Working principles of the GMP+ Feed Support Products (FSP)

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1. **Feed Support Products (FSP): goals, benefits, process and structure**

1.1. **FSP goals and benefits**

The Feed Support Products (FSP) are part of the GMP+ FC scheme. FSP are a tool for risk management of (future) GMP+ companies. Access to FSP helps to set up and implement a HACCP system to analyze risks.

The Feed Support Products are intended to support all (future) GMP+ companies when setting up their company-specific HACCP system. The responsibility for use and implementation remains with the GMP+ certified companies, the Feed Support Products can offer support in this process. The FSP is also intended as a reference for the auditors within the framework of GMP+ certification.

*With the Feed Support Products, GMP+ International offers various information sources in an interactive way. This helps companies with the implementation of a company-specific HACCP system. Furthermore FSP provides ease of use, a uniform source of data, linking of relevant files and efficient searching. The benefits of use are:*

- up-to-date knowledge of risks of feed materials
- up to date knowledge of undesirable substances;
- assessed by independent experts;
- uniform source of knowledge;
- automatically linking of all relevant files.

1.2. **FSP on the GMP+ portal**

At this moment the Feed Support Products only consist of products for implementation of the GMP+ Feed Safety Assurance requirements (and not for the other scopes of GMP+ e.g. Responsibility Assurance). The following products are a part of FSP: *fact sheets, risk assessments, product list, product standards and the GMP+ Monitoring database*. In figure 1 below you can see where the different products can be find on the GMP+ portal

[www.gmpplus.org](http://www.gmpplus.org)
1.3. Process of information use in FSP

FSP can be visualized as a ‘funnel’. Information from several sources is entering FSP. FSP structures and links in a way that information can be used by feed companies for their company-specific HACCP system. Feed companies can give feedback information to further improve the FSP. In figure 2 this process has been visualized.
Figure 2: FSP as a ‘funnel’ with information from different sources structured in FSP and used by feed companies.

In Figure 3 the relationship between the GMP+ FC scheme, FSP and the company specific HACCP system is shown. The GMP+ FC scheme contains the requirements regarding risk assessments, standards and monitoring frequency. Input from FSP can be combined by GMP+ participants to make a company-specific HACCP system and monitoring program.
In figure 4 below, the overall process from collecting to maintaining FSP up-to-date is shown. The different steps and the streaming of information between these steps are visible.
Figure 4: Process of information use in FSP

1. **Gathering information for FSP**
   - Practical information, scientific information, new standards, and RASFF etc.

2. **Structuring information in FSP**
   - FSP with linked information

3. **Making a company specific HACCP system**
   - FSP forum output
   - Practical information, scientific information, new standards, and RASFF etc.

4. **Evaluating FSP Information (maintenance process)**
   - Feedback from GMP companies, monitoring results
   - Changes in or new RA, factsheet, monitoring plan, standards

5. **Communication to stakeholders**
   - FSP newsletters

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**Working principles of the GMP+ Feed Support Products (FSP)**

*March 2019*
1.4. Structure of FSP

The data in FSP consist of the following sources:

1. **Fact Sheets:**
   The fact sheets show background details regarding the hazards and the (explanation of the) severity of the risk to animals and humans. Fact sheets are available for the undesirable substances (hazards) in the Risk Assessments and for processing aids.

2. **Generic Risk Assessments:**
   This section of FSP contains risk assessments of feed materials for Food-producing animals (including goats, poultry, cattle, sheep and pigs, but also horses and rabbits). Farmed fish is not included because farmed fish is more sensitive to contaminants than other types of animal. The risk assessments in the FSP database are of a generic nature and represent a worst-case scenario. The risk analyses can serve as a guideline for the company-specific assessment.

3. **Product List**
   This list gives a short summary of all products available. The products on the list may be used as a feed material in the GMP+ FC scheme.

4. **Product standards:**
   Standards have been issued by legislation and by GMP+ for many hazards in order to be able to determine if a feed material is safe. All the standards are a part of the GMP+ FC scheme, *GMP+ BA1 Product Standards*.

5. **GMP+ Monitoring database**
   Monitoring results are entered in the *GMP+ Monitoring database*. GMP+ participants who make data available from their company’s internal monitoring system can also make use of the *GMP+ Monitoring database*.

More detailed information on the structure and contents of FSP is given in Annex 1.
2. The four core values of FSP

The Feed Support Products operates from 4 core values:

- Practical information;
- Science based;
- Independency;
- Transparency.

It is explained in this chapter how these core values are covered within the FSP.

In figure 5 below the four core values are presented in the process scheme in blue.

*Figure 5: Process of information use in FSP with core values (purple)*
2.1. Core value 1: Practical information

Company specific information
The information in FSP about processing, possible hazards, risk assessments and monitoring data is coming from GMP+ companies. The generic information is published in Risk Assessments and in the GMP+ Monitoring database.

FSP makes it easier for companies to set up and implement their own, specific HACCP system and monitoring plan. Feed companies use different information sources in FSP for their own HACCP system e.g.:
- Risk assessment for information about a production process and the resulting possible hazards,
- Fact sheets for determining the severity of a hazard;
- Monitoring results can be used to assess the likely occurrence of a hazard.

The results and output of the company specific HACCP system, e.g. process information and the resulting risks, monitoring results, are sent back to FSP and serve as input for FSP. In this way, continuous input is given by GMP+ companies to keep the information up-to-date.

Ownership of information in FSP
Factsheets and risk assessments are owned by the GMP+ community. For monitoring data the owner is the GMP+ company that enters monitoring data. The GMP+ company can make a decision whether to share these data with other GMP+ companies or the GMP+ community. When the data are shared with the GMP+ community the (anonymous) data will be used to make a report of all GMP+ company results. When authorized, GMP+ companies can also consult the (anonymous) results of all other GMP+ participants.

2.2. Core value 2: Science based

The structure/framework as well as the contents of FSP are science based.

Structure of FSP
The structure of FSP is based on the CODEX HACCP Principles and on Draft TFAF eWG 2012; “Guidance for governments on prioritizing hazards in feed”. The Codex steps of HACCP and TFAF like identification of hazard/product combinations, risk profiling, prioritization and reporting are covered in FSP by thorough fact sheets, risk assessments and monitoring. A HACCP methodology was developed by GMP+ International which is based on CODEX HACCP principles and can be used by feed companies to set up their company specific HACCP system (HACCP manual of GMP+ International, 2010). Also risk communication by sending newsletters to stakeholders is part of a scientific risk management approach.
Contents of FSP
Science based information is used on different elements of the Feed Support Products, e.g. fact sheets, risk assessments and standards. Examples are:

- Newly emerged risks: if EFSA (European Food Safety Authority) reports on new risks, this information will be included in FSP (see maintenance procedure chapter 3).
- To motivate potential adverse effects of a hazard. The information is published in Fact sheets for both Undesirable substances and Technical aids. In the ‘Reader Factsheets Undesirable substances’ it is explained how likely occurrence and severity of hazards are assessed and shown in factsheets (Annex 5). The severity of hazards indicated in fact sheets and risk assessments was evaluated by scientists of RIKILT.

2.3. Core value 3: Independency

Organization and stakeholders of FSP: IEC and TC FSP
The policy and technical aspects of FSP are regarded by independent committees, namely the IEC and the TC FSP. Also science based information helps to fulfill independency.

The International Expert Committee Animal Feed (IEC) is responsible for the policy aspects of the FSP risks assessment approach. The IEC has the task of providing the scheme holder (GMP+ International) with advice, whether or not requested, with respect to the certification scheme regarding feed safety and feed sustainability / responsibility assurance and the supervision of the implementation of the certification. The IEC has an independent chairman and 17 members from the subsectors in the whole feed & food chain.

The technical committee (TC FSP) has the task of providing GMP+ International with advice regarding the technical aspects of the content of the Feed Support Products (FSP); that means generic risk assessments, fact sheets regarding feed safety hazards, and collective monitoring & survey program. The TC FSP has a maximum of 10 members from the subsectors in the feed & food chain.

GMP+ International provides the Secretariat of both the IEC and TC FSP. The tasks and responsibilities of the IEC and the TC FSP are regulated in the documents “Regulation for GMP+ International Expert Committee Animal Feed” and “Regulation for GMP+ International Subcommittees Animal Feed”.

Composition of TC FSP
The TC FSP has members who are representatives of interested subsectors who, on the basis of their expertise, contribute to the execution of the task of the technical committees. The members come from a GMP+ certified company or from a GMP+ International’s partner.

The TC should as a whole cover all the necessary knowledge areas of FSP. The TC FSP acts as a HACCP team for the FSP. The following knowledge areas should be covered:

- knowledge of HACCP methodology, assessment of risks (severity and occurrence) (all members)
- chemical knowledge about contaminants and analysis methods;
- microbiological knowledge about contaminants and analysis methods;
- practical knowledge on feed ingredients and production processes.
The following knowledge matrix (Table 1) is applicable to the TC FSP:

**Table 1: HACCP knowledge matrix of TC FSP**

<table>
<thead>
<tr>
<th>Participant TC</th>
<th>Knowledge area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and organization representing chemistry contaminants/analysis</td>
<td>HACCP methodology (full coverage of all participants needed)</td>
</tr>
<tr>
<td>Microbiological knowledge contaminants/analysis</td>
<td></td>
</tr>
<tr>
<td>Production of dry feed materials</td>
<td></td>
</tr>
<tr>
<td>Production of liquid feed materials</td>
<td></td>
</tr>
<tr>
<td>Trade and collection</td>
<td></td>
</tr>
<tr>
<td>Production of premixtures and compound feeds</td>
<td></td>
</tr>
</tbody>
</table>

The meeting of TC FSP will at least take place 2 times a year. Besides the regular members of the TC FSP ‘advisors’ can be invited to TC meetings. These advisors are either laboratory representatives, representatives of the Food and Consumer Product Safety Authority, or scientists (e.g., Rikilt). Also independent advisors from certification bodies or consultancy agencies can be invited to (parts of) the TC.

All members of the TC (including (independent) advisors) have signed a confidentiality agreement. The exact composition of the TC FSP is mentioned in annex 3.

### 2.4. Core value 4: Transparency

**Stakeholder communication**

FSP wants to be open in communication to all stakeholders, and transparent in the way of working. A well-balanced multi-stakeholders’ participation is already realized by establishing subcommittees and a technical committee (TC FSP, see core value 2). FSP stimulates the broad participation of stakeholders in discussions to improve the FSP database. All information is published in the Feed Support Products e.g. the acceptance procedure for new Risk assessments, reader fact sheets etc. The information is kept up-to-date by a maintenance procedure which is published as well (chapter 3). Procedures for change are described. Every change will be communicated to the GMP+ community via the FSP newsletter.

The information in FSP like risk assessments also serve as a reference for the auditors within the framework of GMP+ certification.
3. **Maintenance of FSP**

The content of FSP is being supervised by the TC FSP. The content of the different products continuously changes due to new feed legislation, regulations, emerging risks and new scientific information. Changes include new feed materials/products, hazards, new “product-hazard combinations” and new standards (legislation). These changes are periodically processed by GMP+ International within FSP by a maintenance procedure.

Changes in hazards (severity, effect), are processed in factsheets and/or risk assessments. If needed changes in risk assessments, factsheets, GMP+ standards or monitoring program, are discussed within the TC FSP. Reasons for changes can be (among others):

In general:
- New feed legislation;
- Early Warning System (EWS) from GMP+
- Rapid Alert System for Food and Feed (RASFF);
- Feed Crises;
- New scientific information/new hazards (e.g. from TNO, Rikilt, EFSA);
- Practical experiences from companies

The following changes items can be published in FSP without consulting the experts of TC FSP:

All products:
- Language and translation errors;
- References to regulations (e.g. standards in Fact sheets);
- Changes because of changes in feed regulations (e.g. names of contaminants, new or changed standards). This will be agreed by the IEC.
- Removing products from the Product List in FSP because of changes in the negative list of the GMP+ FC Scheme (GMP+ BA 3). This will be agreed by the IEC.

GMP+ Monitoring database:
- Undesirable substances list
- Product list
- Analysis methods list
- Country list

Information must be evaluated on the necessity for taking immediate action. In some cases, immediate action is needed, for instance in case of a newly emerging food risks. Other type of information, for instance scientific information, can be processed in a later stage and will be filed for planned maintenance of FSP information (annually).

If new non-conformities related to food and feed safety occur there must be a short term evaluation about the consequence for feed (if it is a non-conformity from food) and the consequences for FSP. New hazards can be communicated in a short term to the feed sector.
In the table in Annex 6 the type of information, the frequency, the resulting change in documents and the consultation part are shown.

GMP+ companies are being informed of changes in risk assessments and/or factsheets by means of newsletters. All sent newsletters can be found on the GMP+ portal www.gmpplus.org (under “in the Spotlights”). Changes (date of last change, which changes and the reason for changes) in Factsheets and/or Risk Assessments are made visible in the FSP newsletter.

The maintenance process can be visualized as follows:
The outcoming of the different activities will be evaluated by GMP+ International, subsequently and the TC FSP will be consulted (written and/or via the bi-annual evaluation report). After the TC FSP meeting, changes can be processed by GMP+ International and communicated via newsletters.
Annex 1: Contents of FSP

1.1. Generic Risk Assessments

Products/feed materials with Risk Assessments
The FSP is currently intended for all feed materials (including water) which are fed to food-producing animals. An overview of all feed materials is given in the Product List.

The ‘Feed Materials ‘Decision Tree’ (Annex 4) can be used as an aid for categorizing a product. The decision tree uses the answers to a number of questions to categorize the product in question.

With the arrival of the new trade regulation EC/767/2009 there is a new definition for productive livestock, namely food-producing animals. FSP will use this definition. The definition is as follows:

```
Any animal which is fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption, but that belong to a species that is normally used for consumption in the Community;
```

Food-producing animals include, in addition to the usual productive livestock such as goats, poultry, cattle, sheep and pigs, also horses and rabbits.

Farmed fish may be considered as food-producing animals but still fall outwith the scope of the FSP because (farmed) fish are much more sensitive to contaminants than other types of animal. This is particularly relevant in the estimation of the severity in a risk assessment.

Feed materials for pets do not, by the way, have to be included in the FSP. This is not a requirement of the GMP+ FC scheme.

It is mandatory to include a feed material in the FSP. The obligation applies to all standards with the scope "production / trade of feeds for productive livestock". The GMP+ FC standard contains the following requirements:

```
For each type of feed material to be purchased or received, there should be a generic risk assessment in the Feed Support Products (FSP).

If it is a feed material for which there is no risk assessment in the Feed Support Products of GMP+ International, then the participant should first offer a risk assessment to GMP+ International for inclusion in the database referred to. Only after inclusion in the database the feed material may be sold or received.
```
**Risk Assessment**

The risk assessment contain process diagrams of the (primary) production process, an inventory of possible hazards in feed material, an estimate the risk of a hazard (likely occurrence x severity) and control measures that may be taken in order to control these hazards.

The risk assessments in the database are of a generic nature and represent a worst case scenario. The hazards which are specified in the analysis do not self-evidently have to be applicable in the company-specific analysis as the generic risk analysis represents a worst case scenario. It concerns a combination product-process, in which differences may arise in detail in the production process per company.

Each individual GMP+ company should:

- Carry out a risk assessment in accordance with the criteria of the Manual HACCP feed sector. The risk analyses in FSP can serve as a guideline for the company-specific assessment. When hazards from the FSP risk assessment are not applicable on individual company level, a motivation is needed. This can be done via the HACCP analyses administration.
- Determine and enter the likely occurrence itself.
- The estimation of the **severity** is equal for all the hazards in all the risk assessments. It is a characteristic of the substance (for example a chemical contaminant) or the product (bacteria, glass, etc.).
- Adapt the severity as stated in FSP. The company can deviate from the FSP severity. This deviation needs to be motivated.

The (generic) risk assessments of feed materials fully comply with the requirements referred to in the HACCP manual for the animal feed sector (2008). The system allows for searching by product name or by risk assessment. Each risk assessment can subsequently be viewed in digital format with background information for each hazard, an explanation of the severity and applicable standards.

The sections of a Risk Assessment are:

- data sheet;
- flow chart;
- risk analysis.

Details can be found in detail Annex 1.

The structure of the risk assessments are in accordance with the HACCP manual 2008.
Interactive ways of making a company specific RA

From a generic Risk Assessments GMP+ companies can click through to the applicable product standards, monitoring results of the past period for the hazard concerned, or to a fact sheet which substantiates the severity.

With a module it is possible to convert the generic risk assessment to Excel and adjust it to a company-specific situation. The ‘hazard report’ is a tool for gathering the risks of all selected feed materials and to show these risks in one single hazard report.

1.2 GMP+ Monitoring database

In the GMP+ Monitoring database a company can manage and share the results of their monitoring program. The more results GMP+ participants share (anonymously) with the GMP+ Community, the more information is available for all GMP+ participants. The information can be used for drawing up and evaluating their companies own monitoring program and to assess the likely occurrence of a hazard. GMP+ International uses it to adjust the GMP+ requirements.

1.3 Fact sheets

The information in the fact sheets can be used in the implementation of a company specific HACCP analysis, for example in determining the severity of a hazard. The undesirable substances are called hazards in the risk assessments. Information is provided in the fact sheets about the hazard and the reason for its severity to animals and humans. There are also fact sheets for a number of (groups of) processing aids. Processing aids are used in the production of feed materials.

Processing aids are used in the production of feed material. The use of processing aids is allowed within the GMP+ context provided that the user demonstrates with a hazard analysis that the unintentional, but technically inevitable, presence of residues or their derivates does not affect animal health, human health or the environment and has no technological effect on the finished product.

The fact sheets contain details related to the the hazard analysis. This contains a section on any undesirable substances present in animal feed and its effects on humans, animals and the environment; control measures that may be taken; and the risks that may result from high or low doses of processing aids.

1.4. Standards

Standards have been issued by legislation and by GMP+ for many hazards These are available in Appendix BA1 of the GMP+ FC scheme. In FSP, different sources of information are linked with each other. For example, monitoring results that are above applicable standards will be highlighted, and from a risk assessment it is possible to click through to the applicable standard.
Annex 2: Explanation of the sections of a Risk Assessment

1. Data sheet

The data sheet contains the following:

a. List of products stating the products which are included in the risk analysis in question plus a definition of the product
b. List of processing aids used in the treatment and processing step

Explanation:

Re. a. The (product) definitions match as far as possible the definitions used within the EU, Regulation EC (no) 767/2009. If no EU definition is available then the German Positiv Liste is consulted.

Re.b. The use of processing aids is permitted in GMP+ if it is demonstrated on the basis of a hazards analysis that the unintentional but technically unavoidable presence of residues of these processing aids or their derivatives in the end product has no detrimental effects on animal health, human health or the environment and no technological effect at all on the end product. Fact sheets have been included for the following groups of processing aids in the FSP with information about the group of processing aids in question which can serve as input for the GMP+ certified companies when carrying out the hazards analysis referred to earlier. These include the following processing aids:

1. Organic solvents
2. Mineral salts
3. Inorganic acids
4. Hydroxides
5. Coagulants and flocculants
6. Catalysts
7. Anti-foaming agents

2. Flow chart

2.1 Layout

A flow chart can be divided up into a main process and sub-processes. The drawing up of a main process can be useful if the process is complicated because of many process steps and/or if there are many input and output flows. The following main process steps are identified in a risk assessment:

1. Cultivation
2. Harvesting / preservation (at the farm)
3. Transport / storage
4. Treatment / processing
Each main process is then worked out in a more detailed subprocess where all the process steps are shown separately.

2.2 Use of colour

Colours are used to clarify the input and output of a process. The colours have the following meanings:

<table>
<thead>
<tr>
<th>Colour</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>black (colour code 23)</td>
<td>Feed material. These products &amp; the definition are specified in the data sheet.</td>
</tr>
<tr>
<td>dark grey (colour code 17)</td>
<td>interim product which is not sold (directly) as a feed. The product is then processed or treated.</td>
</tr>
<tr>
<td>light grey (colour code 15):</td>
<td>Input: processing aids and/or feed additives Output: these products are sold outside the feed sector.</td>
</tr>
</tbody>
</table>

3. The (generic) risk analysis

The hazards in each production phase are summarised in the risk analysis. An estimate is then made of the likely occurrence that a hazard may occur and of the consequences (severity) involved. Where necessary suggestions are made for the control measures to be taken.

The structure of the risk analysis contains the following sections:

**Process step**

Each risk assessment contains a representation of the flow chart for a product.

The following main process steps are distinguished:

1. cultivation
2. harvesting and preservation at the farm
3. transport
4. storage
5. treatment / processing

The main stages are linked by numbers to the subprocesses as specified in the subprocess diagram

**Hazard**

A hazard can be described as a contaminant in a feed material or a situation which can lead to it and which has adverse consequences for the health of humans and animals.
The potential hazards which may make animal nutrition or feed unsafe for consumption by humans or animals should be listed for each process step where account should be taken of:

1. Hazards from the raw materials (basic materials) and auxiliary agents (additives which are added during the process)
2. Hazards from the process steps (see the flow chart)

**Category**
Hazards can be subdivided into three categories, physical, chemical and microbiological hazards.

**Risk ranking**
The risk estimation comprises the two elements Likely occurrence X Severity. The following applies:

**Severity**
Severity is the consequence for the health of the target animal and also the consequential damage to humans when products of animal origin are consumed. The severity should be based on literature, practical experience and/or experimental data, etc., and is classified into three levels: small, medium and high. (Source: HACCP manual 2008)

**Likely occurrence**
The likely occurrence is the probability that the hazard will occur in the end product at the moment of consumption by humans and/or the target animal. The likely occurrence is based on measurements, observations or expectations in a company-specific situation and it is divided into three levels: small, medium and high. (Source: HACCP manual 2008)

**Information sources:**

**Standards**
This column contains a specification of the standards which apply under EU feed legislation and/or GMP+ specified in appendix 1 of GMP+.

If there is no standard in appendix 1 then another standard should be used. Consider the advice from EFSA.

**Note:**
The user is referred to the standards which apply to all types of feeds such as complete feeds, etc. This is because feed materials as such may be fed to animals but they can also be used for further processing. This company-specific information (further processing / target animal / mix percentage) is only known when consulting the Feed Support Products.

**Analysis data**
In this column a link to the GMP+ Monitoring database is included. The user can click on this link and find analyse data about the specific undesirable substances in a specific product.
Flowchart
In this column a link to the flowchart is included. The number that is mentioned links to the process step where the hazard can occur.

Suggestion for control measure
This column makes a suggestion for a control measure. Account should be taken of the fact that:
- a single hazard may be controlled by multiple control measures, and
- a single control measure can control multiple hazards
Annex 3: Working procedure for submitting proposals for change of information in FSP

1. Generic
An application for the inclusion of a Risk Assessment or other elements in FSP like comments on factsheets can be submitted by a (future) GMP+ certified company but also by others such as sector organizations, certification bodies or consultancy agencies.

The process flow for submission of proposals like a new Risk Assessment is shown in figure 6 below. In the text below the steps are explained for submitting a Risk Assessment. Comments can be given on other documents as well like fact sheets.

An application of a Risk Assessment can be submitted using the template available for this purpose (on the GMP+ website FSP/Risk Assessments/Risk Assessment Submission).

2. Submission of a risk assessment
The applicant should draw up a proposal for a risk assessment in accordance with the standard format established by GMP+. Additional information can also be sent to assist in the acceptance of the risk assessment. The risk assessment will be screened by GMP+ for completeness. The applicant will receive a confirmation of receipt. This is not yet a screening of the content of the risk assessment.

3. Initial screening by GMP+ International
Initial screening by GMP+ International. The following sections will be checked / examined during this initial screening:
   a) Product name and definition,
   b) All the processing aids used,
   c) Flowcharts: All inputs and outputs (for example raw materials, processing aids used, interim products, waste products, etc.) should be mapped out.
   d) Risk estimation: the applicant should include all (potential) hazards in the hazards analysis table
   e) Screening by GMP+ (if necessary) of relevant product-specific information such as published company information, GMP+ fact sheets, EFSA reports, publications by, among others, nVWA, RIKILT and TNO.

The applicant will receive an email with the findings of this screening (questions, suggestions, corrections). Once all the questions from the first screening have been answered, the risk assessment will be included as a draft in the Feed Support Products. GMP+ International will decide whether it is necessary to continue with the consultation stage.
Criteria for ‘bypassing’ the consultation stage and for direct publication in FSP are:

- Language and translation errors;
- Changes because of changes in feed regulations (e.g. names of contaminants, new or changed standards);
- Removing products from the Product List in FSP because of changes in the negative list of the GMP+ FC Scheme (GMP+ BA 3).

4. Consultation stage external

4.1 General consultation stage
A draft will be published on this forum for a certain period. All the forum members are invited to give remarks and comments. The comments are visible for all members of the forum. The advice from the other members will be brought under the attention of the TC FSP.

The consultation will result in a second draft.

4.2 Pre Consultation TC FSP
A second draft and a summary of the comments will be placed in the forum group TC FSP. The TC FSP experts are invited to give remarks and comments. GMP+ International evaluates the reactions from the experts and will do a proposal.

Remarks can be categorized in three categories:
Summary of the préconsultation TC FSP (Risk Assessments and Fact sheets)

Legend:
A : Risk assessments where is no discussion about can be published in FSP.
B : When additional information is needed about a risk assessment GMP+ International will contact the applicant. The new information will be processed. If possible the risk assessment can be published in FSP. In case of doubt, the TC FSP will be consulted again.
C : Risk assessments where is discussion about (different options) will be put on the agenda of the next meeting with the TC FSP.

4.3 Meeting TC FSP
Risk assessments where is discussion about on the TC FSP forum (option c) will be put on the agenda of the next meeting with the Technical Committee FSP. The conclusion will be formalized in meeting minutes.

Any questions or comments will be communicated to the applicant. Depending on the answer, the risk assessment should be presented (in a meeting or by mail) again to the experts of TC FSP. This process will stop when there is a positive advice from TC FSP and it is approved for publication in the Feed Support Products.

5. Publication in the Feed Support Products
The Risk Assessment will be published in three languages (Dutch, English and German) in the FSP. Fact sheets are only published in English.
The GMP+ participants will be informed by the FSP newsletter about the publication of new feed material and fact sheets in FSP.
Figure 6: Process flow for submitting proposals for change in FSP

Start

Template Risk Assessment

Submission of proposal by applicant

Initial screening by GMP International

External consultation needed?

yes

no

General consultation stage (forum discussion)

Draft Risk Assessment or other FSD document

A: no discussion about proposal accepted

B: additional information needed from applicant

Doubt about additional information?

yes

no

Publication of new proposal in FSP

Approved by TC FSD?

yes

no

End

Output

Proposed Risk Assessment or other FSD document

E-mail to applicant with findings of the initial screening

Draft Risk Assessment or other FSD document

Advice from forum

Second Draft Risk Assessment or other FSD document

E-mail to applicant

New RA or revised other document in FSD

Input

Contact form or forum

Draft Risk Assessment or other FSD document

Second Draft Risk Assessment or other FSD document

Process

A: no discussion about proposal accepted

B: additional information needed from applicant

C: discussion needed in TC FSD

D: no

E: yes

Pre-consultation TC FSD (forum group discussion)

Additional information needed?

yes

no

End
Annex 4: Feed materials Decision Tree

**FEED MATERIAL decision tree**

START

Is the product specified in Annex III, Chapter 1 of Reg. (EC) no. 767/2009 (List of prohibited materials)?

Yes

Product prohibited for processing in feed

No

Is the product specified in GMP+ BA3: Minimum Requirements for the Negative List? (GMP+)

Yes

Product prohibited for processing in GMP+ certified feed

No

!! THE PRODUCT IS PERMITTED IN PRINCIPLE AS FEED / IN FEEDINGSTUFF !!

Does the product comply with the following definition in Reg. (EC) no. 767/2009 Article 3 g)?

*Product of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as a carrier in premixes*.

Yes

The product is very probably a feed material

Check this by proceeding further in this FEED MATERIAL decision tree and if necessary the FEED decision tree and the PRODUCTS IN FEEDS decision tree.

No / Don't know

Is the product in:

- The appendix to Reg. (EU) no. 2017/1017 (Catalogue of feed materials),
- The register of feed materials of the European Feed Sector according to Reg. (EC) no. 767/2009 art. 24 section 6, (see http://www.feedmaterialsregister.eu) (Note: The registry has no legal status)
- The appendix to Reg. (EU) no. 892/2010 ("grey listed" products of both additives and other products formerly not recognized as feed materials before the implementation of this regulation),
- The FSP Product list of the GMP+ FSA scheme? (GMP+)

No

The product is very probably not a feed material.

Go through the FEED and PRODUCTS IN FEEDS decision trees to determine the nature of the product.

2 3

**END**

Is the product similar to one of the products in the appendix to Reg. (EU) no. 892/2010 ("grey listed" products of both additives and other products formerly not recognized as feed materials before the implementation of this regulation)

- The text of consideration 4 of Reg. (EU) no. 892/2010

*From a comparison between the characteristics of the products mentioned in the repertoire of additives for feed and in the feed catalogue, several criteria can be derived for the division of products such as feed, feed additives and other products. Useful criteria for this function include:
1) the production and processing method, 2) the level of standardisation, 3) the homogenisation, 4) the purity, 5) the chemical definition, and 6) the method in which the products are used. For the benefit of coherence, products with comparable characteristics must be categorized by analogy. For products for which there were doubts whether they were feed additives, an examination has been carried out in accordance with the criteria of Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.*

Yes

The product is a feed material

2 3

The product is a feed material

No / Don’t know

The product is very probably not a feed material.

Go through the FEED and PRODUCTS IN FEEDS decision trees to determine the nature of the product.

2 3

!!! THE PRODUCT IS A FEED MATERIAL !!!

The feed material may be put on the market on the following conditions:

- The norms for undesirable substances according to Dir. 2002/32/EC and according to GMP+ BA1 Specific feed safety limits are not exceeded (if exceeded then in a number of cases detoxification / decontamination is possible (Reg. (EC) no. 767/2009 art. 20, Dir. 2002/32/EC art. 8)).
- The norms for residues of crop protection agents according to Reg. (EC) no. 396/2005 are not exceeded.
- If a claim is attached to the feed material then this must comply with the requirements as stated in Reg. (EC) no. 767/2009, Article 13

* In the event of doubt at GMP+ International or in the Technical Committee FSP about the status or purpose of a product, the company will have to obtain an official permit as a feed material in Brussels (EC). GMP+ can handle the risk assessment on the basis of the official permit.
Working principles of the GMP+ Feed Support Products (FSP)

FEED decision tree

Does the product comply with the following definition in Reg. (EC) no. 767/2009 Article 3 h?

*Mixture of at least 2 feed materials, whether or not containing feed additives, intended for oral animal-feeding, as complete or complementary feed;*

**Yes**

The product is a compound feed

Type of compound feed:
- Complete feed
- Milk replacers
- Complementary feed (including mineral feeds)

**No**

NOTES
If in a mixture of 2 feed materials the level on one feed material is a maximum of 3% and this feed material serves to bind the other feed material and/or to denaturise it, then the mix is still considered to be a feed material (Reg. (EC) no. 767/2009, Appendix I sub 4).

Does the product comply with the following definition in Reg. (EC) no. 1831/2003 Article 2 a?

*Substances, micro-organisms and preparations which are not feed materials or premixes and which are added deliberately to animal feed or water with the intention of achieving one or more of the following functions:*

The product favoursfavourably influences:
- The characteristics of the feed,
- The characteristics of animal products,
- The environmental consequences of animal production,
- The animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or
- Does the substance or the product satisfy the nutritional needs of animals?
- Does the substance or product have a coccidiostatic or histomonostatic effect?

**Yes**

The product is a feed additive

!! IMPORTANT!!
The marketing and use of feed additives is strictly regulated

Check whether the feed additive is permitted in the EU for the use you intend and/or the animal category
Use the Community Register of Feed Additives for this

It is forbidden to market feed additives which are not permitted in the EU

**No**

Does the product comply with the following definition in Reg. (EC) no. 1831/2003 Article 2 e?

*Mix of feed additives or mixes of one or more feed additives using a carrier of feed materials or water which are not intended for direct feeding to animals*

**Yes**

The product is a premixture

**No**

The product is very probably not a feed.

Go through the PRODUCTS IN FEEDS decision tree to determine the nature of the product.

The feed may be put on the market on the following conditions:
- The norms for undesirable substances according to Dir. 2002/32/EC and according to GMP+ BA1. Specific feed safety limits are not exceeded (if exceeded then in a number of cases detoxification / decontamination is possible (Reg. (EC) no. 767/2009 art. 20, Dir. 2002/32/EC art. 8));
- The norms for residues of crop protection agents according to Reg. (EC) no. 396/2005 are not exceeded;
- If a claim is attached to the compound feed then this must comply with the requirements as stated in Reg. (EC) no. 767/2009, Article 13.
Working principles of the GMP+ Feed Support Products (FSP)

PRODUCTS IN FEED decision tree

1. Does the product comply with the following definition in Reg. (EC) no. 1831/2003 Article 2 h?
   - "substances which are themselves not consumed as animal feed but which are deliberately used in the processing of animal feed or feed materials in order to meet a particular technical objective"
   - Yes
   - The product is a processing aid
     - NB: the unintentional but technically unavoidable presence of residues of these substances or their derivatives in the end product may have no detrimental effects on animal health, human health or the environment and no technological effect at all on the end product
   - No

2. Does the product comply with the following definition in the Veterinary Medicinal Products Act, Article 1?
   - "Substance, or mixture of substances, of human, animal, vegetable or chemical origin, including animals, plants, parts of animals or plants as well as micro-organisms and viruses which are intended whether or not after treatment or processing to be used for:
     - the healing, slimming or prevention of any condition, sign of disease, pain, injury or invalidity in an animal;
     - the healing, improvement or change to the functions of the organs of the animal;
     - the detection of a disease or invalidity in animals through use on an animal"
   - Yes
   - The product is a medicated feedingstuff
     - !! IMPORTANT!!
     - The marketing and use of medicated feedingstuffs is strictly regulated
     - Visit the website of the Dutch Medicines Evaluation Board for more information (http://www.cbg-meb.nl/dieren)
   - No

3. Does the product comply with the following definition in Dir. 98/8/EC Article 2.1.a?
   - "Active substances (chemical elements and their compounds, and micro-organisms) and preparations (mixes or solutions which consist of two or more substances) put up in the form in which they are supplied to the user, contain one or more active substances and are intended to destroy, render harmless, prevent the action of or otherwise to exert a controlling effect on any harmful organism by chemical or biological means"
   - Yes
   - The product is very probably not permitted for use in feedingstuff
     - END
   - No

DISCLAIMER
These decision trees have been created with the greatest possible care. The decision trees contain references to various relevant elements of the legislation and regulations. Anyone who markets feeds and/or products for processing in feeds is subject to all the applicable legislation and regulations. The user may derive no rights from these decision trees. GMP+ International BV is not liable for any claim or loss of income as a result of the use of these decision trees.
Annex 5: Reader Fact sheets undesirable substances

The reader provides an explanation about the contents and scope of the chapters addressed in the fact sheets and is published here.
## ANNEX 6: Maintenance of information in FSP with type of information, frequency, the resulting change in FSP documents and the consultation part.

<table>
<thead>
<tr>
<th>Type of information</th>
<th>Activities and frequency</th>
<th>Resulting change in FSP</th>
<th>Responsible for monitoring and evaluating information</th>
<th>Consultation and decision needed in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newsletters and publications on relevant (scientific or other) information e.g. new hazards, change in severity of hazards: Science organizations: - Rikilt - RIVM - WUR - TNO (Supervisory) Authority: - EFSA - WHO Food Safety Newsletter - FAO - Codex - NVWA - FSA (UK)</td>
<td>Continuous gathering: No action needed in case of no information for FSP. Immediate action needed in case of a negative effect on human/animal or environment is realistic. Otherwise: File information and evaluate/discuss every 6 months the effect for the products of FSP</td>
<td>Product list Risk Assessment, Fact sheets, Standards GMP+ Monitoring database GMP+ Monitoring program</td>
<td>GMP+ International: All: in relation to their FSP product</td>
<td>TC FSP</td>
</tr>
</tbody>
</table>
### Type of information

- Food Safety News (US)
- FDA recalls, market withdrawals and safety alerts (US)
- CDC / ATSDR (US)
- Food Standards (AUS+NZ)

US-EPA, INCHEM reports and scientific publications (via e.g. PubMed, Bio Info Bank Library)

**General:**
- Safe Food Safe Feed
- All About Feed
- Food Holland
- Agri Holland

Relevant developments in new and **changing feed regulations** (EU);
- List of prohibited materials
- Contaminants/undesirable substances (incl. MRLs)
- Processing aids
- Feed additives
- Medicated feed
- Biocides and pesticides
- Toxicology GSFI developments

<table>
<thead>
<tr>
<th>Type of information</th>
<th>Activities and frequency</th>
<th>Resulting change in FSP</th>
<th>Responsible for monitoring and evaluating information</th>
<th>Consultation and decision needed in:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Continuous gathering and process in FSP every 6 months,</td>
<td>Product List, Risk Assessment, Fact sheet, GMP+ Monitoring program</td>
<td>GMP+ International: LQ</td>
<td>TC FSP</td>
</tr>
<tr>
<td>Type of information</td>
<td>Activities and frequency</td>
<td>Resulting change in FSP</td>
<td>Responsible for monitoring and evaluating information</td>
<td>Consultation and decision needed in:</td>
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<tr>
<td>---------------------</td>
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<td>------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>Changing standards</strong> (Standards GMP+ BA 1 (including references to Feed Regulations))</td>
<td>Continuous gathering and directly process in FSP</td>
<td>Standards GMP+ BA 1 (incl. references to Feed Regulations), Fact sheet GMP+ Moni GMP+ Monitoring program</td>
<td>GMP+ International: LQ</td>
<td>FSP, IEC</td>
</tr>
<tr>
<td><strong>New feed materials</strong>, changes in Negative list of the GMP+ FC Scheme (GMP+ BA 3)</td>
<td>Continuous gathering and process in FSP every 6 months, discuss in TC FSP. Products added to the Negative list will be directly removed from the Product List in FSP*</td>
<td>Products list, Risk Assessments Fact sheets GMP+ Monitoring program</td>
<td>GMP+ International: LQ</td>
<td>IEC</td>
</tr>
<tr>
<td><strong>EWS</strong> evaluation and notifications and annual reports (Early Warning and Response System)</td>
<td>Continuous/weekly gathering and process every 12 months, discuss in TC FSP. If urgent directly inform TC FSP and directly process in FSP. Directly process new standards in FSP</td>
<td>Fact sheet, Risk Assessment, GMP+ Monitoring Program</td>
<td>GMP+ International: All: in relation to their FSP product</td>
<td>TC FSP</td>
</tr>
<tr>
<td><strong>Monitoring data</strong> from the GMP+ Monitoring database: - Annual report of the results - GMP+ monitoring program</td>
<td>Evaluation of results every 12 months</td>
<td>Risk Assessment, Monitoring Program</td>
<td>GMP+ International: JK</td>
<td>TC FSP</td>
</tr>
</tbody>
</table>
### Working principles of the GMP+ Feed Support Products (FSP)

<table>
<thead>
<tr>
<th>Type of information</th>
<th>Activities and frequency</th>
<th>Resulting change in FSP</th>
<th>Responsible for monitoring and evaluating information</th>
<th>Consultation and decision needed in:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FSP annual report</strong></td>
<td>Evaluation of findings every 6 months</td>
<td>All FSP Products</td>
<td>GMP+ International: LQ</td>
<td>TC FSP</td>
</tr>
<tr>
<td>Other Private feed <strong>standards</strong></td>
<td>Continuous gathering and process in FSP every 12 months, discuss in TC FSP</td>
<td>All FSP products</td>
<td>Members of TC FSP/GMP+ International:</td>
<td>TC FSP</td>
</tr>
<tr>
<td><strong>Findings from GMP+ audits</strong></td>
<td>Continuous gathering and process in FSP every 12 months, discuss in TC FSP</td>
<td>Risk Assessment, Fact Sheets, GMP+ Monitoring program</td>
<td>GMP+ International: All: in relation to their FSP product</td>
<td>TC FSP</td>
</tr>
<tr>
<td><strong>Other information e.g.:</strong></td>
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</tr>
<tr>
<td>Non-conformities related to food and feed safety:</td>
<td>Continuous gathering</td>
<td>Hazard in RA, new or update of Fact sheets, GMP+ Monitoring program</td>
<td>GMP+ International: All: in relation to their FSP product</td>
<td>If urgent directly inform TC FSP and directly process in FSP,</td>
</tr>
<tr>
<td>- Recall in food</td>
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<tr>
<td>- Recall in feed</td>
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<tr>
<td>Incoming reports/questions about the content of FSP via contact form FSP on the portal, by telephone</td>
<td>Continuous gathering and process in FSP every 6 months, discuss in TC FSP if relevant</td>
<td>Products list, Risk Assessment, Fact Sheets, Standards, GMP+ Monitoring Program FSP working principles</td>
<td>GMP+ International: All: in relation to their FSP product</td>
<td>TCFSP</td>
</tr>
<tr>
<td>Screening of FSP (Working links, up to date text, figures etc.)</td>
<td>Check database FSP every 12 months and directly process in FSP</td>
<td>Links, text, figures</td>
<td>GMP+ International: HB</td>
<td>No</td>
</tr>
</tbody>
</table>
Working principles of the GMP+ Feed Support Products (FSP)

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