

GMP+ Feed Certification scheme

BA

Module: Feed Safety Assurance

GMP+ BA4

Minimum requirements for
Sampling and Analysis

4

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EN

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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

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.

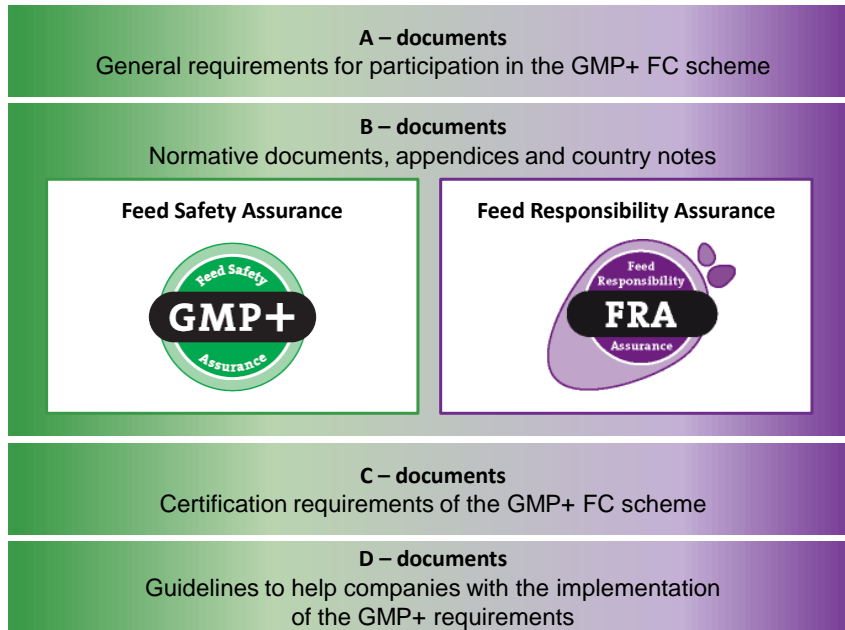
Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

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:

GMP+ Feed Certification scheme



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

An important part of the monitoring is the testing of the samples. In Chapter 2 of this appendix GMP+ BA4 *Minimum Requirements for Sampling and Analysis*, there are testing requirements for feed materials. Chapter 3 and 4 contain testing requirements for a number of types of compound feeds.

In drawing up and implementing a monitoring plan, the participant should include at least these required tests, 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 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 recontamination 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).*Note: Samples taken under Gafta or Fosfa rules might contribute to assurance about correct sampling and samples.*

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*, appendix 4 (Grain, seeds and legumes from uncertified origin), appendix 5 (Intervention grain) and appendix 6 (Palm oil). The monitoring required in these protocols is leading.
- f. Testing must – preferably – be carried out by a laboratory which certificate is accepted within the GMP+ FSA module . See GMP+ BA10 *Minimum Requirements for Purchasing* for a list of accepted laboratory schemes. Further, the testing in question must be under the scope of the certification/accreditation. For more details is referred to the applicable GMP+ standards.
Note: The dioxin and dioxin like PCB's required in section 2.2 must always be carried out by an ISO17025-accredited or a GMP+ B10-certified laboratory.
- g. Regarding seasonal and/or incidental products, testing must be carried out at the start of production, from the first batch or crop.
- h. Following the determination of Salmonella in feed materials, further classification (serological and phage type) must be carried out. The protocol applies as included in appendix I.

- i. 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.
- j. It is permissible 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

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

Variable	Explanation
Frequency	The number of samples to be tested (on a yearly basis)
Volume	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. Kilograms must be assumed for some feed materials for which, on a yearly basis, only a small quantity is produced, traded or processed.
Chance	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: <ol style="list-style-type: none"> a. History: see also below b. Seasonal influences c. Possibility of recontamination. This applies in particular to microbiological parameters. d. New source / new suppliers e. Have there been recent incidents. It is up to the participant to decide that the chance value can be lowered.

Variable	Explanation																												
	<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> <p>a. 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.</p> <p>b. Testing results from GMP+ International's GMP+ Monitoring database may also be used in determining testing frequency if the participant can show representativeness.</p>																												
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 data-bbox="730 813 1201 913"> <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> <p>This leads to the following factors:</p> <table border="1" data-bbox="635 1014 1455 1413"> <thead> <tr> <th>Undesirable substance</th> <th>Value</th> </tr> </thead> <tbody> <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>Feed medicines</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> </tbody> </table> <p>The established values are all high. This seems logical as these are risky undesirable substances.</p>	Seriousness is great	factor 5	Seriousness is moderate	factor 3	Seriousness is small	factor 1	Undesirable substance	Value	Heavy metals	5	Pesticides	5	Insecticides	5	Feed medicines	5	Mycotoxins	5	Salmonella	5	Fungi	3	Animal components	5	Dioxin	5	Nitrites	5
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	<p><u>Note:</u></p> <p>a. Calculated frequencies should always be rounded upwards. The minimum frequency is 1.</p> <p>b. Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content.</p>																												

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



Note: This section has been prepared in close cooperation with Ovocom vzw, and is also part of the Ovocom GMP system FCA Standard (Feed Chain Alliance)

2.2.1 Scope

2.2.1.1 *Products*

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.

Furthermore, these requirements also apply to imported oils & fats, directly sold to the feed industry, and to products used in the internal flows.

These requirements are meant to be integrated in the monitoring plan, which a GMP+ certified company is required to implement and to carry out.

2.2.1.2 *Operators*

Feed business operators placing on the market oils or products derived thereof which are intended for use in feed, including compound feed, must have these products analyzed in accredited laboratories for the sum of dioxins and dioxin-like PCBs². For detailed requirements, see section 2.2.5 Sampling and Analysis.

This monitoring applies to producers as well as to traders and import operators. Traders and import operators are exempt from monitoring:

1. If they dispose of an analysis result, covering the purchased batch (No. of batch must be included in the analysis report) and;
2. If their own monitoring, determined on the basis of their HACCP analysis, does not require a new analysis of the purchased batch.

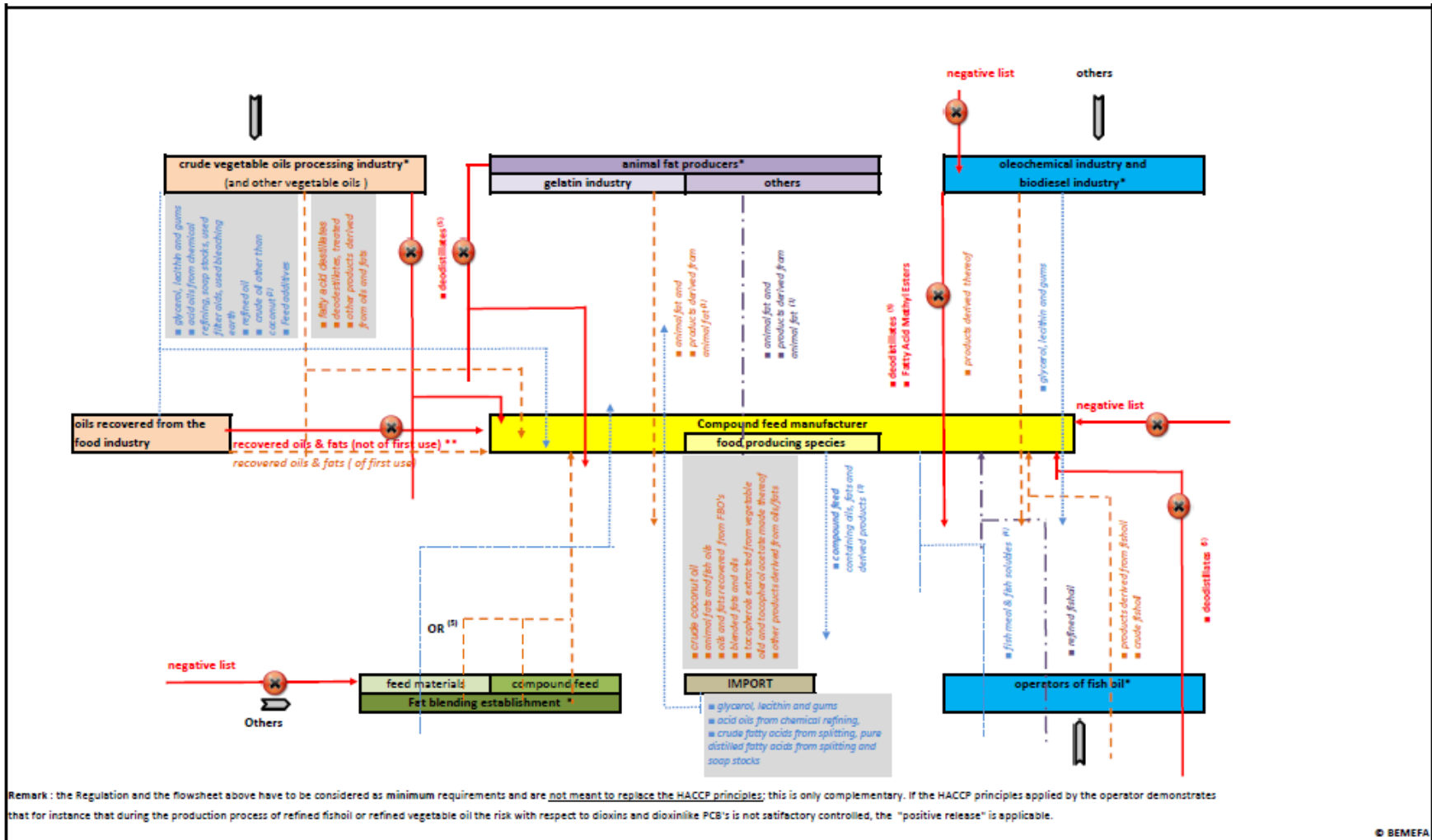
¹ These requirements are based on EU-legislation, as laid down in Reg. (EU) No. 183/2005 (Annex.II) including the amendments regulated by Regulation (EU) No. 2015/1905.

² In compliance with Commission Regulation (EC) No 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013.

2.2.1.3 Overview

In this paragraph, a schematic overview of different companies from the fat and oil chain is presented. This overview is prepared by Bemefa, Belgium. ([Link to original pdf](#))

MODALITIES OF APPLICATION						
*	traders / operators placing in the market included					
**	ALL recovered oils & fats that are not of first use (not only from food industry) belong to the negative list					
(1)	e.g. fatty acids, fatty acid distillates, soap stocks, acid oils, ...					
(1)	delivery of crude palm (or other) oil is applicable for instance for traders and producers of crude oil (not necessarily the crude vegetable oil processors).					
(2)	Sampling frequency of 1 % of the batches of manufactured compound feed containing oils, fats and derived products is not applicable if these are purchased from suppliers that fulfill their obligations. Monitoring according to the general HACCP principles is only necessary in case the production process would increase the risk for contamination (dioxin and dioxin-like PCBs). According to BEMEFA, this is not the case.					
(4)	In Belgium those feed materials were subject to mandatory analysis for the sum of dioxins and dioxin-like PCBs but they do not fall under the scope of Regulation 225/2012					
(5)	processed and not processed					
	incoming flows according to Regulation 225/2012					
	<table border="0"> <tr> <td>"regime I"</td> </tr> <tr> <td>"regime II"</td> </tr> <tr> <td>"regime III" - 2000 T</td> </tr> <tr> <td>"regime III" - 5000 T</td> </tr> <tr> <td>"regime IV"</td> </tr> </table>	"regime I"	"regime II"	"regime III" - 2000 T	"regime III" - 5000 T	"regime IV"
"regime I"						
"regime II"						
"regime III" - 2000 T						
"regime III" - 5000 T						
"regime IV"						
	<p>positive release : see 2.2.4</p> <p>(A) The operator placing the feed on the market is responsible for the sampling and analyses. Only if the analysis result is favorable, the feed can be delivered (together with the report of analysis of the concerned batch as a proof)</p> <p>(B) the buyer is responsible for the sampling and the analyses , but only starts using the feed after receipt of a favorable analysis report. This derogation is only possible with buyer's approval and with informing of the competent authority. There is a written agreement between supplier and purchaser.</p> <p>(C) The operator placing the feed on the market is responsible for the sampling and analyses. Feeds are stored at location of purchaser. Only if the analysis result is favorable, the feed can be delivered (together with the report of analysis of the concerned batch as a proof) and used. This derogation is only possible with buyer's approval and with informing of the competent authority. There is a written agreement between supplier and purchaser.</p>					
(7)	<p>blended fat : (A) in case of a mixture of at least two feed materials (= compound feed, also implying that the maximum limit for compound feed are applicable) :</p> <ul style="list-style-type: none"> ▶ "positive release" is compulsory. <p>(B) in case of a feed materials (maximum limits for feed materials are applicable) :</p> <ol style="list-style-type: none"> 1. The utilized oil, fats, and derived products are purchased from operators who fulfill their obligations (and they provide the necessary documents as a proof of that) <ul style="list-style-type: none"> ▶ "positive release" is not compulsory (HACCP can be applied), <u>except</u> if the production process would increase the risk of contamination (dioxin and dioxin-like PCBs). <p>The documents (providing the proof with respect to the blended ingredients), are provide to the buyer (customer) of the blended fat (feed material), together with the composition of the feed material (upon delivery at the latest). If there is an agreement between supplier and purchaser a conformity note can be provided as a proof.</p> 2. Not all the utilized oil, fats, and derived products are purchased from operators who fulfill their obligations (or they cannot provide the necessary documents as a proof of that) <ul style="list-style-type: none"> ▶ "positive release" is compulsory. 					
analysis :	analysis is carried out in accredited laboratories for the sum of dioxins and dioxin-like PCBs in accordance with Commission Regulation (EC) No 152/2009					



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 vegetable oils and fats	Any products, derived from crude or recovered vegetable oils, obtained through oleochemical or biodiesel processing or distillation, chemical or physical refining, other than refined oil. 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: the refined oil, products derived from refined oil, and feed additives.	
Fat blending	The mixing of crude oils, refined oils, animal fats, oils recovered from the food industry and/or products derived thereof, for the production of blended oils or fats, with the only exception of the storage of consecutive batches. Manufacturing of compound feed or, in case of all components belonging to the same entry in PART C of the Annex to Commission Regulation (EU) No 68/2013 which are derived from the same plant or animal species, of feed materials by mixing crude oils, refined oils, animal	Fat blending, is under EU Legislation, only allowed with an approval in accordance with Regulation (EC) No 183/2005. 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

Term	Description	Remarks
	fats, oils recovered from food business operators, falling within the scope of Regulation (EC) No 852/2004, or products derived thereof to produce a blended oil or fat, with the exception of the: sole storage of consecutive batches, and exclusive mixing of refined oils;	
Positive Release	The analysis results of dioxins and dioxin-like PCBs must be available, attached to and within the specifications before any use in feed materials such as compound feed and premixtures.	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 applicable 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	<p>This notion concept does not define the batch size, but rather a minimum analysis frequency.</p> <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,</p>	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 material. This is indicated in the tables with processes and products in section 2.2.3 below.

Term	Description	Remarks
	<p>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>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>
<p>Representative sampling: (source: ISO 5555 : Animal and vegetable fats and oils — Sampling).</p>	<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

The minimum monitoring frequency, depends on the type of fat/oil, and is indicated in every one of the following tables shown as follows:

Class	1	2	3	4
	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 ³	Not applicable. Products are forbidden for feed.	The presence of dioxins and dioxin-like PCB's is possible: 100% monitoring with a Positive Release. One analysis per batch (max.1000 tons ⁴)	The presence of dioxins and dioxin-like PCB's is highly unlikely: One representative analysis per 2000 tons or 5000 tons ⁵ (with a minimum of one representative analysis per year)	Monitoring of Dioxin and dioxin-like PCB's must be based on the company's internal risk assessment ⁶

³ If not further specified, a batch of products to be analyzed shall not exceed 1000 tons.

⁴ If 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.

⁵ One representative analyse per 2000 tons for specific fish oils and per 5000 tons for specific animal fats (cat-3) with a minimum of one representative analysis per year. See tables below.

⁶ 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 analysis, required in the following tables.

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

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: - 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;

		<ul style="list-style-type: none"> - 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 %). <p>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;</p> <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. (3) The name shall be supplemented by the indication of the botanical or animal origin. (4) The name shall be amended or supplemented to specify the fatty acids used. (5) The name shall be amended or supplemented to specify the organic acid.</p>		

For all feed materials named in accordance with the catalog, the monitoring is carried out in accordance with the class in the table below:

1. Companies producing products listed below (by processing oil seeds) and/or placing products listed below on the feed market Crushing of oil seeds and refining of oils, including imported products																	
Processes and products ^a	Description	Palm	Palm	Rape	Soya	Sun-flower	Coconut	Ground-	Linseed	Maize	Shea kernel	Safflower	Sesame	Walnut	Cotton-	Castor	Other Oil
Pressing and extraction																	
Crude oil/fat	Oils and fats from pressing/extraction	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Degumming																	
Lecithin, glycerol and gums		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Storage																	
Tank bottom ^b	Viscous, solid remains on the bottom of a tank	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
General ^c																	
Products derived from vegetable oils and fats – others then mentioned in this table 1.	any product derived directly or indirectly from crude or recovered vegetable oils and fats, obtained through by oleochemical process or biodiesel production, or distillation, chemical or physical refining, other than refined oil, products derived from refined oil and feed additives	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
used filter aids & used bleaching earth		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Physical refining																	
Refined oil/fat ^d	Oils/fats treated, in order to remove color, odor and off taste	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Feed additives		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Fatty acid distillates	Distillates originating from deodorization during physical refining	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Chemical refining																	
Refined oil/fat ^d	Oils/fats treated to remove color, odor and off taste	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Feed additives		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4

Soap stock and acid oils	Caustic soda refining and soap stock splitting	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Deodistillates, treated	Deodistillates, obtained through deodorization during chemical refining, treated specifically	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

- a) A batch subject to a Class 2 monitoring may comprise maximum 1000 tons of these products
- b) Any company, producing or handling this product, must have it defined within its internal documentary system. A traceability must be in place (in/out and volumes concerned).
- c) Meal (or expeller) are not considered as products derived from vegetable oils.
- d) Including products derived from refined oils/fats

2. Companies producing products listed below (from animal fat production and/or bringing products listed below on the feed market, including imported products)	Animal fats from land animals						Fish oil
	Tallow	Lard	Pig fat	Ruminant fat	Poultry fat	Animal fat (multi-species)	Fish oil
Processes and product ^a							
Fat processing							
Fat processors, edible fats and oils, (Regulation (EC) 853/2004)	3	3	3	3	3	3	
Animal by-products cat.3-operators, fats and oils (Regulation (EC) 1069/2009)	3	3	3	3	3	3	
Chemical refining							
Acid oils & soap stocks	3	3	3	3	3	3	
Distillates obtained from deodorization after chemical refining	3	3	3	3	3	3	
Physical refining							
Fatty acid distillates	3	3	3	3	3	3	
Gelatin production							
Fat from gelatin production ^b	2	2	2	2	2	2	
Fish oil processing ^b							
Crude fish oil							2
Oils with no monitoring history, unspecified origin, or from Baltic Sea							2
Soap stock and acid oils from fish oil							2
Oils from fish by-products from non-EU approved establishments manufacturing fish for human consumption							2
Oil from blue whiting or menhaden							2
Products (outgoing batches) derived from crude fish oil other than refined fish oil – others than mentioned in this table 2 under “fish oil processing”							2
Refined fish oil (and all other fish oils not specified above)							3 ^c

- a) *Producers and, if appropriate, traders of animal fat: when subject to a Class 3 monitoring, one representative analysis per 5000 tons shall be carried out with a minimum of one representative analysis per year. 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.*
- b) *Operators of fish oil or gelatin: when subject to a Class 2 monitoring, a batch may comprise maximum 1000 tons of fish oil or fat*
- c) *Producers and, if appropriate, traders: When subject to a Class 3 monitoring, one representative analysis per 2000 tons shall be carried out. 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.*

3 Companies producing products listed below (oleochemical processing & biodiesel production) and/or bringing products listed below on the feed market, including imported products	Fats from vegetable or animal origin used as raw material for oleochemical or biodiesel production								
Processes and product ^a	See GMP+ BA3 <i>Minimum requirements Negative List</i> for fat products, not allowed for use in feed production	Coconut Oil (crude)	All other products derived from oils and fats	Other vegetable oil (crude and refined)	Oils and fats recovered from food business operators	Acid Oils and Soap Stocks	lecithin, glycerol and gums and other products ⁷	Animal fat and fish oil (with the exception of the ones already tested by supplier)	Blends
INCOMING batches	1	4	2	4	2	4	4	2	2
Oleochemical production (OUTGOING)									
Products derived from the processing of the indicated products	1	4	2	2		4	4	2	2
Biodiesel production (OUTGOING)									
Fatty acids with methyl esters (fatty matter) ^b	1	1	1	1		1	1	1	1
All other products derived from the processing of the indicated products	1	4	2	2		4	4	2	2

a) When subject to a Class 2 monitoring a batch may comprise maximum 1000 tons

b) Fatty acids with methyl esters (also called fatty matter) collected after methanol recovery at a biodiesel production, are prohibited for feed purposes, since lipophile additives, used in biodiesel production, concentrate in fatty acids.

NOTE : If products are derived from several incoming products, and one of the incoming products are UCO's (recovered from the food industry or other) or Category 1 or 2 Animal Fats, these derived products are not allowed for use in feed (Class 1).

⁷ Acid oils from chemical refining, crude fatty acids from splitting, pure distilled fatty acids from splitting and soap stocks.

4 Companies producing products listed below (fat blending) and/or bringing products listed below on the feed market, including imported products	Mixtures of oils/fats and/or products thereof for fat blending							
Processes and product ^a	See GMP+ BA3 Minimum requirements Negative List for fat products, not allowed for use in feed production	Coconut Oil (crude)	All Other products derived from oils and fats	Other vegetable oil (crude and refined)	Oils and fats recovered from food business operators	Lecithin, glycerol, gums and other products ^e	Animal fat and fish oil (with the exception of the ones already tested by supplier)	Blends
INCOMING batches	1	2	2	4	2	4	2	2
OR ^b								
Batches of blended fats intended for feed (OUTGOING)	1							2

- a) When subject a to Class 2 monitoring, a batch may comprise maximum 1000 tons
- b) If blending results in a compound feed (cf. Reg (EC) 767/2009), there must be compliance with all relevant (legal) requirements and the option 'batches of blended fats intended for feed (OUTGOING)' is always applicable. In case blending does not result in a compound feed, the fat blender shall declare (to the competent authority and eventually to the GMP+ CB), in the context of his risk assessment, which alternative (incoming or outgoing batches) he will choose.
- c) Acid oils from chemical refining, crude fatty acids from splitting, pure distilled fatty acids from splitting and soap stocks

5 Imports ^a		Placing the following feed on the market:						
	Coconut Oil (crude)	Fatty Acids Destillates and Deo-destillates, Tocopherols extracted from vegetable oil and tocopheryl acetate made thereof	Other products derived from vegetable-oils and fats	Other vegetable oil (crude and refined)	Oils and fats recovered from food business operators	Lecithin, glycerol and gums and other products ^c	Animal fat and fish oil (with the exception of the ones already tested by supplier)	Blends ^d
Process and product^b								
INCOMING batches	2	2	2	4	2	4	2	2

- a) Imports concern 1) import from outside the European Union (EU) to the EU, and 2) imports between non-EU member states.
- b) When subjected to Class 2 monitoring, a batch may comprise maximum 1000 tons
- c) Acid oils from chemical refining, crude fatty acids from splitting, pure distilled fatty acids from splitting and soap stocks
- d) Blended fats and oils

2.2.4 Positive release

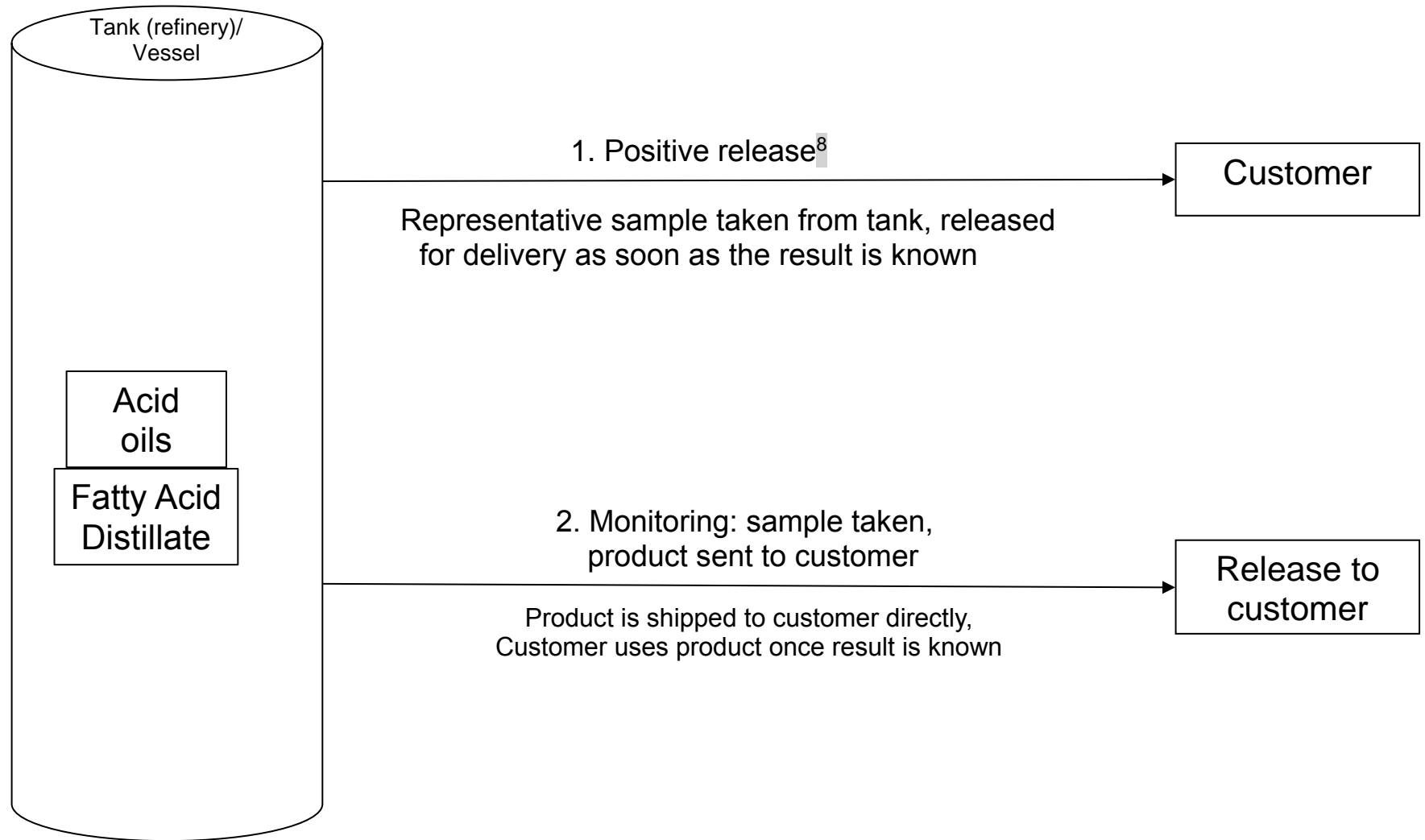
To comply with the Positive Release requirements, companies (producers and, if appropriate, traders, see section 2.2.1.2) within the supply chain, may use several systems. In this section, a number of systems, are explained. These systems are allowed to be used by GMP+ certified companies, active within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

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.

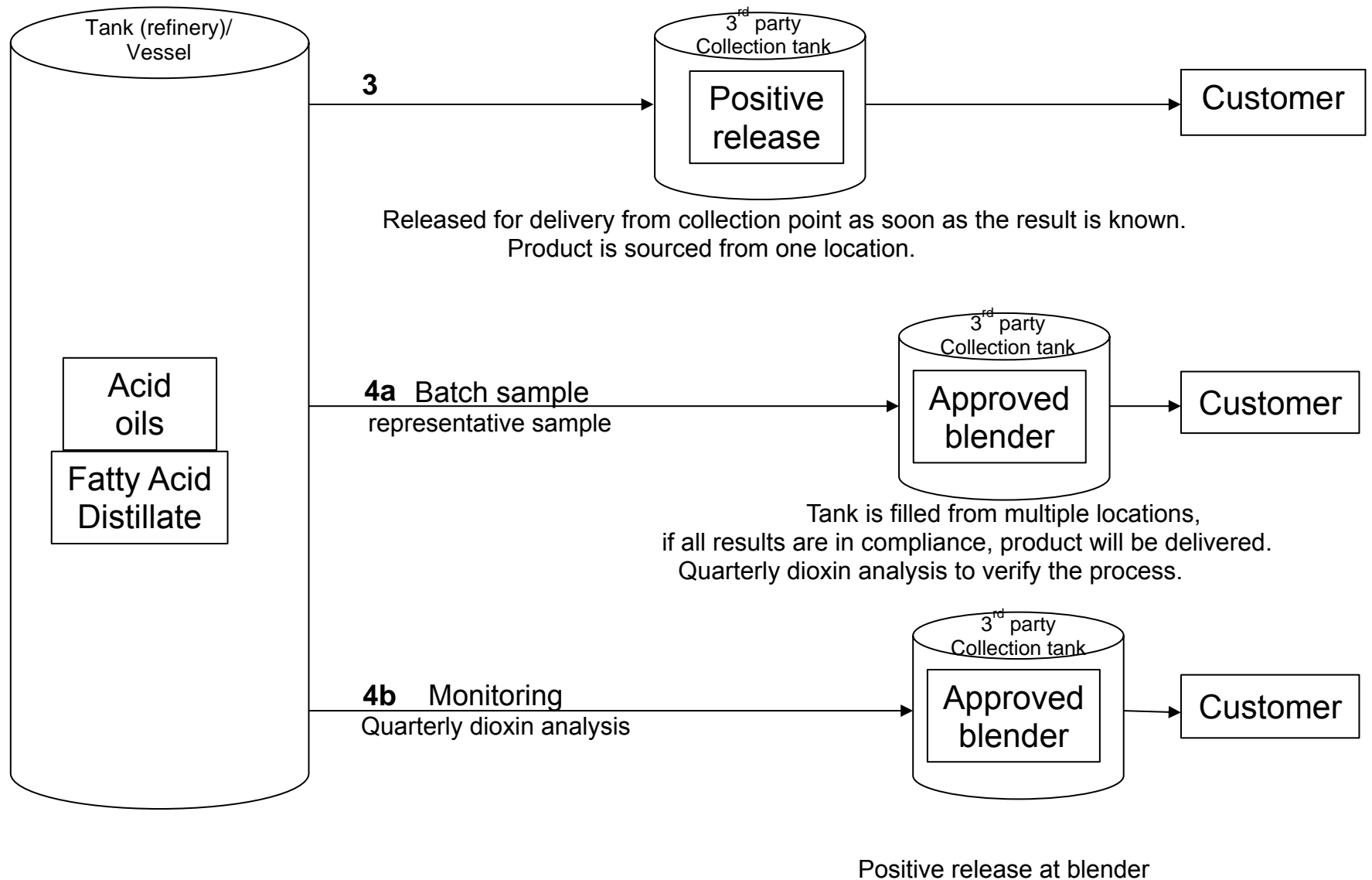
No.	Option	Remarks
1	The producer, takes a representative sample of the product located at his storage tank, he then sends the sample to a laboratory for the analysis of dioxin and dioxin-like PCBs. The product is shipped, and delivered to the customer, once the test results are known, and are within 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 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.	<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. - The tank does not necessarily have to be located in the same country as the production site.

No.	Option	Remarks
		<ul style="list-style-type: none"> - 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).</p> <p>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.</p> <p>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.</p> <p>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 Conformity Note must be clear, unambiguous and verifiable.

No.	Option	Remarks
		<p>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.



⁸ Example 1 to 4b: positive release not necessary in case the blend consists for 100% out of Acid Oils.



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.

2.2.5.2 *Analysis*

The analysis, as regards the levels of dioxins and dioxin-like PCBs must be performed by a laboratory, accredited according to ISO 17025 or GMP+ B10 for dioxin/dioxin like PCB's in oil, fats and fatty acids/distillates as scope.

The laboratory must use an officially recognized method of analysis, in accordance with the Commission Regulation (EC) No 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013. The certificate of analysis must indicate clearly the results of both dioxin and dioxin like PCB's. The level of both these contaminants, must not exceed the maximum residue levels (see GMP+ BA1 *Specific Feed Safety Limits*).

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.

2.2.5.3 *Batch size*

In the tables, 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.

2.2.5.4 *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 appendix 6 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.

2.4 Monitoring Aflatoxin B1 in feed materials (for use in feed) for dairy cattle

2.4.1 Introduction

This part of the protocol gives requirements for sampling and analyzing Aflatoxin B1 in feed materials for dairy cattle or for the preparation of compound feeds for dairy cattle.

2.4.2 Scope and application

2.4.2.1 *Companies*

This protocol applies to GMP+ compound feed manufacturers and suppliers of single feed materials for dairy cattle.

Note: A company may agree with his supplier of the feed materials to use relevant Aflatoxin B1 testing results, provided by the supplier.

2.4.2.2 *Feed products*

This protocol applies to feed materials for dairy cattle or for the preparation of compound feeds for dairy cattle.

2.4.3 General additional requirements

-

2.4.4 Inspection frequency

The following sampling and analysis schedule must be used for testing for Aflatoxin B1 in feed materials for dairy cattle and for the manufacturing of compound feeds for dairy cattle.

A participant which delivers the following feed materials in single form for dairy cattle must have an analysis certificate of the said (origin) batch, or of the testing based on his own sampling.

A participant which delivers compound feeds for dairy cattle must upon purchase or receipt of the following feed materials have an analysis certificate, supplied by the supplier of the said (origin) batch, or of the testing on the basis of his own sampling.

Feed materials class 1	All batches must be tested, whereby the analysis must concern (origin) batches of no more than 500 tons
	<p>The following come into this category:</p> <ol style="list-style-type: none"> 1. Groundnut expeller and - meal, all origins 2. Kapok expeller, all origins 3. Cotton seed expeller and - meal, all origins 4. Coconut (by-)products, all origins 5. Maize and maize by-products, all origins except EU, unless analyzed according to 2.3, and USA. 6. Palm kernels and palm kernel by-products, unknown origin 7. Safflower seed meal, all origins

Guidance

If maize and/or maize by-products have already been analyzed in accordance with the requirements in 2.3, those analysis results may be used to comply with the requirements in 2.4.

Feed materials class 2	All batches must be tested, whereby the analysis must concern (origin) batches of no more than 3,000 tons
	<p>The following come into this category:</p> <ol style="list-style-type: none"> 1. Palm kernels and palm kernel by-products, all known origins except Indonesia and Malaysia 2. Rice by-products, all origins

2.4.5 Sampling method

The sample taker must take representative samples in accordance with the general GMP+ FSA requirements, as laid out in GMP+ BA13 *Minimum requirements for sampling*.

For maize, the sampling must be carried out in accordance with the method as described in Regulation (EC) no. 152/2009, including the changes as stipulated by Regulation (EU) no. 691/2013, under the following conditions:

- Sampling must be carried out on the entire batch. Sampling of a part of the batch is not acceptable in the context of this protocol. If the whole batch in the warehouse is not accessible for sampling, a sampling plan should be made and documented, that covers the accessible part of the batch. The part of the batch that has not yet been sampled and tested, should be monitored once it's possible and safe to get access.
- Collective samples can never weigh less than 10 kg.

2.4.6 Analysis method

Samples must be analyzed on Aflatoxin B1 level.

This analysis must be carried out by a laboratory which is ISO17025 accredited or GMP+ B10 certified for the Aflatoxin B1 analysis in feed products.

2.4.7 Additional corrective actions in the event of deviations

In case a final sample exceeds the Aflatoxin B1 product standard (see GMP+ BA1 *Specific Feed Safety Limits*), the products are considered non-compliant.

The normal GMP+ requirements regarding non-conforming products must be followed. These include separation of products, informing customers, sending a EWS report to GMP+ International and inform the authorities.

2.4.8 Reporting of analysis results

The GMP+ participant that applies this protocol must enter the results of the analysis into the GMP+ Monitoring database and (anonymously) share them with the GMP+ community.

3 Sampling and analysis of compound feeds

3.1 Protocols relating to Salmonella-sampling and analysis

In the following protocols include requirements with respect to the monitoring for and analysis of Salmonella and Enterobacteriaceae in compound feeds for poultry, pigs, cattle and other animals.

Results from the analysis must be shared with the GMP+ Community in the GMP+ Monitoring database.

Classification of Salmonella-positive samples

As in the determination of Salmonella in feed materials there will be classification (serological type and possibly phage type). The protocol applies as included in appendix I. The poultry feeds, cattle feeds and pig feeds should be fully classified.

3.2 Protocol P1: Sampling and analysis of Salmonella and enterobacteriaceae in feeds for poultry

1. Target group

Manufacturers of poultry compound feeds intended for delivery to livestock holders.

2. Products

Compound feeds intended for poultry.

3. General additional requirements.

If a Salmonella-positive result is obtained then this should be classified in accordance with appendix I.

4. Inspection frequency

The following situations are distinguished with respect to the animal feeds supplied to poultry farmers

- 4.1 Technologically-treated poultry compound feeds
 - A) which are delivered as such
 - B) which are delivered together with separate feed materials
- 4.2 Non-technologically-treated poultry compound feeds
- 4.3 Final product check

Depending on the situation, requirements will be established for the entry check, production process control, and control in the logistical process. The frequency of inspection is dependent on previously obtained inspection results.

4.1 Technologically-treated compound feeds

Poultry feeds should be supplied Salmonella-free.

4.1.A. For producers of technologically-treated poultry feeds (for example pressing, acidification, etc.) the following requirements apply:

1. The compound feed manufacturer shows by way of an entero reduction test under which conditions the entero reduction is at least a factor 1000. These conditions should be used as set-up parameters for the production of treated poultry feed. The entero reduction test should be carried out at least twice per year. The compound feed manufacturer must be able to demonstrate that these set-up parameters are used in the production of poultry feeds. This applies from the beginning to the end of production.
2. Each company has its own responsibility and specifies the critical points for its own business situation and determines a minimum sampling plan. A sampling process diagram should be part of the sampling plan. This shows the critical points for the process control.

The producer should apply process control at those points which are critical with respect to possible recontamination with Salmonella, including

- a. Coolers, inside where there are possible condensation sites
- b. Air supply from the cooler at places where the air is sucked in
- c. Each point in the production line after the press where recontamination of the product by, for example, dust, enzymes, wheat may occur.
- d. Inside of the ready product silo on the top.
- e. Each point after the production line where recontamination can occur such as open places, loading.
- f. Transport of the ready product to the client.

A representative number of samples should be taken and examined from the critical points mentioned above with a minimum of 10 per production line.

3. With respect to sampling the sampling protocol applies (where applicable) as specified in § 6 of this Protocol P1. Where this is not possible (because of dust, means of transport, for example) use may also be made of the sponge/swabbing method where a minimum of 200 cm² is taken (sponged/swabbed).
4. The critical points must be examined for Salmonella. The frequency of inspection must be once per month and if this is negative for a half year then the frequency can be reduced to once per two months. In the event of a positive finding analysis must be done again once per month for at least half a year. The positive samples must be classified.
5. In the event of contamination corrective actions will be taken immediately until there is demonstrable compliance with the norms.
6. At the request of the poultry farmer the research data related to the above will be made available to him or her.

- 4.1.B. For producers of technologically-treated poultry feeds with separate mixed feed materials the following requirements for separately mixed feed materials apply in addition to the requirements with respect to production of technologically-treated poultry feeds (see section 4.2.A).
1. Only 'non-Salmonella-critical' feed materials may be mixed separately. For Salmonella-critical feed materials see GMP+ BA4 *Minimum Requirements for Sampling and Analysis*, (appendix 3.5 Protocol 4).
 2. Any contamination which could possibly occur during reception, transport and storage of these (=non-Salmonella-critical) feed materials must be prevented. The critical points where recontamination with Salmonella can occur must be checked monthly for this⁹. These critical points are also indicated in the process diagram (see section A2). These include as a minimum the reception of feed materials, internal transport and storage (= logistical process).
 3. A representative number of samples should be taken and examined from the critical points mentioned above with a minimum of 3.
 4. The critical points must be examined for Salmonella. The frequency of inspection must be once per month and if this is negative for a half year then the frequency can be reduced to once per two months. In the event of a positive finding analysis must be done again once per month for at least half a year. The positive samples must be classified.
 5. In the event of contamination corrective actions will be taken immediately until there is demonstrable compliance with the norms.
 6. At the request of the poultry farmer the research data related to the above will be made available to him or her.
- 4.1.C. For companies with an annual production of poultry feeds of up to 7,500 tons per year

A company with a lesser annual production (<7500 tons of poultry feeds) may decide to comply with the requirements of this section instead of the relevant requirements with respect to process control in section 4.2A and section 4.2B.

It has been established that for an annual production of poultry feed of 7,500 tons or less, a company should carry out a process check 4x per year (or per production batch) where a sample is taken at 5 critical points. A mix sample may then be made up from these 5 samples and then analysed. The relevant ISO instructions apply with respect to the pooling of samples. This means a total of about 4 analyses per year.

If this results in a positive outcome then 5 samples should then be analysed again separately in order to trace the contamination.

If the mix sample is negative then it can also serve as end product sample.

⁹ This relates to a number of extra critical points in the logistical process in addition to the critical points in the production process specified in section A2.

4.2 Technologically-untreated compound feeds

Poultry feeds should be supplied Salmonella-free.

The following requirements apply with respect to the entry check for feed materials:

1. The compound feed manufacturer will make the following distinction in feed materials in the production of technologically-untreated poultry feed:
 - non-Salmonella-critical feed materials can be processed without an analysis of the batch in question being availableSalmonella-critical feed materials (see GMP+ BA04 *Minimum Requirements for Sampling and Analysis*) can only be processed if the batch in question, after sampling and analysis, appears to be Salmonella-free on the responsibility of the compound feed manufacturer
 - a. As an exception to this Salmonella-critical feed materials may also be processed with an analysis result for the batch in question not being available if it is made demonstrable that the feed material in question is from a specific manufacturer (=origin) and/or has undergone a specific treatment and therefore complies with the norm 'non-Salmonella-critical'. Before this exception clause can be used at least 10 consecutive deliveries must be Salmonella-negative.
 - b. After this, every 5th batch must be sampled and analysed with a negative result. In the event of a positive result each batch must again be sampled and analysed until 10 consecutive deliveries are found to be Salmonella-negative.
2. Method of sampling of feed materials:
 - a. Salmonella-critical and non-Salmonella-critical feed materials are both sampled in the manner described in § 6 of this protocol P1.
 - b. Sampling is done on the responsibility of the compound feed manufacturer. (N.B. the sampling may take place elsewhere, for example during the loading of the feed material)
 - c. For batches of up to 100 tons, at least 1 sample is taken and for batches of more than 100 tons at least 5 samples are taken. For the latter a mix sample may be made for the analysis.

The following requirements apply with respect to the *process control* during the production of poultry feeds:

3. Each company has its own responsibility and specifies the (representative) critical points for its own business situation and determines a minimum sampling plan. A sampling process diagram should be part of the sampling plan. This shows the critical points for the process control.

The critical points in the production process for recontamination of *Salmonella* may, for example, be:

- a. Internal transport from the intake point
- b. Each point in the production line after the grinder/mixer where recontamination of the product by, for example, dust, enzymes, wheat may occur.
- c. Inside of the ready product silo on the top.
- d. Each point after the production line where recontamination can occur such as open places, loading.
- e. Transport of the ready product to the client.

A representative number of samples should be taken from the critical locations in the production process and these should be examined for the presence of *Salmonella* with a minimum of 5 per production line.

4. With respect to sampling (where applicable) the sampling protocol applies as specified in § 6 of this Protocol P1. Where the necessary quantity of sampling material (dust and residues of feeds) cannot be obtained (because of dust, means of transport, for example) use may also be made of the sponge/swabbing method where a minimum of 200 cm² is taken (sponged/swabbed).
5. The frequency of examination for these critical points must be once per month and if this is negative for a half year then the frequency can be reduced to once per two months. The critical points must be examined for *Salmonella*. In the event of a positive finding, sampling and analysis must be done again once per month for at least half a year. The positive samples must be classified in accordance with appendix 1.
6. In the event of contamination immediate corrective actions will be taken until there is demonstrable compliance with the norms.
7. At the request of the poultry farmer the examination data related to the above will be made available to him or her by the compound feed manufacturer.
8. A company with a lesser annual production (<7500 tons of poultry feeds) may decide to comply with the requirements of section 4.2C instead of the relevant requirements with respect to process control in this section 3.

4.3 Poultry compound feeds (end products)

The sampling and analysis of the distinguishable types of end product must be done in accordance with the minimum frequency (per company unit) indicated in the table below.

Type of compound feed	Minimum inspection frequency, calculated per 24-ton delivery
Top breeding ¹⁰	1 in 2 batches (50%)
Raising increase ¹¹	1 in 5 batches (20%)
Breeding ¹¹	1 in 10 batches (10%)
Broilers	1 in 20 batches (5%)
Laying-hens and breeding hens	1 in 20 batches (5%)
Raising breeding turkeys	1 in 5 batches (20%)
Breeding turkeys	1 in 10 batches (10%)
Meat turkeys	1 in 30 batches (3 1/3%)

5. Additional corrective actions in the event of a Salmonella-positive result

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6. Sampling method

The samples of end product for process control on the basis of Enterobacteriaceae must be taken at a point that is as close as possible before loading the bulk container (or the filling of the sacks). The size of the samples to be taken is at least 60 grams, sufficient to compose a sample and a duplicate sample of 25 grams each.

The samples of compound feed should be taken from the product flow at a point as close as possible before the loading of the bulk container (or the filling of the sacks), or, in the event of process control, as close as possible to the critical point in the process.

7. Analysis method

The analysis will be carried out by a laboratory certified under the GMP+ FSA scheme for the determination of Salmonella or by an equivalent laboratory. See GMP+ BA10 *Minimum Requirements for Purchasing*

8. Reporting analysis results

8.1 The GMP+ Monitoring database

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.

8.2 Certification Body

For every observation of *Salmonella enteritidis* (S.e.) and *Salmonella typhimurium* (S.t.) in compound feed for the egg sector there should be immediate consultation with the certification body about the effectiveness of the previous measure.

¹⁰ meat and egg sectors, respectively

¹¹ If, during an uninterrupted period of 2 years inspection of the type of feed in question, no Salmonella-positive sample is found then a minimum sampling frequency may be used of 1 in 30 batches (31/3%) .

3.3 Protocol 2: Sampling and analysis for Salmonella and enterobacteriaceae in compound feeds intended for pigs, cattle and other animal species (with the exception of poultry)

1. Target group

Manufacturers of other compound feeds including manufacturers of mixes of wet by-products than those intended for poultry.

2. Products

Other compound feeds than those intended for poultry (including the mixes of other wet by-products).

3. General additional requirements

If a Salmonella-positive result is obtained then this should be classified in accordance with appendix I.

4. Inspection frequency

The inspection of the distinguishable types of end product must be done in accordance with the minimum frequency (per company unit) indicated below. This depends on the treatment the product has had.

4.1 Salmonella reduction treatment

In the event of Salmonella-reducing treatment, testing for Enterobacteriaceae and/or Salmonella must be carried out.

4.1.1 Salmonella

If it is decided to test for Salmonella then the test should take place as follows;

Samples should be taken-compound feeds for analysis for Salmonella.

The following table clarifies the number of samples to be taken.

Annual production of compound feed for other types of animal than poultry by business unit (for wet mixes, the quantities of dry matter)	Number of samples per quarter
up to 2,000 tons	2
up to 4,000 tons	2
up to 6,000 tons	3
up to 8,000 tons	4
up to 10,000 tons	5
up to 20,000 tons	10
up to 30,000 tons	15
up to 40,000 tons	20
more than 40000 tons	25

4.1.2 Enterobacteriaceae

If testing for Enterobacteriaceae has been opted for then this must be done per production line on which Salmonella-reducing treatment is carried out, through:

- sampling and analysis twice a year at the critical points in the production process in order to determine the course of the level of Enterobacteriaceae to test the production process (thermal treatment);
- 5 samples per quarter of end product per line and analysis of these samples.

In addition, at least twice a year, sampling and analysis for Salmonella must take place at critical points in the production process.

4.2 No Salmonella-reducing treatment

If no Salmonella-reduction treatment takes place then there should be an inspection as intended in § 4.1.1.

4.3 Wet compound feeds

As a replacement for Salmonella testing, the participant can also carry out tests on pH or temperature. The participant should take at least one sample per quarter, per product and have it tested.

In the event of the pH being measured and there is compliance with the maximum pH as specified in GMP+ BA01 Product Standards, then sampling and analysis for Salmonella is not mandatory.

5. Additional corrective actions in the event of a Salmonella-positive result

If a sample of end product is found to be Salmonella-positive then sampling and analysis for Salmonella should be carried out at critical points in the production process.

6. Sampling method

The samples of compound feed should be taken from the product flow at a point as close as possible before the loading of the bulk container (or the filling of the sacks), or, in the event of process control, as close as possible to the critical point in the process. The samples of end product for process control on the basis of Enterobacteriaceae must be taken at a point that is as close as possible before loading the bulk container (or the filling of the sacks). The quantity of the samples to be taken is at least 60 grams, sufficient to compose a sample and a duplicate sample of 25 grams each.

7. Analysis method

The analysis will be carried out by a laboratory certified under the GMP+ FSA scheme for the determination of Salmonella or by an equivalent laboratory. See GMP+ BA10 Minimum Requirements for Purchasing

8. Reporting analysis 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.

3.4 Protocol P4: Sampling and analysis of Salmonella-critical feed materials (raw materials)

Introduction

On the basis of the sampling and analyses data for the 'output check' from producers / importers / shipping agents of feed materials and the 'input check' of the GMP+-certified compound feed manufacturers GMP+ International maintains the following list of Salmonella-critical feed materials.

Salmonella-critical feed materials

There are currently no feed materials assessed as Salmonella-critical.

3.4.1 Protocol 4A: Sampling and analysis of Salmonella-critical feed materials

1. Target group

Producers of Salmonella-critical feed materials

2. Products

Salmonella-critical feed materials.

Each year, the report "Plan to control Salmonella in the feed sector" is used to determine which feed materials are Salmonella-critical.

3. General additional requirements

At the production location there should be a list showing the following details:

- a. number of vehicles loaded
- b. the quantity delivered per ship
- c. which vehicles were sampled
- d. the number of samples per ship
- e. date of sending samples to the laboratory
- f. results (and the classification if Salmonella-positive).

This list will be filed and made available on request to the inspector of the supervising body.

If a Salmonella-positive result is obtained then this should be classified in accordance with appendix I.

4. Inspection frequency

For each production location at least one sample per delivery day will be examined during loading (from the factory) for the presence of Salmonella.

5. Additional corrective actions

-

6. Sampling method

Per production location a sample of at least 25 grams will be taken per vehicle of the first delivery of the day and then of every fourth vehicle delivery. If ships are being loaded then a sample should be taken per 500 tons or part thereof.

The sample material will be scooped from the product flow during loading and will be packed in sterile sample pots. The manufacturer sends the samples within 2 working days of the sample being taken and gives the laboratory the order to make a mix sample of the material and to have it analysed.

7. Analysis method

The analysis will be carried out by a laboratory certified under the GMP+ FSA scheme for the determination of Salmonella or by an equivalent laboratory. See GMP+ BA10 Minimum Requirements for Purchasing

8. Reporting analysis 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.

3.4.2 “Bonus/penalty” requirements with respect to the sampling and analysis of Salmonella-critical feed materials

A producer of a Salmonella-critical feed material must comply with the minimum sampling and analysis established in the protocol in question. A producer can, however, on the basis of demonstrably good sampling and analysis results be eligible for a decrease in the sampling and analysis frequency. The producer should comply with the following requirements:

- a. The producer has in the previous year complied with all the Salmonella sampling and analysis obligations as specified in GMP+ BA4 *Minimum Requirements for Sampling and Analysis*, Protocol P4. This means that it has complied with the frequency of sampling and analysis and has sent the analysis results to the GMP+ Monitoring database in accordance with requirements.
- b. The Salmonella incidence of the feed material in question has in the previous 4 quarters been lower than 3% per quarter on the basis of regular sampling and analysis in which:
 1. the Salmonella incidence of 3% relates to end product control ex-factory;
 2. The Salmonella incidence of 3% relates to all Salmonellas (all serological classifications)
 3. the Salmonella incidence is calculated on the basis of the prescribed frequency of sampling in GMP+ BA4 *Minimum Requirements for Sampling and Analysis*, Protocol P4.
- c. The producer has in the previous year carried out a proper process control in which all the critical points in the process have been made clear and proper control measures have been taken (in accordance with the HACCP system).

If the producer complies with the established requirements (items a to c) then instead of the prescribed minimum mandatory sampling and analysis he may make do with the following sampling and analysis frequency:

The producer carries out Salmonella sampling and analysis on the basis of in company HACCP.

The minimum sampling frequency is determined via the system detailed in Chapter 2 of GMP+ BA4 *Minimum Requirements for Sampling and Analysis* using the following formula:

$$\text{Freq.} = \frac{\sqrt{\text{Production volume}} * 1 * 5 * 5}{100}$$

For an explanation of this formula see Appendix 2 of GMP+ BA4 *Minimum Requirements for Sampling and Analysis*. In the above formula a decision has been made on a factor 1 for the history and for a factor 5 for the seriousness.

This formula is derived from a general formula which takes into account the production annual volume and in which a correction factor can be applied for the history, the chance of recontamination and the seriousness.

- a. If the cause of a higher Salmonella incidence than 3% (of end products) in a quarter is to be found in one incident then the producer may make do with the monitoring as specified in point a. There is an incident if the Salmonella incidence of end products after the observation of the incident
 1. Is higher for a maximum of one month (30 days) than 3% and
 2. More than 1 positive result is found within 14 days.
- b. Per two successive quarters only 1 incident may occur.
- c. If the producer has a Salmonella incidence in two successive quarters 3% of end products (which is not the result of one incident) then the producer must inform his certification body of the measures taken.
- d. If the producer does not comply with items a. to d. then for a period of at least one year he should carry out Salmonella sampling and analysis as prescribed in GMP+ BA4 *Minimum Requirements for Sampling and Analysis* for the Salmonella-critical feed material in question.

4 Other sampling and analysis protocols

4.1 Protocol P7: 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

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4. Inspection frequency

The following numbers of samples from feeds for ruminants must be taken for the microscopic tests for the presence of tissue proteins from mammals.

Inspection table per production location for BSE control

Production in tons per year	Samples / Quarter
< 5,000	1
5,000 < < 10,000	1
10,000 < < 20,000	2
20,000 < < 30,000	2
30,000 < < 40,000	2
>40,000	3

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

In accordance with animal feed legislation.

6. Sampling method

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7. Analysis method

The analysis will be carried out by a laboratory certified under the GMP+ FSA scheme for the determination of Salmonella or by an equivalent laboratory. 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.

ANNEX 1: Protocol for the serological classification of Salmonella

Participants in the GMP+ FSA scheme for the animal feed sector are obliged have Salmonella-positive samples of feeds or feed materials classified.

The poultry feeds, cattle feeds and pig feeds should be fully classified. The feed materials should be classified for the serotypes Enteritidis, Typhimurium, Infantis, Virchow, Hadar, Java and Agona. The serological classification should be carried out by the RIVM or by GMP+ B10 *Laboratory Testing* certified for the serological classification of Salmonella or accredited for ISO 17025 (for Salmonella classification). The costs of the classification will be charged to the (animal feed) company.

The purpose of this classification is to establish more accurately any relationship among Salmonella types in feed materials, the compound feeds produced from them, live animals which eat these feeds and also animal products. It is an aid in investigating the possible cause of Salmonella contamination in a subsequent link in the chain.

The procedure is as follows:

- a. New companies participating will report once only to the RIVM at telephone number 030-2742126.
- b. The RIVM will then send you a transmission medium as quickly as possible including packaging material. This is the standard RIVM packaging with white/pink forms. These forms must be replaced by the green forms for the animal feed project. These forms will be sent to newly registered companies separate from the packaging material.
- c. The packaging material and the new transmission medium will be returned to the sender after each submission. The green forms can be requested each time by telephone at telephone number 030-2742126. The participants who regularly submit a green form to the RIVM must from today also order these forms by telephone.
- d. The green RIVM form should be fully completed and sent to the RIVM together with the identified salmonella culture. The form should contain the following details:
 1. Name/address/place of the sender;
 2. Company ordering the sampling of the product (possibly in code form);
 3. Type of feed or fodder from which the salmonella was isolated;
 4. Country of origin of the feed.

For the first consignment the technique for isolating Salmonella should be specified once and also any future changes in the technique used.