plan are correctly entered and that the corrected versions are distributed to the persons concerned. The last is particularly important with regard to telephone numbers, fax numbers and e-mail addresses.

3.11 Registration of data and experiences

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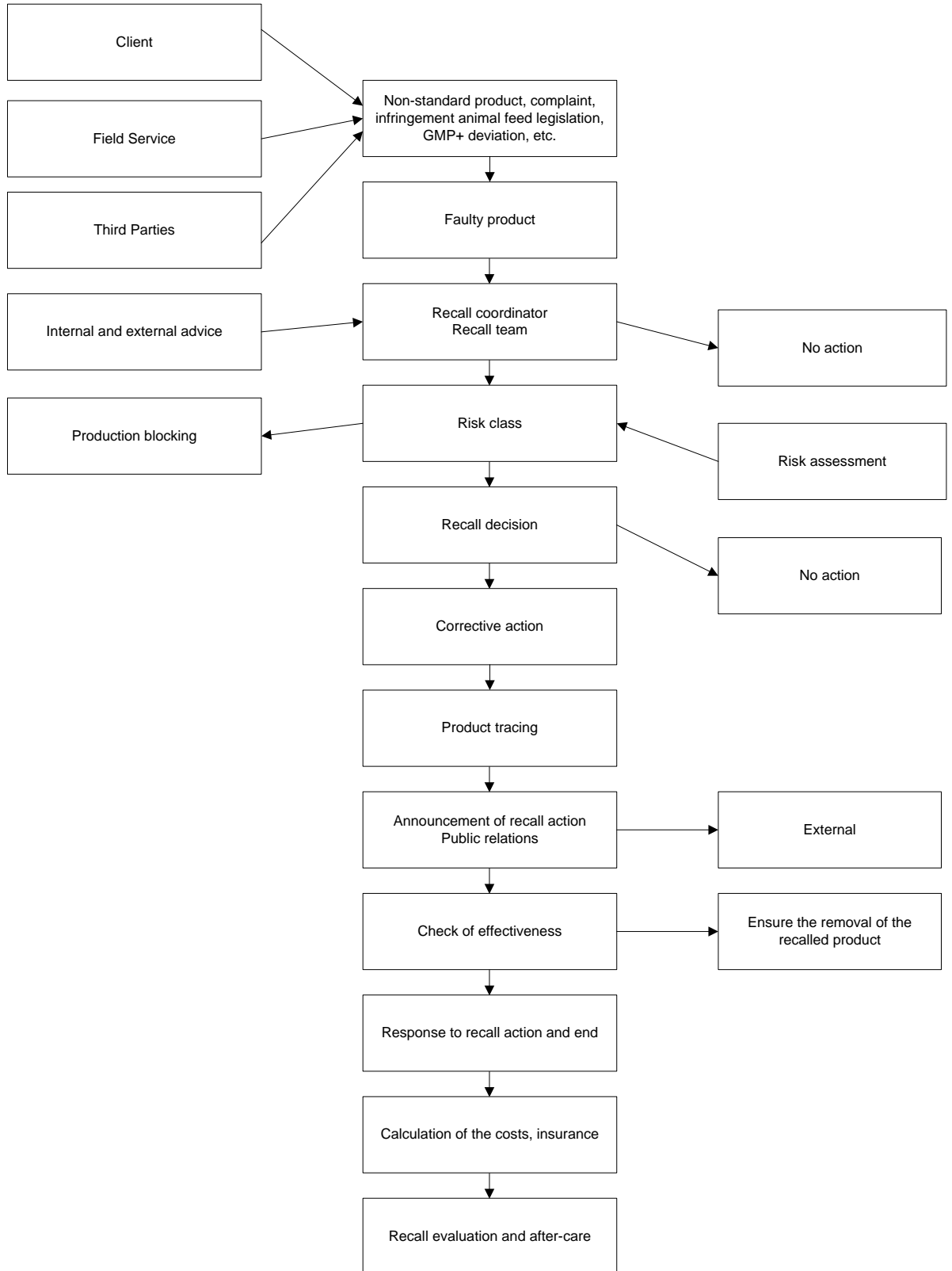
3.12 Reporting and evaluation

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3.13 After-care

The recall coordinator together with the recall team makes sure that all the data of the recall action is collected, makes up the reports, makes sure that an evaluation takes place and works out the points of improvement. The end result will be processed in the recall plan.

4 APPENDIX: FLOW CHART:



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