GMP+ International

QM Milch

GMP+ BCN DE1

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GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 09-2015	This is a new document	Not applicable	Not applicable
0.1 / 05-2018	Textual corrections	Annex 1	01-07-2018

TABLE OF CONTENTS

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 was published. For this purpose, two modules were created: GMP+ Feed Safety Assurance (focused on feed safety) and GMP+ Feed Responsibility Assurance (focssed on responsible feed).

GMP+ Feed Safety Assurance is a complete module with standards 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 standards, such as requirements for a feed safety management system, for application of HACCP principles, to traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

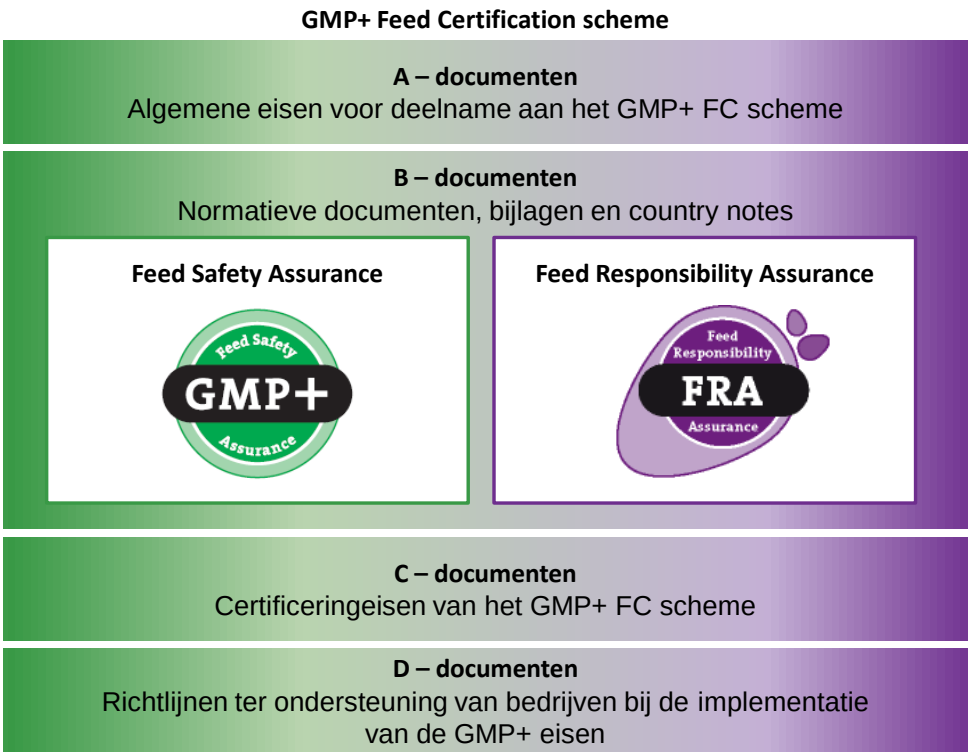
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The feed sector is confronted with requests to operate more responsibly. This includes, for example, the sourcing of soy and fishmeal, produced and traded with respect 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. GMP+ International facilitates the demands from the market via independent certification.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. 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 following 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+ BCN-DE1 *QM-Milch* and is part of the GMP+ FSA module.

2 Scope, application and certification

2.1 Background

In the context of the „Futtermittelvereinbarung QM-Milch“ (Agreement feed materials QM-Milch) dairy cattle feed must meet a number of requirements, of which a QM-Milch approved feed safety system must guarantee that these requirements have actually been met.

The QM-Milch program is intended to guarantee that only high quality milk is being produced and processed. More information is available on the website of QM-Milch www.qm-milch.de.

The GMP+ FC scheme offers such a system for feed safety. A GMP+ certified company meets the requirements in respect of the safety of dairy cattle feed as specified by QM-Milch e. V. These requirements are summarized in this Country Note QM-Milch, which refers to the relevant GMP+ requirements and describes a series of specific requirements.

2.2 Scope

In addition to a reference to existing GMP+ requirements, this Country Note also contains extra requirements in respect of feed companies that deliver in the context of the QM-Milch program, which was established by the German dairy industry for the production and delivery of feed materials for dairy cattle (cows).

The requirements imposed on feed companies relate to the inspection and monitoring of specific undesirable substances in dairy cattle feed, the assessment of the results and informing QM-Milch of these results and a number of other elements.

2.3 Application and certification

A GMP+ participant that delivers feed to dairy farmers and wishes to demonstrate that it meets the QM Milch requirements, can apply this Country Note as addition to the application of one of the other applicable GMP+ standard documents.
Whether the relevant requirements of QM-Milch have been met is demonstrated by means of a certificate issued by the certification bodies accepted by GMP+ International.

Additional scope: **QM-Milch**

The certification is carried out for each company site (as with the certification for other GMP+ standards). The certification according to this *Country Note* is explicitly registered in the GMP+ International Company Database and listed on the GMP+ certificate.
Such a company will be listed as a QM-Milch approved feed supplier and is approved to deliver dairy cattle feed to farmers, who participate in the QM-Milch program.

In practice, this concerns producers and suppliers of compound feeds and feed materials of whom the GMP+ feed safety management system covers at least one or several of the following scopes:

- Production of compound feed
- Trade in compound feed
- Production of feed materials
- Trade in feed materials

As indicated in paragraph 2.1, this country note contains all requirements that are important to QM-Milch e.V. In part, this consists of a summary and / or reference to relevant requirements from other GMP+ standards. This can more or less be considered a mnemonic. Another part concerns additional ('new') requirements. Below, this distinction is represented in an overview (as an aid in its use).

Paragraph	Reference to existing requirement	Additional (new)
4.1	X	
4.2	X	
4.3		X
5.1		X
5.2		X
5.3		X
Annex 1	x	

3 Terms and definitions

For the definitions, please see GMP+ A2 *definitions and abbreviations*.
In addition, the following definitions apply in the context of this Country Note

Participant	The compound feed company that applies a GMP+ standard and is GMP+ certified as such.
Dairy feed	Compound feed or feed materials for dairy cattle

4 Monitoring

4.1 General

The participant has a suitable monitoring plan to monitor dairy cattle feed produced for the dairy farmers participating in the QM-Milch program and delivered to them.

The monitoring plan must at least meet the GMP+ requirements regarding monitoring and include periodic and systematic monitoring for the following substances:

- Aflatoxin B1
- Dioxin
- Dioxin-like PCBs
- Non-dioxin-like PCBs

In this context, please see:

- The relevant GMP+ requirements in respect of monitoring (GMP+ BA4) associated with the GMP+ standards B1, B2 and B3:
  - par. 2.1, stipulating general requirements for the determination of the correct analysis frequency regarding undesirable substances
  - par. 2.2 with requirements in respect of the analysis regarding Dioxin and (non-) dioxin-like PCBs and
  - par. 2.3.2 for the minimum frequency of analyses regarding Aflatoxin B1.

A summary of these monitoring requirements is available in annex 1 of this Country Note.

4.2 Sampling and analysis

The samples must be taken by the participant (or on behalf of the participant) in accordance with the requirements according to GMP+ BA13 *Minimum requirements sampling.*

The analyses must be carried out by a laboratory, certified (in accordance with the GMP+ B10 *Laboratory testing)* or, in accordance with ISO 17025, accredited for carrying out such feed material analyses.

4.3 Reporting and sharing data

The analysis results must be uploaded to the *GMP+ Monitoring database* and shared with the „QM-Milch“ group. This allows the participant to anonymously share the analysis results with the manager of QM-Milch. Based on the analyses carried out by the participants in this Country Note, the manger can draw up reports.

Explanation:
To become a member of the QM-Milch group in the GMP+ Monitoring database, the participant must sign up once, using the designated form. As soon as the application has been received, the participant is invited via the GMP+ Monitoring database to join the QM Milch group. The GMP+ Monitoring database is available on the website of GMP+ International: www.gmpplus.org.

5 Assessment and follow-up measures

5.1 Limit

For the analyses carried out in accordance with the requirements of this Country Note, the following limits apply:

Parameter	Limit	
Aflatoxin B1	1 ppb	QM target value
Dioxin	0.5 ppt	EU action limit
Dioxin-like PCBs	0.5 ppt	EU action limit
Non-dioxin-like PCBs	10 ppb	EU max. value

Explanation
Irrespective of this Country Note, the limits as specified in Appendix GMP+ BA1 'Specific feed safety limits' shall apply. When an action limit or maximum value is exceeded, the participant must act in accordance with the relevant GMP+ requirement (see Appendix GMP+ BA5 'EWS' for instance). The limits specified in this Country Note relate to the measures as referred to in par. 5.2.

5.2 Exceedence of limit

If a limit from paragraph 5.1 is exceeded:

a. The participant must notify GMP+ International immediately at the moment of detection; this must be done immediately and with the help of the designated web form. GMP+ International* reserves the right to test the accuracy.
b. GMP+ International must immediately inform QM-Milch e.V. and the certification body of the participant of the information of the web form,
c. The participant must analyze the feed material again to confirm the result of the first analysis,
d. The participant must check, based on an HACCP analysis, which products could have caused the elevated level and further analyze these products. The cause of the exceendences must be found. QM-Milch is notified of this.

5.3 Providing information

QM-Milch, respectively the regional services, have the right to ask the participants to provide information regarding the size and the gravity of the incident. The participants are obligated to provide the required information, for instance, regarding their efforts to find the cause of the contamination and regarding the results of the extra inspections. This information is handled confidentially by QM-Milch.

QM-Milch and the regional services may decide to pay a visit to the participants to have themselves convinced of the measures taken on site. The participants are obligated to provide the required information. This information is handled confidentially by QM-Milch.

In addition, GMP+ notifies QM-Milch e.V. the same way, of exceedences observed in other proprietary inspections and uploaded to the GMP+ Monitoring database. This applies both to item 5.2 and item 5.3 of the Country Note.

Annex 1: Principles and summary of the GMP+ Monitoring requirements

Principles for the GMP+ monitoring requirements

Feed companies participating in the GMP+ FC scheme, guarantee under their own responsibility, that risk based HACCP[1] concepts (risk assessments) are applied in accordance with the guidelines for a risk analysis of the Regulation (EC) No. 178/2002. GMP+ standards require constant attention to and awareness of possible risks. To this end, it is necessary for companies to control these risks and to verify this with the help of a risk assessment based monitoring plan.

The risk management is carried out in accordance with the requirements of Regulation (EC) No. 178/2002 by means of monitoring via the GMP+ Monitoring database (after a risk assessment of the feed company has taken place – HACCP). With this monitoring, the effectiveness of specific measures, taken to control the risks detected, be confirmed. Moreover, it must be verified that specific parameters have remained within the limits.

The *GMP+ FC scheme* assumes the principles that the entire feed industry must be involved in this. This means that every feed company (as a first step within the chain) must introduce and apply a feed safety management system for feed.

The participation of the feed companies in this system in accordance with Regulation (EC) No. 178/2002 has two major advantages: the risks are controlled exactly where they arise and in case of an incident, direct access to the producer is guaranteed.

Since there is a risk that feed materials, in particular during production and delivery, are contaminated with Aflatoxin, Dioxin, dioxin-like PCBs and non-dioxin-like PCBs, the risks must be controlled at an early stage in all phases and monitored as such in accordance with the procedures of the risk management.

The evaluation of the analysis results of the feed materials is an essential part of the HACCP concept. A verification method for the efficient function of the HACCP system, is the frequent analysis of the microbiological and chemical properties of the end products (feed materials and compound feeds). In this, the product specifications are assessed/evaluated based on the required parameters for the undesirable substances (feed materials, respectively compound feed). When the analysis results do not meet the product specifications, appropriate corrective measures are to be taken.

The HACCP concept must be frequently verified by the feed companies in the contest of the risk analysis. Company specific process diagrams, the overview diagram and the changing of the raw materials used, must be adjusted to the current practices.
To this end, all changes of the production process must be adjusted to new risks and documented in the HACCP concept.

[1] HACCP relates to the detection and control of critical control points in the context of the risk assessments, as a first step of the risk analysis (Regulation (EC) No. 178/2002; article 3). The monitoring is part of the next phase: the risk management.

As a result of this chain principle, specific monitoring is required for the feed companies in the *GMP+ FC scheme*. Special requirements are included for this in the *GMP+ BA4 Minimum requirements inspection and analysis*.

Summary of the GMP+ monitoring requirements

Participants that produce, distribute, process or store feed materials (feed materials, respectively compound feeds) must draw up, realize and implement a monitoring plan based on their own risk assessment.

The monitoring plan must be based on a solid and reliable risk assessment based on representative analysis results; in addition, the monitoring plan must be documented.

Information (such as EWS, RASFF or other signals regarding possible hazards) that may affect the existing monitoring plan, must be evaluated. Where necessary, the monitoring plan must be adjusted immediately.
The frequency of the analyses must be as such, that the fact that all established risks remain controllable, is sufficiently guaranteed.

The required documentation must always be up to date and be part of the verification of the feed safety management system (FSMS).

<table>
<tr><th>Parameter</th><th>Feed material products</th><th>For more information, see:</th></tr>
<tr><td>Aflatoxin B1</td><td>1. Maize, processed or unprocessed, of the origin specified below
2. Maize byproducts, extracted from maize, of the origin specified below

From the following countries of origin:
See therefore protocol Aflatoxine B1.

<table>
<tr><td>~~Argentina~~</td><td>~~Italy~~</td></tr>
<tr><td>~~Brazil~~</td><td>~~Poland~~</td></tr>
<tr><td>~~Serbia~~</td><td>~~Romania~~</td></tr>
<tr><td>~~Bulgaria~~</td><td>~~Slovakia~~</td></tr>
<tr><td>~~Croatia~~</td><td>~~Spain~~</td></tr>
<tr><td>~~Greece~~</td><td>~~Ukraine~~</td></tr>
<tr><td>~~Hungary~~</td><td></td></tr>
</table>
To be analyzed per batch as follows:

<table>
<tr><th>Means of transportation</th><th>Max. batch size</th></tr>
<tr><td>Seagoing vessel (the load of which is instantly loaded into an inland waterway vessel or a coaster)</td><td>Inland waterway vessel or coaster</td></tr>
<tr><td>Seagoing vessel (the load of which is instantly loaded into a storage area)</td><td>max. 2000 ton</td></tr>
<tr><td>Inland waterway vessel</td><td>Inland waterway vessel</td></tr>
</table>
</td><td>GMP+ BA4, 2.3.1</td></tr>
</table>

<table>
<tr><th>Parameter</th><th>Feed material products</th><th>For more information, see:</th></tr>
<tr><td></td><td><table><tr><td>Rail</td><td>Rail</td></tr><tr><td>Truck, ex storage / storage hall</td><td>max. 2000 tons</td></tr></table></td><td></td></tr>
<tr><td></td><td>Dairy cattle feed or for the production of compound feed for dairy cattle:<table><tr><td>Class 1 Feed material</td><td>Of all batches, an analysis must be carried out, in which the analysis must relate to the (original) batches of max. 500 tons</td></tr><tr><td></td><td>The following falls into this category:

1. Peanut biscuits and meal of random origin
2. Kapokcake of any origin
3. Cottonseed biscuits and meal or any origin
4. Coconut (by) products of any origin
5. Maize and maize by products of any origin, except for EU (unless they are analyzed in accordance with GMP+ BA4 par. 2.3.1.) and USA.
6. Palm kernels and palm kernel byproducts of unknown origin
7. Safflower seed of any origin</td></tr><tr><td>Class 2 Feed material</td><td>Of all batches, an analysis must be carried out, in which the analysis must relate to the (original) batches of max. 3000 tons</td></tr><tr><td></td><td>The following falls into this category:
1. Palm kernels and byproducts of any known origin, except for Indonesia and Malaysia
2. Rice byproducts of any origin</td></tr><tr><td>Class 3 Feed material</td><td>All batches must be analyzed based on the results of the proprietary risk assessment of the company</td></tr><tr><td></td><td>The following falls into this category:
1. All other individual feed materials</td></tr></table></td><td>GMP+ BA4, 2.3.3</td></tr>
<tr><td>Dioxin and dioxin-like PCBs</td><td>• Oil and fatty products obtained from the processing of oilseeds, oil refinery, processing of animal fats and / or fatty mixtures,
• that are used in feed materials and
• that are processed, distributed, stored or used by GMP+ certified companies.

These requirements also apply to
1. imported oils and fats sold directly to the feed industry and for products processed in internal flows.

Feed companies that market oils or products extracted therefore, that are intended for use in feed materials, including compound feeds, must have these products analyzed.</td><td>GMP+ BA4, 2.2</td></tr>
</table>

Parameter	Feed material products	For more information, see:
	The monitoring frequency depends on the risk profile of the fat products and is required per 1000 tons (as positive release per ton or based on the results of the proprietary risk assessment of the company). For the defined risk profile, please see GMP+ BA4, par. 2.2.	
Non-dioxin-like PCBs	To be analyzed in combination with the above-mentioned analysis for dioxin or dioxin-like PCBs in oils and fatty products.	

Remarks:

- To be applied are the analysis methods approved based on the feed legislation.

- The Explanation for the authorization and registration of feed companies (feed materials" of the BMEL and the BVL must be applied:

  7.1."Feed companies that market fats, oils or products extracted therefrom (including refined oils, glycerin, lecithin, gummi) for use in feed materials, must have these products analyzed by an accredited laboratory, for the sum of dioxins and dioxin-like PCBs, subject to the HACCP principles, in accordance with Regulation (EC) No. 152/2009 of the Commission."

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