



Minimum requirements for Sampling and Analysis

GMP+ BA 4

Version EN: 1 January 2024

GMP+ Feed Certification scheme



History of the document

Revision no. - Date of approval	Amendment	Concerns	Final imple- mentation date
0.0 / 10-2009	Previous versions can be found in History		20-10-2010
0.1 / 09-2010			01-01-2011
1.5 / 03-2014			15.03.2014
1.6 / 07-2014			01.07.2014
2.0 / 06-2014	Editorial changes: All editorial changes are put together in a fact-sheet Part B : Protocols for the measurement of carry-over is moved to the GMP+ BA2 <i>Control of residues</i>	Entire Document	01-01-2015
2.1 / 12-2016	The Protocol Monitoring Aflatoxin B1 has been published on the GMP+ Portal as a separate document.	2.3	09.01.2017
3.0 / 01-2017	Document is updated according to the Regulation (EU) No. 2015/1905	2.2	01.03.2017
	Legal requirements for traders are emphasized.	2.2	01.03.2017
	Buyers must be informed whether the supplier carries out the representative analyses. Buyers will be periodically informed of the results.	2.2	01.03.2017
	For labeling of feed materials that fall under this dioxin monitoring should be used – where possible – the names listed in Regulation (EU) no. 68/2013	2.2.3	01.03.2017
3.1 / 03-2017	Addition Footnote nr. 7	2.2.3 Table 3	01.03.2017
4.0 / 05-2018	Link is added to the GMP+ B11 <i>Protocol for GMP+ registration for laboratories</i>	2.1 2.2.1.2/2.2.5.2 Aflatoxin B1 protocol Protocol P1 Protocol P2 Protocol P4 Protocol P7 Annex 1	01-07-2019
5.0 / 11-2020	Requirements for the maximum batch size are aligned with the legislation.	2.2	15-12-2020
	Requirements for monitoring of blended fats are aligned with the legislation.	2.2. Table 4	15-12-2020
6.0 / 10.2021	Editorial changes	2	01-01-2023
	Requirements for monitoring of fats and oils are merged and clarified.		
7.0 / 10.2022	Editorial changes	Entire document	01-01-2024
	General monitoring requirements have been added	2.1	
	Monitoring protocol of Aflatoxin B1 in feed materials (for use in feed) for dairy cattle deleted.	2.4	

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	Monitoring requirements for Salmonella have been updated	3	
	Protocol for the serological classification of Salmonella deleted	Annex 1	
8.0 / 10.2023	Editorial changes	3	01-01-2025
	Omission corrected	2.2.3	

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.

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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 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, for traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

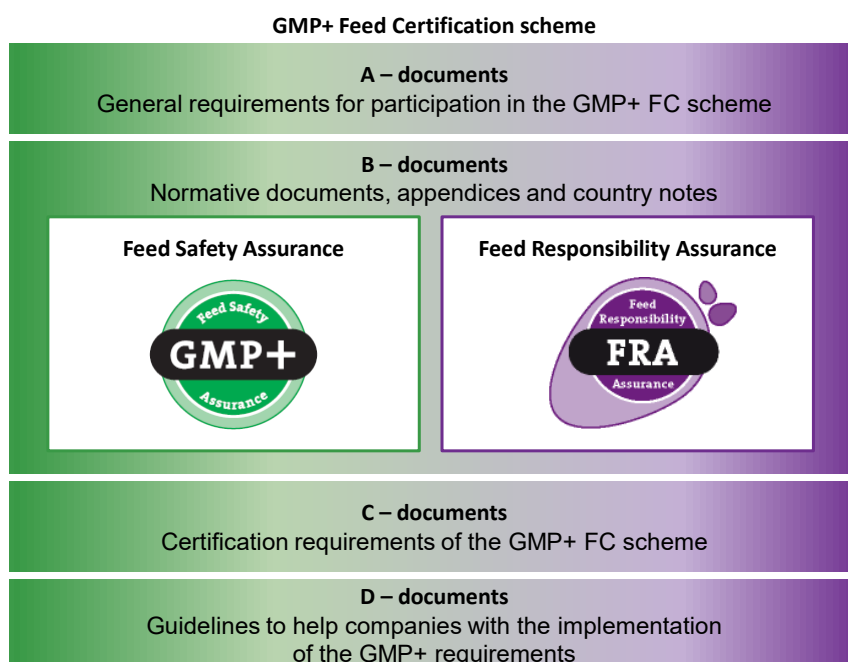
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and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

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 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.gmp-plus.org).

This document is referred to as appendix GMP+ BA4 *Minimum Requirements for Sampling and Analysis* and is part of the GMP+ FSA module.

1.3 In-Company sampling and testing

In various GMP+ standards it is required that a participant must carry out monitoring and verification (in addition to the monitoring) of the HACCP-plan. This monitoring and verification consist for a large part of systematically sampling and testing of feed products. Hereafter, this is referred to as monitoring.

The nature and intensity of the monitoring is to a great degree determined by the results of the risk assessment carried out by the participant. This assessment includes in any event the received products and raw materials ('suppliers and supply chain'), the in-company production or handling process and also the feeds which are finally delivered to the customers.

In drawing up and implementing a monitoring plan, the participant should include at least the required tests as stated in this document, if they are relevant. The requirements are aimed to provide a transparent basis in the monitoring plan which the participant must draw up.

Note: It is not a GMP+ requirement that testing must be carried out for undesirable substances for which product standards have been established in the feed legislation. However, every participant must comply with the statutory requirements.

2 Sampling and testing of feed materials

2.1 General requirements

The participant, who produces, trades, processes or stores the feed material must set up, implement and carry out a monitoring plan, based on the participant's own risk assessment.

The monitoring plan must be motivated, based on a sound and reliable risk assessment, supported by representative testing results, and must be documented.

Information (like EWS, RASFF or other signals about possible risks) that might influence the established the monitoring plan must be assessed. If necessary, the monitoring plan must be adapted immediately.

Frequency of testing must give sufficient assurance that all identified risks remain under control.

The GMP+ certified company must follow the minimum monitoring frequencies as established in the monitoring protocols in this document. If the hazard analysis shows that additional monitoring is needed, the GMP+ certified company must increase the monitoring frequency in accordance with the result of the hazard analysis.

Unless the monitoring protocols in this document state otherwise, the GMP+ certified company must take samples in accordance with the requirements as laid down in document GMP+ BA13 *Minimum Requirements for Sampling*.

The required documentation must be kept up-to-date, and must be part of the verification of the feed safety system.

Guidance

The identified risks in the operation and the feed ingredients themselves should be inspected and sampled (monitored) to ensure that they remain under control.

The information in the GMP+ International's Feed Support Products (FSP) (to be consulted via the website of GMP+ International) may be helpful in

- defining risks,*
- establishing control measures, and*
- setting up a proper monitoring plan to verify the effectiveness of the control measures.*

To define the testing frequency guidance is given in a separate box at the end of this section.

These requirements should stimulate a participant to be constantly aware of possible risks, and require him to act accordingly, to assure the feed safety at any time. On the other hand, these requirements are formulated in a way to give flexibility to set up a monitoring plan that is driven by the participant's own risk assessment.

Note:

- a. The risk assessment must also include the relevant links in the supply chain.
- b. A participant may make use of representative testing results from other companies (for example: suppliers). This particularly applies to testing results for undesirable substances where the level theoretically speaking no longer changes, such as heavy metals, pesticides, dioxin.
Note: 'representative' does not necessarily mean: 'from the delivered batch'.
- c. Special attention must be given to microbiological risks. Example: Microbiological re-contamination can occur after production. If there is no risk of recontamination, the participant is allowed to use the microbiological testing results provided by previous links in the chain.
Example: The feed material is sold while still stored in the same place.
- d. Special attention must be given to the representativeness of the
 - testing results received from suppliers: qualifications of the laboratory; used method; detection limit, etc)
 - sampling and samples (correct method; do they really represent the feed material, etc).

If there is any doubt, uncertainty or unclearness, the participant must verify on the representativeness.

- e. Certain feed materials can be bought under so-called gatekeeper conditions. See for this GMP+ BA10 *Minimum requirements for purchase*. The monitoring required in these protocols is leading.
- f. Testing must be carried out by a laboratory approved for this under the GMP+ FSA module. See GMP+ BA10 *Minimum Requirements for Purchasing*.
- g. Regarding seasonal and/or incidental products, testing must be carried out at the start of production, from the first batch or crop.
- h. The International Expert Committee of GMP+ International constantly monitors the performance and the functioning of the GMP+ FSA module. To make careful and well-balanced decisions about possible and necessary additions and adaptations in the GMP+ FSA -module, studies and evaluation reports are made and results of audits are summarized. Related to this, GMP+ International might request participants to provide monitoring results.
- i. It is possible for participants to carry out their monitoring plan together (in a collective monitoring plan). The following requirements apply with respect to this option:
 1. The scope of the monitoring plan must be established ('which feed materials are included') and which companies are participating.
 2. The collective monitoring plan must be representative for the feed materials which the manufacturers produce, trade, treat and / or process. Its representativeness must be motivated.
 3. All the participating companies will obtain all the relevant sampling and testing results.

4. The collective monitoring plan must comply with the above GMP+ requirements and with the other relevant GMP+ requirements. The audit will check this during the audit.

Guidance about frequency

As a guidance, the frequency of testing (on a yearly basis) can be calculated using the following formula

$$\text{Frequency} = \frac{\sqrt[3]{\text{Volume}}}{100} * \text{'chance'} * \text{'seriousness'}$$

Variable	Explanation						
Frequency	The number of samples to be tested (on a yearly basis)						
Volume	<p>Volume in tons of feed materials per year. In principle, the number of samples to be tested is based on the quantity of feed material which is produced, traded, processed or stored. As the quantity of feed material increases, the number of samples per ton will decrease.</p> <p>Kilograms must be assumed for some feed materials for which, on a yearly basis, only a small quantity is produced, traded or processed.</p>						
Chance	<p>The standard value for chance is 1. The participant may raise or lower this value if reasons are given. The following considerations may apply to this:</p> <ol style="list-style-type: none"> History: see also below Seasonal influences Possibility of recontamination. This applies in particular to micro-biological parameters. New source / new suppliers Have there been recent incidents. <p>It is up to the participant to decide that the chance value can be lowered.</p> <p>The participant should select a chance value which is below one on the basis of (historical) testing results. The following must be kept in mind:</p> <ol style="list-style-type: none"> Testing results should be representative. The historic testing results which are considered as representative may differ per undesirable substance. For some undesirable substances the testing results for an area can be considered to be representative while, for other undesirable substances, only testing results for the same production location is representative. Testing results from GMP+ International's GMP+ Monitoring database may also be used in determining testing frequency if the participant can show representativeness. 						
seriousness	<p>This factor expresses the degree of harmfulness of an undesirable substance. For the value for seriousness use can be made of information of the Feed Support Products (FSP):</p> <table> <tr> <td>Seriousness is great</td><td>factor 5</td></tr> <tr> <td>Seriousness is moderate</td><td>factor 3</td></tr> <tr> <td>Seriousness is small</td><td>factor 1</td></tr> </table>	Seriousness is great	factor 5	Seriousness is moderate	factor 3	Seriousness is small	factor 1
Seriousness is great	factor 5						
Seriousness is moderate	factor 3						
Seriousness is small	factor 1						

Variable	Explanation																						
	<p>This leads to the following factors:</p> <table> <tr> <th>Undesirable substance</th><th>Value</th></tr> <tr> <td>Heavy metals</td><td>5</td></tr> <tr> <td>Pesticides</td><td>5</td></tr> <tr> <td>Insecticides</td><td>5</td></tr> <tr> <td>Veterinary Medicinal products</td><td>5</td></tr> <tr> <td>Mycotoxins</td><td>5</td></tr> <tr> <td>Salmonella</td><td>5</td></tr> <tr> <td>Fungi</td><td>3</td></tr> <tr> <td>Animal components</td><td>5</td></tr> <tr> <td>Dioxin</td><td>5</td></tr> <tr> <td>Nitrites</td><td>5</td></tr> </table> <p>The established values are all high. This seems logical as these are risky undesirable substances.</p>	Undesirable substance	Value	Heavy metals	5	Pesticides	5	Insecticides	5	Veterinary Medicinal products	5	Mycotoxins	5	Salmonella	5	Fungi	3	Animal components	5	Dioxin	5	Nitrites	5
Undesirable substance	Value																						
Heavy metals	5																						
Pesticides	5																						
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Salmonella	5																						
Fungi	3																						
Animal components	5																						
Dioxin	5																						
Nitrites	5																						
<p>Note:</p> <ol style="list-style-type: none"> Calculated frequencies should always be rounded upwards. The minimum frequency is 1. Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content. 																							

2.2 Specific requirement for monitoring of fats and oils as regards dioxin and dioxin like PCB's

2.2.1 Scope

This chapter provides specific requirements¹ for monitoring the levels of dioxin and dioxin-like PCB's in oil and fat products, which

- originate from the processing of oil seed, oil refining, animal fat processing and/or fat blending, and;
- are used in feed, and
- are produced, traded, stored, transported or used by GMP+ certified companies.

This monitoring applies to GMP+ certified companies that produce or trade the abovementioned products.

GMP+ certified companies are exempt from monitoring if they dispose of an analysis result, covering the purchased batch (unique reference of the batch must be included in the analysis report).

2.2.2 Definitions

Term	Description	Remarks
Batch	an identifiable quantity of feed, determined as having common characteristics, such as origin, variety, type of packaging, packer, consignor or labeling, and, in the case of a production process, a unit for production within a single plant, using uniform production parameters, or a number of such units, when produced in continuous order, and stored together	A batch, subject to a Class 2 monitoring, may comprise maximum 1000 tons For an explanation of the Classes, see 2.2.3.
Products derived from oils and fats	Any product derived directly or indirectly from crude or recovered oils and fats by oleochemical process or biodiesel production, or distillation, chemical or physical refining, other than: <ul style="list-style-type: none"> • the refined oil, • products derived from refined oil, and • feed additives. 	
Fat blending	Manufacturing of compound feed or, in case of all components belonging to the same entry in PART C of the Annex to Commission Regulation	Fat blending, is under EU Legislation, only allowed with an approval in accordance with Regulation (EC) No 183/2005.

¹ These requirements are based on EU-legislation, as laid down in Reg. (EU) No. 183/2005 (Annex.II) including the amendments regulated by Regulation (EU) No. 2015/1905.

Term	Description	Remarks
	<p>(EU) No 68/2013 which are derived from the same plant or animal species, of feed materials by mixing crude oils, refined oils, animal fats, oils recovered from food business operators, falling within the scope of Regulation (EC) No 853/2004, or products derived thereof to produce a blended oil or fat, with the exception of the:</p> <ul style="list-style-type: none"> • sole storage of consecutive batches, and • exclusive mixing of refined oils. 	<p>A (collection) tank may be exclusively filled with a product from one single production facility. This is to be considered as one batch, even if the tank is loaded discontinuously. One must not consider this as fat blending, therefore an approval is not required. This situation is described in section 2.2.4, Option 3</p>
Positive Release	Release of batch of a product, intended for use in feed, only after analytical tests show that the levels of undesirable substances do not exceed the maximum levels as laid down in BA1.	Several options as regards acceptable Positive Release systems are provided in section 2.2.4.
Refined oil or fat	Oil or fat that has undergone the process of refining as referred to in No 53 of the glossary of processes listed in part B of the Annex to Regulation (EU) No 68/2013.	
Representative analysis per 2000 tons	<p>This notion concept does not define the batch size, but rather a minimum analysis frequency.</p> <p>A representative analysis per 2000 tons is independent of the definition of a batch size. A batch may, after all, be smaller or larger than 2000 tons, whereas the representative analysis has 2000 tons as upper limit.</p> <p>A sample is listed as representative, if it has the same characteristics as the products under examination</p>	<p>A representative analysis per 2000 tons is applicable is to producers and, if appropriate, traders (see section 2.2.1.2) of fish oil. This is indicated in the tables with processes and products in section 2.2.3 below.</p> <p>At the latest at the time of delivery, a statement that the representative analyses are carried out will be provided to the buyer. The buyer will be periodically informed of the results of these analyses.</p>
Representative analysis per 5000 tons	This notion concept does not define the batch size, but rather a minimum analysis frequency.	A representative analysis per 5000 tons is applicable to producers and, if appropriate, traders (see section 2.2.1.2) of animal fat and product derived thereof belonging to category 3

Term	Description	Remarks
	<p>A representative analysis per or 5000 tons is independent of the definition of a batch size. A batch may, after all, be smaller or larger than 5000 tons, whereas the representative analysis has 5000 tons as upper limit.</p> <p>A sample is listed as representative, if it has the same characteristics as the products under examination</p>	<p>material. This is indicated in the tables with processes and products in section 2.2.3 below.</p> <p>At the latest at the time of delivery, a statement that the representative analyses are carried out will be provided to the buyer. The buyer will be periodically informed of the results of these analyses</p>
Representative sampling: (source: ISO 5555 : Animal and vegetable fats and oils — Sampling).	<p>The purpose of representative sampling is to obtain a small fraction from a lot in such a way that a determination of any particular characteristic of this fraction will represent the mean value of the characteristic of the lot. The lot shall be sampled by repeatedly taking increments at various single positions in the lot. These increments shall be combined by mixing to form a bulk sample from which representative laboratory samples shall be prepared by dividing.</p>	

2.2.3 Monitoring frequency

It is important to highlight that the monitoring frequencies, as is specified in the following tables, are not meant to substitute the individual feed business operator's HACCP system, and do not exempt a feed business operator from applying the HACCP principles, which includes the establishing of an adequate monitoring plan. This monitoring plan must, at least, include the minimum monitoring frequency laid down in the following tables as follows:

Class	1	2	3	4
Product	Not allowed for feed. Included in the tables for reason of transparency and completeness See also GMP+ BA3 'Minimum requirements Negative List'	Product for use in feed	Product for use in feed	Product for use in feed
Monitoring frequency	Not applicable.	100% monitoring with a Positive Release. ² One analysis per batch (max. 1000 tons ³)	One representative analysis per 2000 tons or 5000 tons ^{3 4} (with a minimum of one representative analysis per year)	Based on the company's internal risk assessment
Rationale	Products are forbidden for feed.	The presence of dioxins and dioxin-like PCB's is possible	The presence of dioxins and dioxin-like PCB's is unlikely	The presence of dioxins and dioxin-like PCB's is highly unlikely

The labeling of feed materials that fall under this monitoring should – where possible – use the names listed in Regulation (EU) no. 68/2013 (European Catalogue of feed materials). Such a name ensures that the product is identified with certainty and to determine the monitoring (class 1, 2, 3 or 4) to which this feed material has been subjected with maximum precision.

In case the name used is not included in Regulation (EU) no. 68/2013, only monitoring conform product class 1 (forbidden products) or product class 2 can be applied (see tables under point 2.2.3). Class 3 or class 4 monitoring can only be applied for products of which the name is included in the European Catalogue of feed materials and for which a product class 3 or 4 has been identified in the tables mentioned under point 2.2.3

² Several options as regards acceptable Positive Release systems are provided in § 2.2.4

³ If it can be demonstrated that a homogenous consignment is bigger than the maximum batch size and has been sampled in a representative way, the results of the analysis, of the appropriately drawn and sealed sample, will be considered acceptable.

⁴ Applicable to producers and, if appropriate, traders:

- one representative analysis per 2000 tons for specific fish oils
- one representative analysis per 5000 tons for specific animal fats (cat-3)

with a minimum of one representative analysis per year. See tables below.

At the latest at the time of delivery, a statement that the representative analyses are carried out will be provided to the buyer. The buyer will be periodically informed of the results of these analyses.

Example

On departure at a biodiesel manufacturer, Glycerin must not be analyzed. Nevertheless it is necessary for this document (GMP+ BA4) to be identified as such.

If an identical outbound product has a name other than the one in the Feed Material Catalog ('product x' instead of 'glycerin'), it will be considered 'All other products derived from oils and fats', which means monitoring class 2.

As an example, the table below reproduces several names and definitions listed in the European Catalogue of feed materials (Regulation (EU) no. 68/2013) :

Number	Name	Description
2.20.1	Vegetable oil and fat ⁽²⁾	Oil and fat obtained from plants (excluding castor oil from the ricinus plant), it may be degummed, refined and/or hydrogenated.
2.21.1	Crude lecithins	Product obtained during degumming of crude oil from oilseeds and oil fruits with water. Citric acid, phosphoric acid or sodium hydroxide may be added during degumming of the crude oil
9.2.1	Animal fat	Product composed of fat from warm-blooded land animals. If extracted with solvents, may contain up to 0,1 % hexane.
10.4.6	Fish oil	Oil obtained from fish or parts of fish followed by centrifugation to remove water (may include species specific details e.g. cod liver oil).
10.4.7	Fish oil, hydrogenated	Oil obtained from hydrogenation of fish oil
13.6.1	Acid oils from chemical refining ⁽³⁾	Product obtained during the deacidification of oils and fats of vegetable or animal origin by means of alkali, followed by an acidulation with subsequent separation of the aqueous phase, containing free fatty acids, oils or fats and natural components of seeds, fruits or animal tissues such as mono-, and diglycerides, lecithin and fibres.
13.6.2	Fatty acids esterified with glycerol ⁽⁴⁾	Glycerides obtained by esterification of glycerol with fatty acids. May contain up to 50 ppm Nickel from hydrogenation.
13.6.4	Salts of fatty acids ⁽⁴⁾	Product obtained by reaction of fatty acids with at least four carbon atoms with calcium, magnesium, sodium or potassium hydroxides, oxides or salts. May contain up to 50 ppm Nickel from hydrogenation.
13.6.5	Fatty acid distillates from physical refining ⁽³⁾	Product obtained during the deacidification of oils and fats of vegetable or animal origin by means of distillation containing free fatty acids, oils or fats and natural components of seeds, fruits or animal tissues such as mono- and diglycerides, sterols and tocopherols.

13.6.6	Crude fatty acids from splitting ⁽³⁾	Product obtained by oil/fat splitting. By definition it consists of crude fatty acids C 6 -C 24 , aliphatic, linear, monocarboxylic, saturated and unsaturated. May contain up to 50 ppm Nickel from hydrogenation.
13.6.7	Pure distilled fatty acids from splitting ⁽³⁾	Product obtained by the distillation of crude fatty acids from oil/fat splitting potentially plus hydrogenation. By definition it consists of pure distilled fatty acids C 6 -C 24 , aliphatic, linear, monocarboxylic, saturated and unsaturated. May contain up to 50 ppm Nickel from hydrogenation
13.6.8	Soap stocks ⁽³⁾	Product obtained during the deacidification of vegetable oils and fats by means of aqueous calcium, magnesium, sodium or potassium hydroxide solution, containing salts of fatty acids, oils or fats and natural components of seeds, fruits or animal tissues such as mono- and diglycerides, lecithin and fibres.
13.6.9	Mono- and diglycerides of fatty acids esterified with organic acids ⁽⁴⁾ ⁽⁵⁾	Mono- and diglycerides of fatty acids with at least four carbon atoms esterified with organic acids.
13.6.10	Sucrose esters of fatty acids ⁽⁴⁾	Esters of sachharose and fatty acids.
13.6.11	Sucroglycerides of fatty acids ⁽⁴⁾	Mixture of esters of saccharose and mono and di-glycerides of fatty acids.
13.8.1	Glycerine, crude	By-product obtained from: <ul style="list-style-type: none"> - the oleochemical process of oil/fat splitting to obtain fatty acids and sweet water, followed by concentration of the sweet water to get crude glycerol or by transesterification (may contain up to 0,5 % methanol) of natural oils/fats to obtain fatty acid methyl esters and sweet water, followed by concentration of the sweet water to get crude glycerol; - the production of biodiesel (methyl or ethyl esters of fatty acids) by transesterification of oils and fats of unspecified vegetable and animal origin. Mineral and organic salts might remain in the glycerine (up to 7,5 %). May contain up to 0,5 % Methanol and up to 4 % of Matter Organic Non Glycerol (MONG) comprising of Fatty Acid Methyl Esters, Fatty Acid Ethyl Esters, Free Fatty Acids and Glycerides;

		<ul style="list-style-type: none"> - saponifications of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps. <p>May contain up to 50 ppm Nickel from hydrogenation.</p>
13.8.2	Glycerine	<p>Product obtained from:</p> <ul style="list-style-type: none"> - the oleochemical process of (a) oil/fat splitting followed by concentration of sweet waters and refining by distillation (see part B, glossary of processes, entry 20) or ion-exchange process; (b) transesterification of natural oils/fats to obtain fatty acid methyl esters and crude sweet water, followed by concentration of the sweet water to get crude glycerol and refining by distillation or ion-exchange process; - the production of biodiesel (methyl or ethyl esters of fatty acids) by transesterification of oils and fats of unspecified vegetable and animal origin with subsequent refining of the glycerine. Minimum Glycerol content: 99 % of dry matter; - saponifications of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps, followed by refining of crude Glycerol and distillation. <p>May contain up to 50 ppm Nickel from hydrogenation.</p>
<p>(2) The name shall be supplemented by the plant species.</p> <p>(3) The name shall be supplemented by the indication of the botanical or animal origin.</p> <p>(4) The name shall be amended or supplemented to specify the fatty acids used.</p> <p>(5) The name shall be amended or supplemented to specify the organic acid.</p>		

The monitoring must be carried out in accordance with the class as specified in the table below:

How to read	
EU Food	A producer that is registered (according to art. 6 of Reg. (EC) No. 852/2004) as an EU food operator.
Other	A producer not registered (according to art. 6 of Reg. (EC) No. 852/2004) as an EU food operator.

Table 1: Products ⁵ of vegetable origin	EU food	Other
See GMP+ BA3 <i>Minimum requirements Negative list</i> for oil/fat products not allowed in feed	1	1
Fatty acids distillates (13.6.5)	2	2
Deodistillates, treated	2	2
Acid oils from chem. refining (13.6.1)	4	2
Crude fatty acids from splitting (13.6.6)	4	2 ⁶
Pure distilled fatty acids from splitting (13.6.7)	4	2 ⁶

⁵ These products come from different processes like refining, oleochemical and biodiesel production

⁶ If produced out of vegetable oil (2.20.1, the category is 4

Fatty acids esterified with glycerol (13.6.2) Mono, di and tri glycerides of fatty acids (13.6.3/13.6.9) Salts of fatty acids (13.6.4) Sucrose esters of fatty acids (13.6.10) Sucroglycerides of fatty acids (13.6.11)	4	2 ⁷
Glycerin (13.8.1/13.8.2), Lecithin (2.21.1) and Gums Used filter aids/use bleaching earth Soap stocks (13.6.8) Vegetable oil/fat, crude and refined except for crude coconut oil (2.20.1)	4	4
Crude coconut oil if supplied as feed material (2.20.1)	2	2
Oils/fats recovered from food business operators (2.20.2)	2	2
Other oil/fats products derived from a biodiesel production process out of a non-refined feedstock ⁸	2	2
Imported tocopherols extracted from vegetable oil and tocopheryl acetate made thereof ⁹	2	2

Table 2: Products of animal origin	
See GMP+ BA3 <i>Minimum requirements Negative list</i> for oil/fat products not allowed in feed	1
Animal fat from land animals	
Animal fat processors, edible fats and oils, (Regulation (EC) 853/2004) (9.2.1)	3
Cat. 3 operators, fats and oils, (Regulation (EC) 1069/2009) (9.2.1)	3
Acid oils (13.6.1) & soap stocks	3
Deodistillates, treated	2
Fatty acid distillates (13.6.5)	2
Fat from gelatin production	2
Product from fish oil processing	
Crude fish oil (10.4.6)	2
Fish oil, produced from fisheries with no monitoring history, from unspecified origin or from the Baltic Sea (10.4.6)	2
Fish oil, from fish by-products from non-EU approved establishments manufacturing fish for human consumption (10.4.6)	2
Fish oil, produced from blue whiting or menhaden(10.4.6)	2

⁷ If produced/derived from fatty acids (13.6.6 or 13.6.7), which are in their turn obtained by splitting of vegetable oil (2.20.1), the category is 4

⁸ In the context of this protocol a feedstock is the raw material from which the oil/fat product is produced or derived thereof

⁹ Import from outside the European Union (EU) to the EU and imports between non-EU member states

Products derived from fish oil which is neither refined nor listed in this table (including fish oil refinery by-products)	2
Soap stocks (13.6.8) and acid oils (13.6.1) from fish oil	2
Refined fish oil (and all other fish oils not specified above) (10.4.6)	3

Table 3: Products from fat blending ¹⁰	
See GMP+ BA3 <i>Minimum requirements Negative list</i> for oil/fat products not allowed in feed	1
Incoming products	See tables 1 and 2
or	
Outgoing blends of fats/oils	2

Note: Instead of monitoring incoming batches according to these classifications, a fat blender may choose to monitor 100% of outgoing batches (= class 2). This choice needs to be declared to the auditor. EU-located feed business need also to declare the choice to the competent authority.

¹⁰ See for definition of fat blending paragraph 2.2.2

Minimum requirements for Sampling and Analysis - BA 4

2.2.4 Positive release

To comply with the Positive Release requirements, companies (producers and, if appropriate, traders, see section 2.2.1.2) within the supply chain, may use several systems. In this section, a number of systems, are explained. These systems are allowed to be used by GMP+ certified companies, active within the supply chain. However, if the competent authority, or a customer, has additional requirements, these must also be satisfied.

The analysis results of dioxins and dioxin-like PCBs must be available, before any use in feed materials such as compound feed and premixtures.

Note: with 'shipped' is meant that the product is transported from the producer's facility to (for example) a storage tank, located at the customer's facility. The producer, still owns the product and is therefore responsible for the product. With 'delivered' is meant that the product is not only transported to the customer, but also the ownership of the product is transferred to the customer.

No.	Option	Remarks
1	The producer, takes a representative sample of the product located at his storage tank, he then sends the sample to a laboratory for the analysis of dioxin and dioxin-like PCBs. The product is shipped, and delivered to the customer, once the test results are known, and are within the specifications.	<ul style="list-style-type: none">- For more details as regards sampling and analysis, see section 2.2.5.- Customer will be informed of the results, through means of an Analytical Report.
2	The producer takes a representative sample of the product, located at his storage tank, he then sends the sample to a laboratory for an analysis as regards dioxin and dioxin-like PCBs. Meanwhile, the product is shipped to the customer. The actual delivery of the product (transfer of ownership) will take place once the dioxin analysis results are known and are within the specifications.	<ul style="list-style-type: none">- For more details as regards sampling and analysis, see section 2.2.5.- In order to use this option, there must be an agreement between the producer and the customer.- The customer will be informed of the analysis results, through means of an Analytical Report. .
3	The producer ships the product (from one plant) to a collection tank (located at another site). This can be a tank; located at his own facilities, or at a third-party tank. Sampling, will be performed in the collection tank. The collection tank is exclusively filled with one single batch. The tank can be loaded discontinuously, e.g. by truck, or by vessel, but	<ul style="list-style-type: none">- One single kind of fat/oil product.- One producer/one production plant.- Although the product is shipped from the production plant, the producer remains responsible for the required monitoring. He must arrange the proper corrective actions, if the analysis results exceed the product standards.

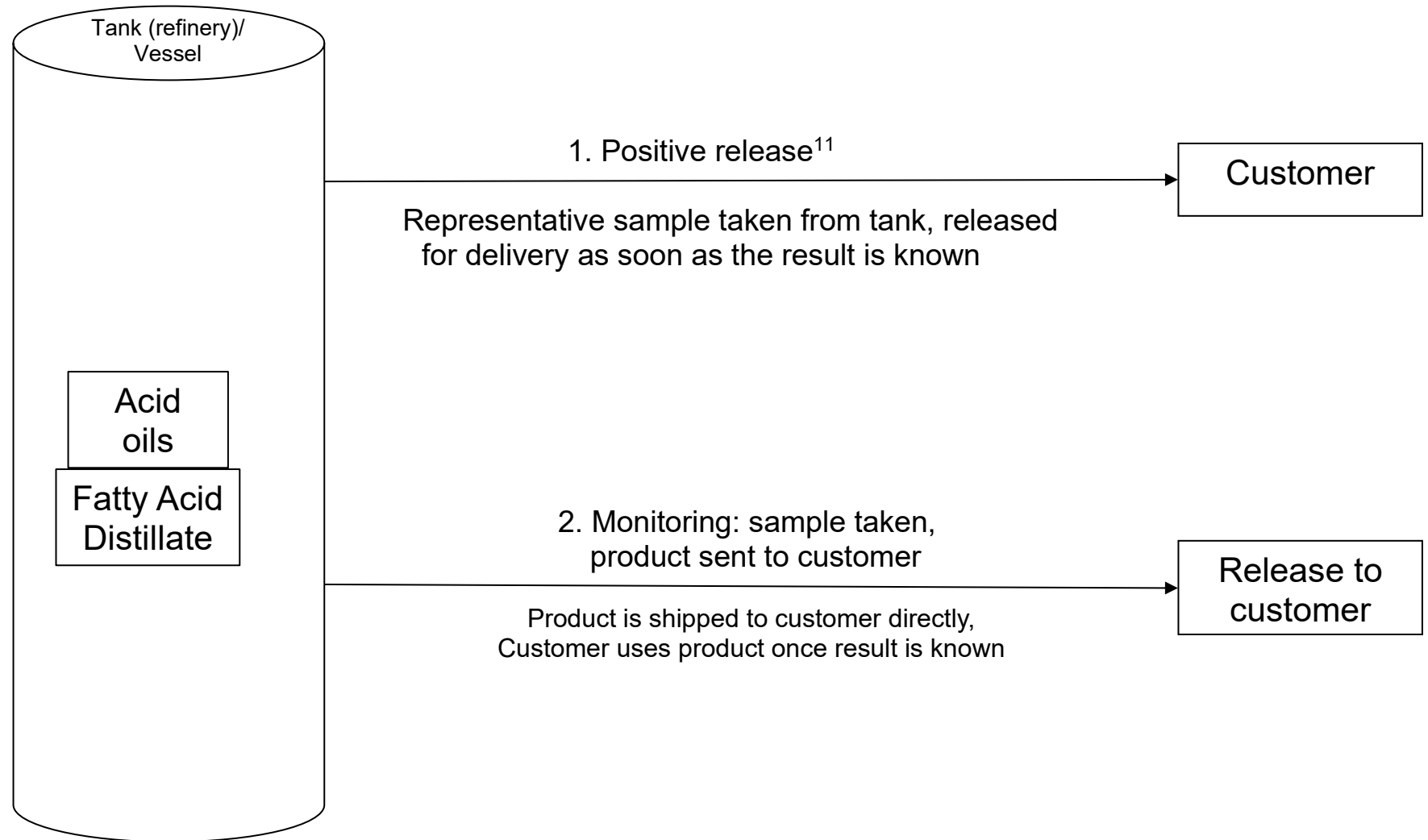
Minimum requirements for Sampling and Analysis - BA 4

No.	Option	Remarks
	<p>the sum of the individual loads, loaded in the tank must correspond with the continuous production of a single plant. The product, will only be delivered from this tank to the customer, if the results of the dioxin analysis are known.</p>	<ul style="list-style-type: none"> - The tank does not necessarily have to be located in the same country as the production site. - The producer will need to have full control of the operational storage activities, or will need to have an agreement with the storage company, upon use of a third-party tank. - Registration of production, transport and storage must be clear and show a complete balance. - See for more details about sampling and analysis section 2.2.5. - The customer is informed of the analysis results, by means of an Analytical Report.
4a	<p>The producer will take a representative sample for the analysis of dioxin and dioxin-like PCB's, before the products leave the production facility. The products are then shipped to a collection tank (which may be located at their own facilities, or with a third-party tank). When all samples, representing the contents of the tank, are falling within the required limits, as regards dioxin and dioxin-like PCB's, the product may then be delivered, from the third-party collection tank, to the customers. For verification purposes, the producer will take a sample of the blend from the collection tank on a quarterly basis, for the analysis of dioxin and dioxin-like PCB's. In case the contents of the tank, are not composed with batches, originating from one single production facility (option 3), the legal entity, operating the tank, will need to have an approval, as a fat blending operator.</p>	<ul style="list-style-type: none"> - This option, is only valid in case that product, delivered to the customer, is a feed material. When the product is a compound feed, this option 4a is not applicable. - There may be more than one production plant involved, also from other producers. - Although the product is shipped from the production plant, the producer stays responsible for the required monitoring. He must have arranged for proper corrective actions, in case the results of analysis exceed the product standards. - The tank does not necessarily have to be located in the same country as the production site. - The producer will need to have full control of the operational storage activities, or will need to have an agreement with the storage company, upon use of a third-party tank. - The registration of production, transport and storage, must be clear, and must provide a complete balance. - The file containing the analysis certificates must be complete, and must be clear. - The customer will be informed of the analysis results, by means of all underlying analysis results, and the composition (including the proportion of the different components), unless the producer and customer agree, that the customer will be informed by means of a Conformity Note. The contents of the

Minimum requirements for Sampling and Analysis - BA 4

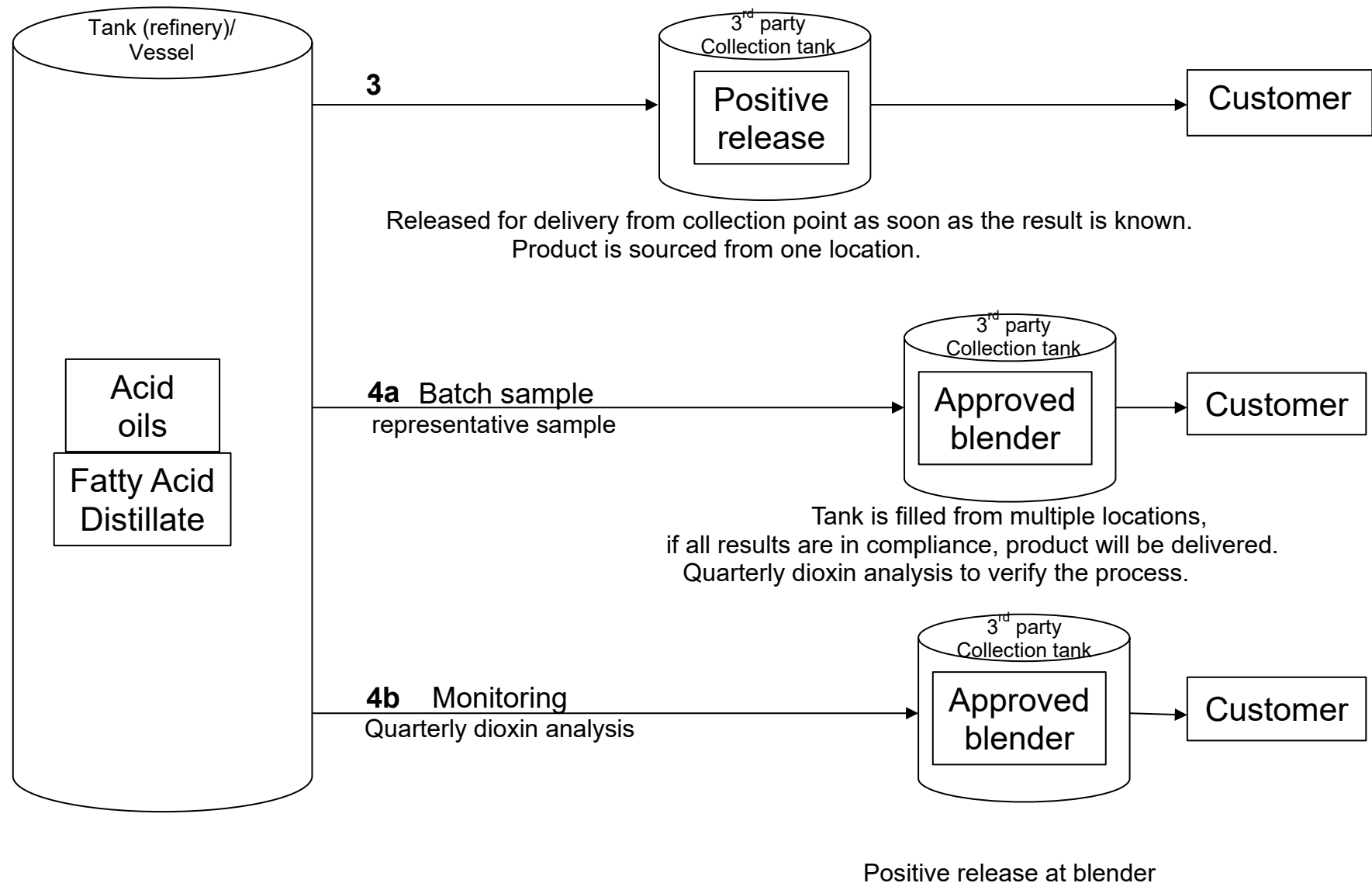
No.	Option	Remarks
		<p>Conformity Note must be clear, unambiguous and verifiable. There must be a clear link between the Conformity Note, the delivered batch and the analysis certificates.</p> <ul style="list-style-type: none"> - The producer is responsible for the quarterly add-on monitoring.
4b	<p>Fat blending: different producers (which can be different plants and/or different legal entities), will deliver the product to the third-party collection tank. Sampling, will take place in the collection tank, at the fat blender's facilities, after production of the fat blend.</p> <p>Each individual producer will monitor all products shipped to the third-party collection tank, via quarterly sampling (as an add-on to monitoring required). The individual producers are obliged to provide the monitoring results to the fat blender.</p>	<ul style="list-style-type: none"> - This option is mandatory, if the fat product is a compound feed. - The product could be one single kind of fat/oil product, or a mixture of different fat/oil products. - Product is owned by fat blender. - The tank does not necessarily have to be located in same country as the production site. - The producer needs to have full control of the operational storage activities, or need to have an agreement with the storage company, upon use of a third-party tank. - The fat blender is responsible for the quarterly add-on monitoring. - The registration of production, transport and storage must be clear and provide a complete balance. - The file, containing the analysis certificates must be complete and must be clear. - The customer will be informed of the analysis results, by means of an Analytical Report of blend.

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¹¹ Example 1 to 4b: positive release not necessary in case the blend consists for 100% out of Acid Oils.

Minimum requirements for Sampling and Analysis - BA 4



2.2.5 Sampling & Analysis

2.2.5.1 *Sampling*

Sampling must be performed in compliance with the general GMP+ requirements. For the sampling of fats and oils, several sampling techniques and procedures are available. Samples must represent the batch. The samples must be taken from homogeneous and clearly identified batches.

In the tables in § 2.2.3 the maximum batch sizes, are indicated. If, can be demonstrated that a homogenous consignment is bigger than the maximum batch size (indicated in the tables= max. 1000 tons), and that it has been sampled in a representative way, the results of the analysis, of the appropriately drawn and sealed sample, will be considered acceptable.

The results should be provided at least once per month to the GMP+ Monitoring database. Results from the analysis must be shared with the GMP+ Community in the GMP+ Monitoring database.

Informing the competent authority must be in compliance with the applicable legal obligations.

2.2.5.2 *Other requirements/remarks*

- There must be a clear link between the delivered batch and the certificate of analysis / analytical report from an approved lab.
- In § 4.3.5 of GMP+ BA10 *Minimum Requirements for Purchase* also monitoring requirements for palm(kernel)oil products are laid down. If applicable, the participant must also comply with these requirements.

2.3 Protocol Monitoring Aflatoxin B1

The Protocol Monitoring Aflatoxin B1 is available [here](#).

The Protocol Monitoring Aflatoxin B1 has been published as a separate document on the GMP+ Portal. This was done due to the frequent changes in the protocol regarding the classification of harvest countries in risk profiles (High, Medium, Low). By publishing the protocol as separate document, a situation is avoided in which, after every change in the protocol, the version date of the GMP+ BA4 has to be adjusted. Frequent changes in the version date of GMP+ BA4 could cause confusion and / or uncertainty among participants about what requirements have been adjusted.

The Protocol Monitoring Aflatoxin B1 must be considered as paragraph 2.3 of GMP+ BA4 *Minimum requirements inspection and analysis* and is required.

3 Monitoring protocol of Salmonella in feed

~~Chapter 3 of the previous version (1 January 2022) of this document has been replaced by a new chapter and, for a better readability, it has been decided to delete here the chapter of the previous version.~~

~~The previous versions of scheme documents can be consulted on the [website](#).~~

3.1 General requirements

3.1.1 Scope

This protocol contains minimum monitoring requirements for Salmonella in feed. Excluded from this scope are feed products in which Salmonella cannot survive due to the intrinsic properties of the feed products: the pH value, temperature and/or low water activity (Aw-value). The exclusion must be based on a documented validation.

Guidance

More information about Salmonella and the conditions under which Salmonella cannot survive can be found in the GMP+ factsheet Salmonella. This factsheet is found on the GMP+ International Portal.

3.1.2 Application

This protocol applies to the GMP+ certified company that:

- produces feed, or
- outsources the production of feed to another company. See GMP+ BA10 *Minimum Requirements for Purchasing* for the requirements for purchasing production or processing on a contract basis.

If responsibilities with regard to the application of this monitoring protocol are transferred to another company, this must be kept as documented information.

3.2 Monitoring frequency

The GMP+ certified company must ensure that the feed does not exceed the Salmonella limits, as laid down in GMP+ BA1 *Specific feed safety limits*.

The ongoing effectiveness of the control measures must be monitored in accordance with the below-mentioned minimum monitoring frequencies. Monitoring is done by analysing representative samples taken of the end-products as close as possible to the end of the production line.

Guidance

Please remind that when having positive Salmonella results you may decide to increase the monitoring frequency.

3.2.1 Compound feed for poultry

The GMP+ certified company that produces compound feed for poultry must sample and analyse the compound feed according to the monitoring frequency as specified in the following table:

Type of compound feed per target animal	Minimum number of samples to be analysed	Minimum number of samples when a validated control measure is applied*
Breeding animals kept as grandparents or great-grandparents	1 per 48 tons	1 per 144 tons
Chickens or turkeys reared for breeding animals other than grandparents and great-grandparents	1 per 120 tons	1 per 360 tons
Chickens or turkeys kept for breeding purposes	1 per 240 tons	1 per 720 tons
Broilers, laying hens and animals reared for laying hens	1 per 480 tons	1 per 1440 tons
Meat turkeys	1 per 720 tons	1 per 2160 tons

~~If the GMP+ certified company applies a validated control measure the above mentioned monitoring frequency may be reduced by 75%.~~ *The validation must be kept as documented information.

Guidance

Be aware that the reduction of the monitoring frequency may not be possible due to national feed related legislation.

A validated control measure is a control measure that has proven to be effective in controlling Salmonella in feed. Heat treatment and acidification are well known and often-used control measures.

~~*Reducing the monitoring frequency by 75% means that a sample is taken from a three times larger volume. For example for breeding animals kept as grandparents or great-grandparents 1 sample per 144 tons can be analysed (instead of 1 per 48 tons).*~~

3.2.2 Compound feed (except feed for poultry)

The GMP+ certified company that produces other compound feed than those intended for poultry must sample and analyse the compound feed at least once per 10,000 tons.

3.2.3 Feed materials

The GMP+ certified company that produces feed materials must sample and analyse each feed material according to the monitoring frequency as specified in the following table:

Annual production of feed material	Minimum number of samples to be analysed	Minimum number of samples when a validated control measure is applied*
Less than or equal to 50,000 tons	8 per year	2 per year
More than 50,000 tons	20 per year	5 per year

~~If the GMP+ certified company applies a validated control measure the above mentioned monitoring frequency may be reduced by 75%.~~ *The validation must be kept as documented information.

Guidance

See Guidance in § 3.2.1

~~Reducing the monitoring frequency by 75% means that fewer samples can be analysed per year. For example in case of an annual production of more than 50,000 tons 5 samples can be analysed per year (instead of 20 per year).~~

3.2.4 Feed additives and premixtures

The GMP+ certified company that produces feed additives or premixtures must sample and analyse the feed additives and premixtures based on HACCP.

3.3 **Analysing**

Salmonella-positive results must be serological classified.

4 Other sampling and analysis protocols

4.1 Sampling and analysis Animal Protein

1. Target group

Manufacturers of compound feeds, including wet mixes, for ruminants.

2. Products

Compound feeds, including wet mixes, for ruminants.

3. General additional requirements

-

4. Inspection frequency

Monitoring is done by analysing the samples taken of end-products on the presence of tissue proteins from mammals in accordance with the below-mentioned minimum frequency:

Production in tons per year	Minimum number of samples to be analysed
Less than 10,000	1 per quarter
Between 10,000 and 40,000	2 per quarter
More than 40,000	3 per quarter

5. Additional corrective actions in the event of the norm being exceeded

In accordance with animal feed legislation.

6. Sampling method

-

7. Analysis method

The analysis will be carried out by a laboratory approved for this under the GMP+ FSA module. See GMP+ BA10 *Minimum Requirements for Purchasing*

8. Provision of results

The results of the determinations should be provided at least once per month to the GMP+ Monitoring database. Results from the analysis must be shared with the GMP+ Community in the GMP+ Monitoring database.

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