Technical Specifications

TS1.7 - Monitoring

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GMP+ International

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Index

Welcome

This Feed Certification scheme document helps you to provide feed safety world-wide. By meeting the requirements set by GMP+ International together with our stakeholders, we aim to help you get the feed certification you need. Please read the information in this document carefully.

Let's make this work together!

1. General monitoring requirements

The requirements listed in this document are **in addition** to those set out in the Feed Safety Management Requirements document.

1.1. Monitoring plan

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

The GMP+ certified company may make use of representative monitoring results from other companies (for example: suppliers). This particularly applies to monitoring 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'.

If there is any doubt, uncertainty or unclearness about the representativeness of the monitoring results from other companies, the certified company must verify on the representativeness.

The GMP+ certified company must determine if specific monitoring requirements described in this document are applicable and must therefore be implemented in the monitoring plan of the certified company.
In case of overlap between different monitoring requirements in this document or other GMP+ FSA documents, the GMP+ certified company must apply the strictest monitoring requirements.

Helpful tip:

Special attention should be given to the representativeness of the
- monitoring results received from suppliers: for example: qualifications of the laboratory; used method; detection limit)
- sampling and
- samples (for example: correct method; do they really represent the feed)

Note: Samples taken under Gafta or Fosfa rules might contribute to assurance about correct sampling and samples.

1.2. Monitoring frequency

The monitoring frequency must give assurance that all identified hazards and determined risks remain under control.

Helpful tip:

Remember that, the monitoring frequency (on a yearly basis) of feed materials can be calculated using the following formula:

$$\text{Frequency} = \frac{\sqrt{\text{Volume}}}{100} * \text{'likelihood of occurrence'} * \text{'severity'}$$

Variable	Explanation
Frequency	The number of samples to be monitored (on a yearly basis)
Volume	Volume in tons of feed materials per year. In principle, the number of samples to be monitored 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.
Likelihood of occurrence	The default value for likelihood of occurrence is 1. The GMP+ certified company may raise or lower this value if reasons are given. The following considerations may apply to this: 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 certified company to decide that the likelihood of occurrence value can be lowered. The certified company must select a likelihood of occurrence value which is below one on the basis of (historical) monitoring results. The following must be kept in mind: a. Monitoring results must be representative. The historic monitoring results which are considered as representative may differ per undesirable substance. For some undesirable substances the monitoring results for an area can be considered to be representative while, for other undesirable substances, only monitoring results for the same production location is representative. b. Monitoring results from GMP+ International's GMP+ Monitoring database may also be used in determining monitoring frequency if the participant can show \ representativeness.
Severity	This factor expresses the degree of harmfulness of an undesirable substance. For the value for severity use can be made of information of the Feed Support Products (FSP): Severity is great factor 5 Severity is moderate factor 3 Severity is small factor 1

<table>
<tr><th>Variable</th><th>Explanation</th></tr>
<tr><td></td><td>This leads to the following factors:
<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>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>
</table>
The established values are all high. This seems logical as these are risky undesirable substances.</td></tr>
<tr><td colspan="2">Note:
a. Calculated frequencies should always be rounded upwards. The minimum frequency is 1.
b. Calculation of the monitoring frequency of liquid or moist feed can be based on 88% dry matter content.</td></tr>
</table>

1.3. Sampling

The GMP+ certified company must take samples in accordance with the requirements as laid down in document TS 1.6 *Sampling*.

1.4. Collective monitoring plan

It is permissible for GMP+ certified companies to carry out their monitoring plan together (in a collective monitoring plan). The following requirements must be applied with respect to this option:

a) The collective monitoring plan must comply with the GMP+ requirements..
b) The scope of the monitoring plan must be established ('which feed is included') and which companies are participating.
c) The collective monitoring plan must be representative for the feed which the manufacturers produce, trade, treat and / or process. Its representativeness must be motivated.
d) All the participating companies must obtain all the relevant sampling and monitoring results.

2. Monitoring protocol of Aflatoxin B1 in Maize and By-products of maize

2.1. General requirements

2.1.1. Scope

This protocol gives specific requirements for sampling and analysing Aflatoxin B1 in:

- maize, processed or unprocessed and
- by-products of maize,

which will be delivered in the GMP+ chain. It applies to all maize harvests.

The monitoring requirements in this protocol must be applied either to the maize or to the maize by-product.

2.1.2. Application

This protocol applies to the GMP+ certified company which trades or processes the products as mentioned in § 2.1.1.

The producer of the maize by-product must apply the protocol to the end product. Food producing companies that purchase and process maize under the conditions of Regulation (EU) No. 1881/2006 (maximum levels for contaminants in foodstuff) are allowed to apply the protocol to the incoming flow of maize if they have a motivation in writing of the concentration factor in the production process and also do a risk-based monitoring on the maize by-product.

If a batch of maize or a maize by-product has already been analysed by a GMP+ certified supplier, this batch is not required to be analysed again. This is also applicable when the supplier is participating in another, accepted feed safety assurance scheme, under the condition that the analysis results are available.

2.1.3. Countries of cultivation

The countries of cultivation[1] of maize are classified into 3 categories: High, Medium and Low. Sampling and analysis of maize from a high risk country must be performed in accordance with the requirements in § 2.2.1.

[1] *If applicable, a country can be divided in different regions.*

Maize from a Medium risk country must be sampled and analysed in accordance with § 2.2.2. For Low risk countries, sampling and analysis must be in accordance with § 2.2.3.

To consult the classification of countries of cultivation click here.

The country of cultivation of the maize must always be known to every link in the supply chain, and the customer must be informed, including the end user.

Helpful tip:

With 'end user' is meant the GMP+ FSA certified company that delivers compound feed to the farmer (= the final link in the GMP+ chain).

2.1.4. Place of sampling

Batches must be sampled at loading (country of cultivation) or at discharge (country of delivery). In case the protocol is applied at discharge, the batch is determined by the means of transport in which the maize or maize by-product is then loaded.

Helpful tip:

This means when a seagoing vessel is discharged in the country of delivery and the maize is directly loaded in an inland waterway vessel, the inland waterway vessel must be considered as a batch and has to be sampled.

2.1.5. Sample preparation

The GMP+ certified company applying this protocol must send at least a 4 kg sample of maize (by-product) to the laboratory for preparation and analysis. The preparation and analysis by the laboratory must be in accordance with the following conditions:

a) The sample must be fully grinded and homogenized before the final sample and out of it the sample for analysis must be taken.
b) The final sample must at least be 500 grams.
c) The sample for analysis must be prepared from the final sample.
d) The remains of the final sample must be retained for re-analysis.

2.1.6. Analysing

2.1.6.1. Analyse method

The sample for analysis must be analysed on Aflatoxin B1.
This analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

2.1.6.2. Sharing of analyse results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations, including origin, within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

Helpful tip 1:

The analysis results you share with the GMP+ Community are used to evaluate the classification of the countries. It is therefore very important to enter the results in the database as soon as possible. Be aware to enter the correct value (in mg/kg!). External communication, e.g. to other scheme owners, will only be done in an anonymous way.

Helpful tip 2:

A laboratory might report the results in ppb's. Be sure to check on this. If so, please divide this result by 1000 before entering in the database. Example: 3 ppb = 0.003 mg/kg.

Helpful tip 3:

The GMP+ certified company who makes use of analysis results from other companies (for example suppliers) should not enter the results into the GMP+ Monitoring database.

2.2. Requirements per classification of countries of cultivation

2.2.1. High risk countries

2.2.1.1. Application

For maize from high risk countries, the first link in the chain is responsible for a correct application of this protocol.

2.2.1.2. Monitoring frequency

Each final sample must be analysed.

2.2.1.3. Size of batches

The batch size of maize or maize by-product is related to the means of transport and must have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling.

Means of transport	Maximum batch size
Seagoing vessel	Max. 2,000 tons
Inland waterway vessel	Inland waterway vessel
Train	Max. 1,500 tons
Truck, from Storage/ warehouse, production location or collection point	Max. 1,000 tons

2.2.1.4. Sampling

2.2.1.4.1. Sampling method

The sampler must take representative samples in accordance with the described in Regulation (EC) No. 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013, under the following conditions:

a) sampling must be undertaken of the whole batch. Sampling of part of the whole batch is not acceptable within the framework of this protocol;
   If the whole batch in the warehouse is not accessible for sampling, a sampling plan must be made and retained as documented information. The sampling plan must cover the accessible part of the batch. The part of the batch that has not yet been sampled and monitored, must be monitored once it´s possible and safe to get access;
b) each aggregate sample must not be less than 10 kg;
c) the sample to be send to the laboratory for preparation and analysis must not be less than 4 kg. See § 2.1.5 and 2.1.6 for requirements regarding sample preparation and analysis by the laboratory.

In case of direct ship-to-ship transshipment (from a seagoing vessel, coaster, inland waterway vessel to an inland waterway vessel) the method described in "GAFTA sampling rules No. 124" is allowed under the following conditions:

d) a representative sample must be taken during loading or unloading of the means of transport.
e) at least 20 incremental samples per 500 tons and at least 40 incremental samples for batches smaller than 1,000 tons.
f) maximum volume of the incremental sample: 1kg
g) minimum 20 kg per (sub)batch of 500 tons
h) at least 1 final sample, which shall not be less than 4 kg. Each final sample must be fully grinded and made homogeneous by the laboratory. See § 2.1.5 and 2.1.6 for requirements regarding sample preparation and analysis by the laboratory.

Note: In cases where maize is stored longer than 3 month in a silo and is not accessible for sampling before delivery to the customer, sampling may be carried out during loading. The results must be available before unloading at the customer or at least before the next processing step or feeding (if there is a written agreement between the seller and the customer).

2.2.1.4.2. Sample taker

Each batch must be sampled by an independent superintendent organization accredited according to:

a) ISO 17020 for an appropriate scope, or alternatively;
b) ISO 9001 for an appropriate scope in combination with a GAFTA[2] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed).

2.2.1.4.3. Other requirements

The period between sampling and delivery must not be longer than three months.
It is possible to separate a batch at a storage location in the country of cultivation within the framework of direct transport per inland waterway vessel, train or truck to the end user. The following additional requirements apply:

a) The batch must be kept in quarantine (separate and identifiable) at the storage location in the country of cultivation.
b) The location must be set up in such a way that representative (cross-section) samples can be taken.

2.2.1.4.4. Information to the Client and End user

Positive release: The analysis results (by means of an original certificate of analysis or an original analytical report of an approved lab, see § 2.1.6.1) must accompany the batch, so each link in the chain is informed.

The end user must be informed about the results of the analysis that have been carried out before using or processing the maize or maize by-product in feed.

[2] *Website GAFTA : https://www.gafta.com/members/superintendents*

There must be a clear link between the delivered batch and the certificate of analysis / analytical report from an approved laboratory (positive release). The information must demonstrate that the sampling was conducted not longer than 3 months before the date of delivery.

In case of stored batches and re-analysis after 3 months, the highest measured Aflatoxin B1 value (from all sampling moments) is leading since it is not obvious that Aflatoxin B1 content could decrease over time. All analysis results applicable for the batch (also the expired results) must accompany the batch.

In case of maize by-products, the food producing company must declare in writing that he has applied the protocol to the incoming flow of maize.

2.2.2. Medium risk countries

2.2.2.1. Application

For maize from medium risk countries, the first link in the chain is responsible for a correct application of this protocol.
Only in case of direct delivery with trucks, the receiving company (in most cases the compound feed company) is responsible for correct application of this protocol.
In case of an end user receives maize from a Medium country by truck it is possible to process this maize

- In dairy feed, only after results of analysis are available.
- In all other feed, the results do not necessarily have to be available before processing. These results can be received later.

Note: This requirement may be different by another scheme. In those case, the first link in the chain is responsible for applying the protocol.

2.2.2.2. Monitoring frequency

Each final sample must be analysed.

2.2.2.3. Size of the batches

All batches must be sampled and analysed, whereby the batch of maize or maize by-product is related to the means of transport and must have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling.

Means of transport	Maximum batch size
Seagoing vessel	Hold
Inland waterway vessel	Inland waterway vessel
Train	Train
Truck, from Storage/ warehouse, production location or collection point	Max. 2,000 tons

2.2.2.4. Sampling

2.2.2.4.1. Sampling method

The sampler must take representative samples in accordance with the method described in Regulation (EC) No. 152/2009, including the amendments regulated by Regulation (EU) No. 691/2013, under the following conditions:

a) sampling must be undertaken of the whole batch. Sampling of part of the whole batch is not acceptable within the framework of this protocol.
If the whole cargo in the warehouse is not accessible for sampling, a sampling plan must be made and retained as documented information. that the sampling plan must cover the accessible part of the cargo. The part of the cargo that has not yet been sampled and monitored, must be monitored once it´s possible and safe to get access.

b) each aggregate sample must not be less than 10 kg.
c) the sample to be send to the laboratory for preparation and analysis must not be less than 4 kg. See § 2.1.5 and 2.1.6 for requirements regarding sample preparation and analysis by the laboratory.

In case of direct ship-to-ship transshipment (from a seagoing vessel, coaster, inland waterway vessel to an inland waterway vessel) the method described in "GAFTA sampling rules No. 124" is allowed under the following conditions:
d) a representative sample must be taken during loading or unloading of the means of transport.
e) at least 20 incremental samples per 500 tons and at least 40 incremental samples for batches smaller than 1,000 tons.
f) maximum volume of the incremental sample: 1kg
g) minimum 20 kg per (sub)batch of 500 tons
h) at least 1 final sample, which shall not be less than 4 kg. Each final sample must be fully grinded and made homogeneous by the laboratory. See § 2.1.5 and 2.1.6 for requirements regarding sample preparation and analysis by the laboratory.

Note: In cases where maize is stored longer than 3 month in a silo and is not accessible for sampling before delivery to the customer, sampling may be carried out during loading. The results must be available before unloading at the customer or at least before the next processing step or feeding (if there is a written agreement between the seller and the customer).

2.2.2.4.2. Sample taker

For medium risk countries, each batch must be sampled by an independent superintendent organization accredited according to:
a) ISO 17020 for an appropriate scope, or alternatively:
b) ISO 9001 for an appropriate scope in combination with GAFTA[3] approval as superintendent for sampling in a relevant application domain (e.g. Animal feed).

In case of the direct transport by truck as described above, sampling can be performed and controlled by the GMP+ certified company in compliance with the requirements in document TS 1.6 *Sampling*, instead of the sampling rules as mentioned above.

2.2.2.4.3. Other requirements

The period between sampling and delivery must not be longer than three months.
It is possible to separate a batch at a storage location in the country of cultivation within the framework of direct transport per inland waterway vessel, train or truck to the end user. The following additional requirements apply:
a) The batch must be kept in quarantine (separate and identifiable) at the storage location in the country of cultivation.
b) The location must be set up in such a way that representative (cross-section) samples can be taken.

[3] *Website GAFTA : https://www.gafta.com/members/superintendents*

2.2.2.4.4. Information to the Client and end User

Positive release: The analysis results (by means of an original certificate of analysis or an original analytical report of an approved laboratory, see 2.1.6.1) must accompany the batch, so each link in the chain is informed.

The end user must be informed about the results of the analysis that have been carried out before using or processing the maize or maize by-product in feed (excluding deliveries by truck).

There must be a clear link between the delivered batch and the certificate of analysis / analytical report from an approved laboratory (positive release). The information must demonstrate that the sampling was conducted not longer than 3 months before the date of delivery.
In case of stored batches and re-analysis after 3 months, the highest measured Aflatoxin B1 value (from all sampling moments) is leading since it is not obvious that Aflatoxin B1 content could decrease over time. All analysis results applicable for the batch (also the expired results) must accompany the batch.

In case of maize by-products, the food producing company must declare in writing that he has applied the protocol to the incoming flow of maize.

2.2.3. Low risk countries

2.2.3.1. Application

For maize from low risk countries, every GMP+ certified company is responsible for a correct application of this protocol, based on HACCP principles.

2.2.3.2. Monitoring frequency

Final samples must be analysed based on a hazard analysis.

2.2.3.3. Size of the batches

The batch of maize or maize by-product is related to the means of transport and must have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling .

Means of transport	Maximum batch size
Seagoing vessel	According the hazard analysis of the GMP+ certified company
Inland waterway vessel	
Train	
Truck, from Storage/ warehouse, production location or collection point	

2.2.3.4. Sampling

2.2.3.4.1. Sampling method

The sampler must take representative samples in accordance with the requirements as described in document TS 1.6 *Sampling*.

2.2.3.4.2. Sample taker

Sampling can be performed by the GMP+ certified company. Sampling must be done, in accordance with the requirements as laid down in document TS 1.6 *Sampling*.

2.2.3.4.3. Information to Client and end User

All links in the chain, including the end user, must be informed (on request) periodically about the analysis results and receive a summary or overview of the results of the application of this protocol.

In case of maize by-products, the food producing company must declare in writing that he has applied the protocol to the incoming flow of maize.

3. Monitoring protocol of Aflatoxin B1 in feed materials (for use in feed) for dairy cattle

3.1. General requirements

3.1.1. Scope

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

3.1.2. Application

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

3.2. Monitoring frequency

The following sampling and monitoring frequency must be used for monitoring for Aflatoxin B1 in feed materials for dairy cattle and for the production of compound feed for dairy cattle.

The GMP+ certified company 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 monitoring based on his own sampling.

The certified company which delivers compound feed 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 monitoring on the basis of his own sampling.

Feed materials class 1	All batches must be monitored, whereby the monitoring must concern (origin) batches of no more than 500 tons
	The following come into this category: 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 analysed according to § 2, and USA. 6. Palm kernels and palm kernel by-products, unknown origin 7. Safflower seed meal, all origins

Helpful tip:
If maize and/or maize by-products have already been analysed in accordance with the requirements in § 2, those analysis results may be used to comply with the requirements in § 3.

Feed materials class 2	All batches must be monitored, whereby the monitoring must concern (origin) batches of no more than 3,000 tons
	The following come into this category: Palm kernels and palm kernel by-products, all known origins except Indonesia and Malaysia Rice by-products, all origins

3.3. Sampling

The sample taker must take representative samples in accordance with the requirements, as laid out in document TS 1.6 S*ampling*.

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:

a) 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 must be made and must be retained as documented information. The sampling plan must cover the accessible part of the batch. The part of the batch that has not yet been sampled and monitored, must be monitored once it is possible and safe to get access.
b) Collective samples must not weight less than 10 kg.

3.4. Analysing

3.4.1. Analyse method

Samples must be analysed on Aflatoxin B1 level.

This analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

3.4.2. Sharing of analysis results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

4. Monitoring protocol of salmonella-critical feed materials

4.1. General requirements

4.1.1. Scope

This protocol gives specific requirements for sampling and analysing of salmonella-critical feed materials.
There are currently no feed materials assessed as salmonella-critical.

4.1.2. Application

This protocol applies to the GMP+ certified company which produce salmonella-critical feed materials.

4.1.3. Documentation requirements

At the production location the following must be retained as documented information:
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).

If a salmonella-positive result is obtained then this must be classified in accordance with Appendix 1 in this document.

4.1.4. Monitoring frequency

The GMP+ certified company must analyse for each production location at least one sample per delivery day during loading (from the factory) for the presence of salmonella.

4.1.5. Sampling

Per production location a sample of at least 25 grams must 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 must be taken per 500 tons or part thereof.

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

4.1.6. Analysing

4.1.6.1. Analyse method

The analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

4.1.6.2. Sharing of analyse results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

4.2. Additional requirements

The GMP+ certified company can lower its sampling and monitoring frequency when the following requirements are complied with:

a) The GMP+ certified company has in the previous year complied with the frequency of sampling and monitoring 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 four 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 the monitoring for salmonella-critical feed material.
c) The GMP+ certified company 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 GMP+ certified company complies with the established requirements (items a to c) then instead of the prescribed minimum mandatory sampling and analysis it may carry out salmonella sampling and analysis on the basis of in company HACCP and the following formula:

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

For an explanation of this formula see § 1.1 in this document. In the above formula a decision has been made on a factor 1 for the history and for a factor 5 for the severity.

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 likelihood of occurrence of recontamination and the severity.

d) 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 GMP+ certified company 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.

e) Per two successive quarters only 1 incident may occur.

f) If the GMP+ certified company has a salmonella incidence in two successive quarters 3% of end products (which is not the result of one incident) then the GMP+ certified company must inform his certification body of the measures taken.

g) If the GMP+ certified company does not comply with items a. to d. then for a period of at least one year he must carry out salmonella sampling and analysis as prescribed for the Salmonella-critical feed material in question.

5. Monitoring protocol of Salmonella and Enterobacteriaceae in feed for poultry

5.1. General requirements

5.1.1. Scope

This protocol gives specific requirements for sampling and analysing of poultry compound feed intended for delivery to poultry livestock farmers.

5.1.2. Application

This protocol applies to the GMP+ certified company which produce compound feed intended for poultry.

5.2. Monitoring frequency

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

A. Technologically-treated poultry compound feed
   i. which are delivered as such
   ii. which are delivered together with separate feed materials
B. Non-technologically-treated poultry compound feed
C. Final product check

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

A. Technologically-treated poultry compound feed
Poultry feed must be supplied Salmonella-free.

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

   a) The GMP+ certified company must show by way of an entero reduction test under which conditions the entero reduction is at least a factor 1000. These conditions must be used as set-up parameters for the production of treated poultry feed. The entero reduction test must be carried out at least twice per year. The GMP+ certified company must be able to demonstrate that these set-up parameters are used in the production of poultry feed. This applies from the beginning to the end of production.

   b) The GMP+ certified company must specify the critical points for its own business situation and must determine a minimum sampling plan. A sampling flow diagram must be part of the sampling plan. This must show the critical control points for the process control.

The GMP+ certified company must apply process control at those points which are critical with respect to possible recontamination with Salmonella, including

1. Coolers, inside where there are possible condensation sites
2. Air supply from the cooler at places where the air is sucked in
3. Each point in the production line after the press where recontamination of the product by, for example, dust, enzymes, wheat may occur.
4. Inside of the ready product silo on the top.
5. Each point after the production line where recontamination can occur such as open places, loading.
6. Transport of the ready product to the client.

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

c) With respect to sampling the sampling protocol applies (where applicable) as specified in § 5.3 in this document. 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 cm^2 is taken (sponged/swabbed).

d) The critical points must be examined for Salmonella. The monitoring frequency 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 monitoring must be done again once per month for at least half a year. The positive samples must be classified.

e) In the event of contamination corrective actions must be taken immediately until there is demonstrable compliance with the norms.

f) At the request of the poultry farmer the research data related to the above must be made available to him or her.

2) For GMP+ certified companies that produce technologically-treated poultry feed with separate mixed feed materials the following requirements for separately mixed feed materials must apply in addition to the requirements with respect to production of technologically-treated poultry feed.

a) Only 'non-salmonella-critical' feed materials may be mixed separately. See for Salmonella-critical feed materials, Chapter 4.

b) 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 this. These include as a minimum the reception of feed materials, internal transport and storage (= logistical process).

c) A representative number of samples must be taken and analysed from the critical points mentioned above with a minimum of 3.

d) The critical points must be examined for salmonella. The monitoring frequency must be once per month and if is the results are negative for a half year then the frequency can be reduced to once per two months. In the event of a positive finding monitoring must be done again once per month for at least half a year. The positive samples must be classified.

e) In the event of contamination corrective actions must be taken immediately until there is demonstrable compliance with the norms.

f) At the request of the poultry livestock farmer the research data related to the above must be made available to him or her.

3) For companies with an annual production of poultry feed of up to 7,500 tons per year

It has been established that for an annual production of poultry feed of 7,500 tons or less, a company must 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 must 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.

B. <u>Non-Technologically-treated poultry compound feed</u>
Poultry feed must be supplied salmonella-free.

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

1. The GMP+ certified company must make the following distinction in feed materials in the production of non-technologically-treated poultry feed:
- non-salmonella-critical feed materials can be processed without an analysis of the batch in question being available.
- Salmonella-critical feed materials can only be processed if the batch in question, after sampling and analysis, appears to be Salmonella-free.

2. Method of sampling of feed materials:
Salmonella-critical and non-salmonella-critical feed materials must be sampled in accordance with § 5.3 in this document.

For batches of up to 100 tons, at least 1 sample must be taken and for batches of more than 100 tons at least 5 samples must be 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 feed:

3. The GMP+ certified company specifies the (representative) critical points for its own business situation and determines a minimum sampling plan. A sampling flow diagram must be part of the sampling plan. This must show the critical control 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 recontaminati 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 must be taken from the critical locations in the production process and these must be monitored 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 § 5.3 in this document. Where the necessary quantity of sampling material (dust and residues of feed) 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 cm^2 is taken (sponged/swabbed).

5. The frequency of monitoring 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 monitored 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 in this document.

6. In the event of contamination immediate corrective actions must be taken until there is demonstrable compliance with the norms.

7. At the request of the poultry livestock farmer the examination data related to the above must be made available to him or her.

C. Poultry compounds feed (Final product check)
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 sampling and monitoring frequency, calculated per 24-ton delivery**
Top breeding[4]	1 in 2 batches (50%)
Raising increase[5]	1 in 5 batches (20%)
Breeding[5]	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%)

5.3. Sampling

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

[4] *meat and egg sectors, respectively*
[5] *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%) .*

5.4. Analysing

5.4.1. Analyse method

The analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

If a Salmonella-positive result is obtained then this must be classified in accordance with Appendix 1 in this document.

5.4.2. Sharing of analyse results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

6. Monitoring protocol of Salmonella and Enterobacteriaceae in compound feed (with the exception of feed for poultry)

6.1. General requirements

6.1.1. Scope

This protocol gives specific requirements for sampling and analysing of other compound feed including manufacturers of mixes of wet by-products than those intended for poultry.

6.1.2. Application

This protocol applies to the GMP+ certified company that produces other compound feed than those intended for poultry (including the mixes of other wet by-products).

6.2. Monitoring frequency

The analysis must be done in accordance with the minimum frequency indicated below.

6.2.1. Salmonella reducing treatment

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

Salmonella

If it is decided to monitor for Salmonella then the monitoring must take place as follows;
Samples must be taken of-compound feed for monitoring 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 40,000 tons	25

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

a) sampling and analysis twice a year at the critical control points in the production process in order to determine the course of the level of Enterobacteriaceae to monitor the production process (thermal treatment);
b) 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 control points in the production process.

6.2.2. No salmonella reducing treatment

If no Salmonella-reduction treatment takes place then there must be an inspection as intended in table above.

Wet compound feed
As a replacement for Salmonella monitoring, the GMP+ certified company can also carry out monitoring on pH or temperature. The certified company must take at least one sample per quarter, per product and must have it monitored.
In the event of the pH being measured and there is compliance with the maximum pH as specified in TS 1.5 *Specific feed safety limits*, then sampling and analysis for Salmonella is not mandatory.

6.3. Sampling

The samples of compound feed must 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 control 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 a close as possible before loading the bulk container (or the filling of the sacks). The quantity of the samples to be taken must at least be 60 grams, sufficient to compose a sample and a duplicate sample of 25 grams each.

6.4. Analysing

6.4.1. Analyse method

The analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

If a Salmonella-positive result is obtained then this must be classified in accordance with Appendix 1 in this document.

6.4.2. Sharing of analyse results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

7. Monitoring protocol of animal protein

7.1. General requirements

7.1.1. Scope

This protocol gives specific requirements for sampling and analysing of compound feed including wet mixes for ruminants.

7.1.2. Application

This protocol applies to the GMP+ certified company that produces compound feed including wet mixes for ruminants.

7.2. Monitoring frequency

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

Monitoring table per production location for BSE control

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

7.3. Analysing

7.3.1. Analyse method

The analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

7.3.2. Sharing of analyse results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

8. Monitoring protocol of Oils and Fats as regards dioxin and dioxin like PCB's

8.1. General requirements

8.1.1. Scope

This protocol provides specific requirements[6] for monitoring the levels of dioxin and dioxin-like PCB's in oil and fat products, which

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

8.1.2. Application

This monitoring applies to GMP+ certified companies that produce or trade the products mentioned under § 8.1.1. GMP+ certified companies must analyse these products for the sum of dioxins and dioxin-like PCBs, carried out by a laboratory approved for this under the GMP+ FSA module. See TS 1.2 *Purchase* for approved laboratories.

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).

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

8.2. 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 TS 1.4 *Forbidden Products and Fuels*	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. [7] One analysis per batch (max.1000 tons[8])	One representative analysis per 2000 tons or 5000 tons[8] [9] (with a minimum of one representative analysis per year)	Based on the company's internal hazard analysis
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 must – 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.

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[7] *Several options as regards acceptable Positive Release systems are provided in § 8.3*

[8] *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.*

[9] *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.

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 above.

Helpful tip:

See Appendix 2 for a list of relevant products with names, description and EU catalogue numbers

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[10] of vegetable origin	EU food	Other
See TS1.4 *Forbidden products and fuels* 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
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) Crude fatty acids from splitting (13.6.6) Pure distilled fatty acids from splitting (13.6.7) Sucrose esters of fatty acids (13.6.10) Sucroglycerides of fatty acids (13.6.11)	4	See Appendix 2
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[11]	2	2

[10] *These products come from different processes like refining, oleochemical and biodiesel production*
[11] *In the context of this protocol a feedstock is the raw material from which the oil/fat product is produced or derived thereof*

Table 2: Products of animal origin	
See TS1.4 *Forbidden products and fuels* 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
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 [12]	
See TS1.4 *Forbidden products and fuels* 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.

[12] *See for definition of fat blending F0.2 Definition list*

8.3. Positive release

To comply with the Positive Release requirements, GMP+ certified companies (producers and, if appropriate, traders, see § 8.1.2) 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.

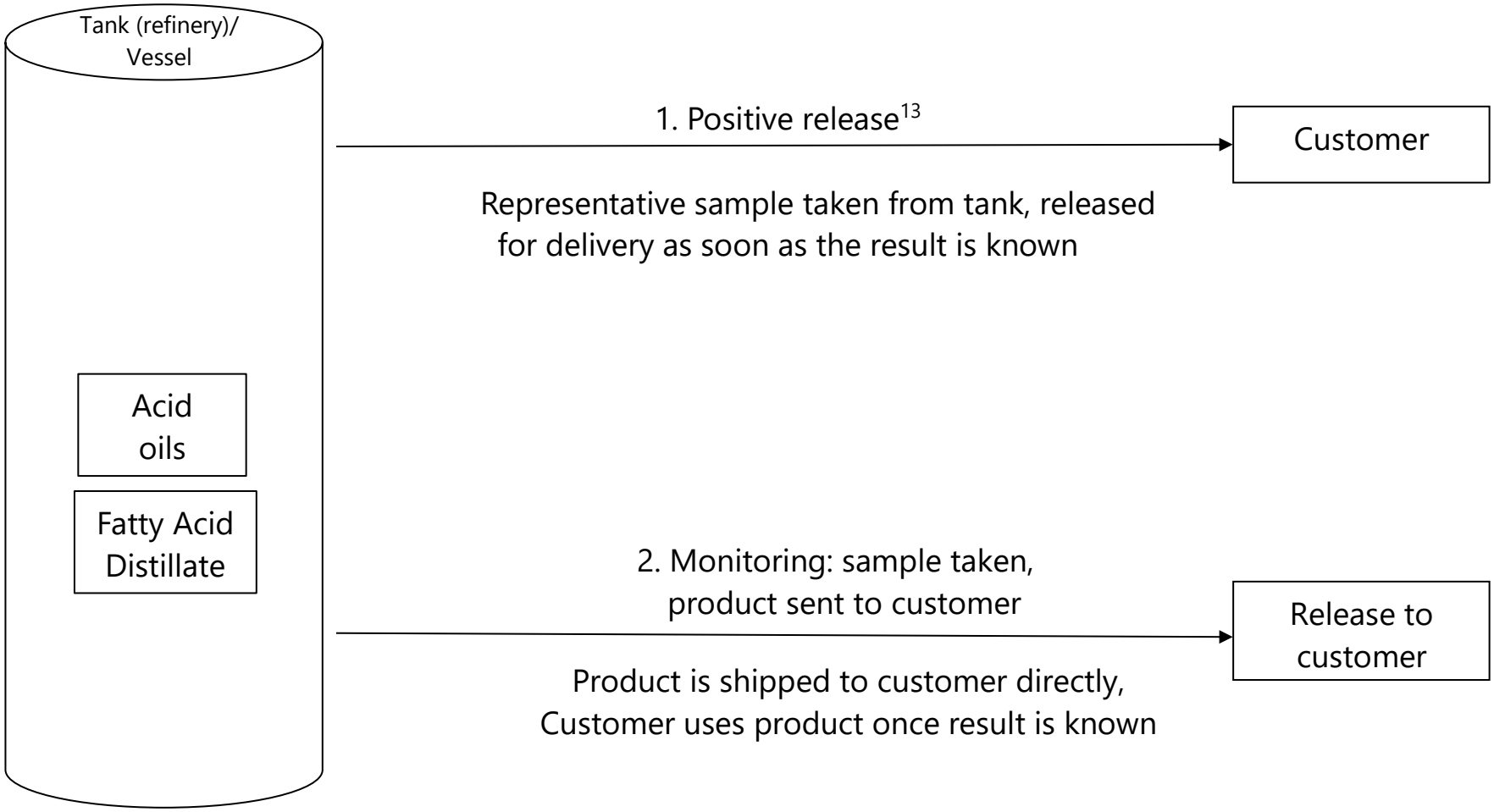
The analysis results of dioxins and dioxin-like PCBs must be available, before any use in feed materials such as compound feed and premixtures.

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.

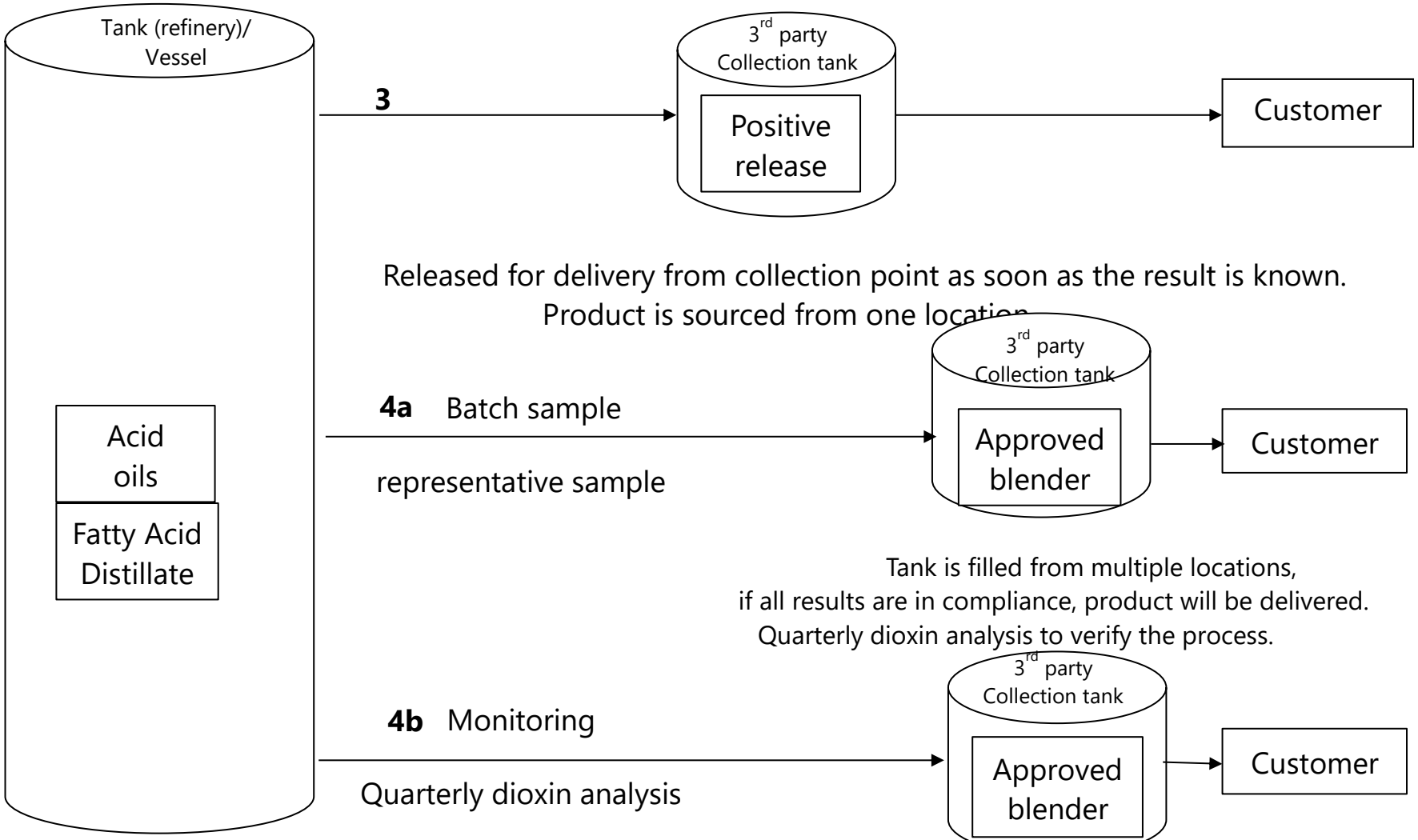
No.	Option	Remarks
1	The producer, takes a representative sample of the product located at his storage tank, he then sends the sample to a laboratory for the analysis of dioxin and dioxin-like PCBs. The product is shipped, and delivered to the customer, once the test results are known, and are within the specifications.	For more details as regards sampling and analysis, see § 8.4. Customer must 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.	For more details as regards sampling and analysis, see § 8.4. In order to use this option, there must be an agreement between the producer and the customer. The customer must be informed of the analysis results, through means of an Analytical Report.

No.	Option	Remarks
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 thank. 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 and dioxin-like PCB's analysis are known.	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. The producer must have full control of the operational storage activities, or must 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 § 8.4. The customer must be informed of the analysis results, by means of an Analytical Report.
4a	The producer ,must 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	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 must have full control of the operational storage activities, or must have an agreement with the storage company, upon use of a third-party tank.

No.	Option	Remarks
	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.	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 must 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 must be informed by means of a Conformity Note. The contents of the 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. The producer is responsible for the quarterly add-on monitoring.
4b	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. 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.	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 must have full control of the operational storage activities, or must 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 must be informed of the analysis results, by means of an Analytical Report of blend.



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


Tank (refinery)/
Vessel
Acid
oils
Fatty Acid
Distillate
3
3rd party
Collection tank
Positive
release
Customer
Released for delivery from collection point as soon as the result is known.
Product is sourced from one location
4a Batch sample
representative sample
3rd party
Collection tank
Approved
blender
Customer
Tank is filled from multiple locations,
if all results are in compliance, product will be delivered.
Quarterly dioxin analysis to verify the process.
4b Monitoring
Quarterly dioxin analysis
3rd party
Collection tank
Approved
blender
Customer
Positive release at blende

8.4. Sampling

Sampling must be performed in compliance with the requirements described in document TS 1.6 *Sampling*. 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 § 8.2 of this protocol, the maximum batch sizes, are indicated. If can be demonstrated that a homogenous consignment is bigger than the maximum batch size 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.

8.4.1. Sharing of analyse results

The GMP+ certified company must upload analysis results of specific feed product and undesirable substances combinations within a month and must share this result anonymously with the GMP+ Community in the GMP+ Monitoring database.

9. Monitoring protocol for By-products of the oils and fats industry

9.1. General requirements

9.1.1. Scope

Any product derived directly or indirectly from crude or recovered oils and fats by oleochemical or biodiesel processing or distillation, chemical or physical refining, other than:

- refined oils,
- products derived from refined oils,
- feed additives,

to be used in feed, from any origin.

The next products are out of scope:

a) products, produced by an EU registered food operator
b) crude or pure distilled fatty acids (13.6.5/13.6.6) derived from vegetable oil (2.20.1)
c) products derived from fatty acids, covered under b

Note: See Appendix 2 for more details about products in scope of this protocol.

'To be used in feed': it does not matter under which specification/status the product is purchased. If destination is feed, the relevant requirements in this document TS 1.7 *Monitoring* applies.

9.1.2. Application

This protocol must be applied by GMP+ certified companies that:

- produce by-products (mentioned in 9.1.1) from the oil and fat industry.
- Trade / import by-products (mentioned in 9.1.1) from the oil and fat industry.

This protocol is not applicable for GMP+ certified companies that produce compound feed which is to be delivered to a livestock farmer.

9.2. Definitions

Term	Explanation
MONG	Matter Organic Non-Glycerol MONG is a residue from glycerin, meaning the vegetable fat-like residues (e.g. triglycerides and fatty acids) from the refining of vegetable glycerin. MONG also contains glycerin, salts and water. So basically everything that is not glycerol / glycerin. This is usually a small percentage that is still in the raw glycerin (defined as 100 less the sum of the percentages of glycerol, ash and water). With further processing of the glycerin, MONG is removed and is thus a byproduct of the glycerin refining. See also F 0.2 *Definition list*.

9.3. Monitoring frequency

Batch by batch, 100% positive release. Batches/lots must be monitored before used in feed. Producer of the by-product is responsible unless agreed (in contract or another official document) to transfer this responsibility for monitoring to his customer. They must also agree that results are shared. Representative monitoring results need to accompany any delivered batch, also to customers.

9.4. Sampling

When shipped by sea vessel or barge

- Shipment to be carried out under a well-known, in the international trade accepted contract (FOSFA, NOFOTA, GROFOR) to assure
  - Independent supervision
  - Sampling per lot
  - Safe previous cargoes and technical equipment
- When shipped by vehicles (tank/container):
  - Sampling of each truck

9.5. Analysing

The analysis of the below mentioned parameters must be performed by a laboratory, approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*.

- Fatty Acid profile
- Moisture and impurities
- Free Fatty Acid
- Dioxins, dioxin-like PCBs, non-Dioxin-like PCBs
- Pesticides
- Heavy metals (Arsenic, Cadmium, Mercury, Lead and Nickel)
- Mineral oil
- PAH's

9.5.1. Sharing of analyse results

Information, which is generated as a result of application of this Appendix, must be unambiguous and must accompany every batch / shipment to demonstrate that requirements have been met.

Appendix 1: Protocol for the serological classification of salmonella

GMP+ certified companies in the GMP+ FSA module for the feed sector are obliged have salmonella-positive samples of feed or feed materials classified.
The poultry feed, cattle feed and pig feed must be fully classified. The feed materials must be classified for the serotypes Enteritidis, Typhimurium, Infantis, Virchow, Hadar, Java and Agona. The serological classification must be carried out by the RIVM or by a laboratory-approved for this under the GMP+ FSA module. See TS 1.2 *Purchase*. The costs of the classification will be charged to the (feed) company.

The purpose of this classification is to establish more accurately any relationship among salmonella types in feed materials, the compound feed produced from them, live animals which eat these feed 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 (0031) 30-2742126.
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 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 (0031) 30-2742126. The GMP+ certified companies who regularly submit a green form to the RIVM must from today also order these forms by telephone.
d) The green RIVM form must be fully completed and sent to the RIVM together with the identified salmonella culture. The form must 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 must be specified once and also any future changes in the technique used.

Appendix 2: Product name and Number according to Reg. (EU) No 68/2013

How to read

Reference is made to this appendix from both chapter 8 and chapter 9. It is good to keep the following in mind:

Chapter 8:

Chapter 8 gives the minimum frequency for analyzing dioxin and dioxin-like PCBs. For most oil and fat products the minimum frequency is stated in the tables in chapter 8. In this appendix 2 the classification for monitoring is only given for those products which are not classified in the tables in protocol 8, for companies which do not have a EU food registration ('other').

Chapter 9:

Chapter 9 requires (additional to chapter 8) for a few oil and fat product (from certain origin and from certain feedstocks) the minimum analysis frequency for a number of parameters. Oil and fat products within scope are indicated with 'yes' in the column 'Within scope of § 9.

Number	Name	Description	§ 8 Class for 'other'	In scope of § 9	Remarks/examples of products falling under this number
1.2.13	Crude maize germ oil	Product obtained from maize germ		No	
1.6.13	Rice bran oil	Oil extracted from stabilised rice bran		No	
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.		No	Castor oil; Palm oil stearin fraction; Rape seed stearin fraction; Sunflower stearin fraction
2.20.2	Used food factory vegetable oils	Vegetable oils having been used by food business operators in accordance with Regulation (EC) No 852/2004 for cooking purposes and which have not been in contact with meat, animal fats, fish or aquatic animals.		No	

2.21.1	Crude lecithins	Product obtained during degumming of crude oil from oilseeds and oil fruits with water. Citric acid, phosphoric acid, sodium hydroxide or enzymes may be added during degumming of the crude oil.		No	
2.22.3	Hemp oil	Oil obtained by pressing of hemp plants and seeds		No	
7.1.4	Algal oil [(1)]	Oil obtained by extraction from algae. May contain up to 0,1 % antifoaming agents.		No	
9.2.1	Animal fat	Product composed of fat from land animals, including invertebrates other than species pathogenic to humans and animals in all their life stages. If extracted with solvents, may contain up to 0,1 % hexane.		No	
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).		No	
10.4.7	Fish oil, hydrogenated	Oil obtained from hydrogenation of fish oil		No	
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 tissues such as mono- and diglycerides, crude lecithin and fibres.	2	Yes	
13.6.2	Fatty acids esterified with glycerol [(4)]derived from 13.6.6 or 13.6.7, produced from vegetable oil (2.20.1) [14]	Glycerides obtained by esterification of fatty acids with glycerol. May contain up to 50 ppm Nickel from hydrogenation.	4	No	

	Fatty acids esterified with glycerol[4], derived from 13.6.6 or 13.6.7, produced from other feedstock [14]		2	Yes	
13.6.3	Mono di and tri glycerides of fatty acids[4], derived from 13.6.6 or 13.6.7, produced from vegetable oil (2.20.1)[14]	Product consisting of mixtures of mono-, di- and triesters of glycerol with fatty acids. They may contain small amounts of free fatty acids and glycerol. May contain up to 50 ppm Nickel from hydrogenation.	4	No	
	Mono di and tri glycerides of fatty acids[4], derived from 13.6.6 or 13.6.7, produced from other feedstock[14]		2	Yes	
13.6.4	Salts of fatty acids[4], derived from 13.6.6 or 13.6.7, produced from vegetable oil (2.20.1) [14]	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.	4	No	Analysis must be done on the fat component (e.g. PFAD) or on the end-product.
	Salts of fatty acids[4], derived from 13.6.5, or salts of fatty acids[4], derived from 13.6.6 or 13.6.7, produced from other feedstock[14]		2	Yes	
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 tissues such as mono- and diglycerides, sterols and tocopherols.	2	Yes	

13.6.6	Crude fatty acids from splitting[3] produced from vegetable oil (2.20.1)[15]	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.	4	No	
	Crude fatty acids from splitting[3] produced from other feedstock[15]		2	Yes	
13.6.7	Pure distilled fatty acids from splitting[3], produced from vegetable oil (2.20.1)[15]	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}, phatic, linear, monocarboxylic, saturated and unsaturated. May contain up to 50 ppm Nickel from hydrogenation.	4	No	Ricin oleic acid (syn. Castor oil acid), CAS no.141-22-0, EC no. 205-470-2 Icosa-5,8,11,14-tetraenoic acid (syn. Arachidonic acid), CAS no. 506-32-1, EC no. 208-033-4; Hexanoic acid (syn. Caproic acid) of vegetable origin, CAS no.142-62-1, EC no. 205-550-7; Octanoic acid (syn. Caprylic acid) of vegetable origin, CAS no.124-07-2, EC no. 204-677-5; Oleic acid (syn. octadec-9-enoic acid) of vegetable origin, CAS no. 112-80-1, EC no. 204-007-1; Linoleic acid (syn. 9,12-Octadecadienoic acid), CAS no. 60-33-3, EC no. 200-470-9; Linolenic acid (syn. (9Z,12Z,15Z)-9,12,15-Octadecatrienoic acid), CAS no. 463-40-1, EC no. 207-334-8; Stearic acid (syn. octadecanoic acid) of vegetable origin, CAS no. 57-11-4, EC no. 200-313-4
	Pure distilled fatty acids from splitting[3], produced from other feedstock[15]		2	Yes	
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		No	

		tissues such as mono- and diglycerides, crude lecithin and fibres.			
13.6.9	Mono- and diglycerides of fatty acids esterified with organic acids[4] [5], derived from 13.6.6 or 13.6.7, produced from vegetable oil (2.20.1)[14]	Mono- and diglycerides of fatty acids with at least four carbon atoms esterified with organic acids.	4	No	
	Mono- and diglycerides of fatty acids esterified with organic acids[4] [5], derived from 13.6.6 or 13.6.7, produced from other feedstock[14]		2	Yes	
13.6.10	Sucrose esters of fatty acids[4], derived from 13.6.6 or 13.6.7, produced from vegetable oil (2.20.1) [14]	Esters of saccharose and fatty acids.	4	No	
	Sucrose esters of fatty acids[4], derived from 13.6.6 or 13.6.7, produced from other feedstock[14]		2	Yes	
13.6.11	Sucroglycerides of fatty acids [4], derived from 13.6.6 or 13.6.7, produced from vegetable oil (2.20.1)[14]	Mixture of esters of saccharose and mono and di-glycerides of fatty acids.	4	No	

	Sucroglycerides of fatty acids(4) , derived from 13.6.6 or 13.6.7, produced from other feedstock [14]		2	Yes	
13.8.1	Glycerine, crude [Glycerol, 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; - 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; - saponification of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps. May contain up to 50 ppm Nickel from hydrogenation.		No	

13.8.2	Glycerine [Glycerol]	Product obtained from: - 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; - saponification of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps, followed by refining of crude Glycerol and distillation. May contain up to 50 ppm Nickel from hydrogenation.		No	
13.11.1	Propylene glycol; [1,2-propanediol]; [propane- 1,2-diol]	Organic compound (a diol or double alcohol) with formula $C_3H_8O_2$. It is a viscous liquid with a faintly sweet taste, hygroscopic and miscible with water, acetone, and chloroform. May contain up to 0,3 % di-propylene glycol.		No	
13.11.2	Mono-esters of propylene glycol and fatty acids (4)	Mono-esters of propylene glycol and fatty acids, alone or in mixtures with di-ester	2	Yes	

Explanation:

[14] This product is out of scope of § 9 only in case produced/derived from fatty acids covered under 13.6.6 or 13.6.7, which are in their turn obtained by splitting of vegetable oil falling under the Catalogue of feed materials number 2.20.1.

[15] The products 13.6.6 and 13.6.7 are out of scope of § 9 only in case the feedstock used to produce these products is vegetable oil falling under the Catalogue of feed materials number 2.20.1. When other products are used as the feedstock„ the products 13.6.6 and 13.6.7 are within scope of § 9.

(1) The name must be supplemented by the species.

(2) The name must be supplemented by the plant species.

(3) The name must be supplemented by the indication of the botanical or animal origin.

(4) The name must be amended or supplemented to specify the fatty acids used.

(5) The name must be amended or supplemented to specify the organic acid.

Feed Support Products

That was a lot of information to digest and one might ask, what is the next step? Luckily we can offer support for the GMP+ Community when doing this. We provide support by means of various tools and guidances but as each company has a shared responsibility to feed safety, and therefor tailor-made solutions cannot be offered. However, we do help by explaining requirements and provide background information about the requirements.

We have developed various supporting materials for the GMP+ Community. These include various tools, ranging from Frequently Asked Questions (FAQ) lists to webinars and events.

Supporting materials related to this document (Guidelines and FAQ's)
We have made documents available which give guidance to the GMP+ requirements as laid down in the module GMP+ FSA and GMP+ FRA. These documents give examples, answers to frequently asked questions or background information.

GMP+ Monitoring database
The GMP+ Monitoring database contains analysis results from you and other users. It is possible to generate reports based on this data. We have a manual and a frequently asked questions document available.

Where to find more about the GMP+ International Feed Support Products

Fact sheets

More information: https://www.gmpplus.org/en/services/feed-support-products/fact-sheets/

Review fact sheets: GMP+ Portal https://gmpplus.org/en/feed-certification-scheme-2020/gmp-fsa-fra-certification/support/

GMP+ Monitoring database

At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

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