Question & Answer List

Feed Safety Database

Version 7

Feed for Food

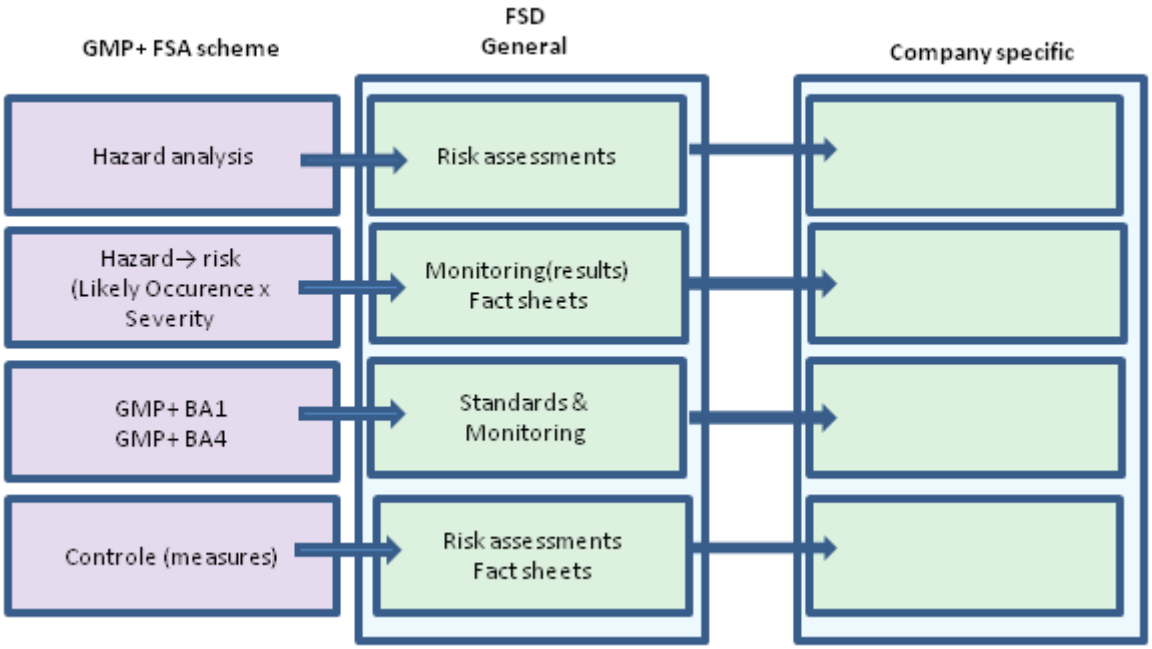
TABLE OF CONTENTS

1 What is the purpose of the FSD?

The Feed Safety Database (FSD) is an interactive database which is part of the GMP+ FSA Scheme. The FSD comprises various parts of the GMP+ FSA scheme: risk assessments, monitoring results, product standards and fact sheets. The approved feed materials in the FSD are quality assured here.

The Feed Safety Database is intended to support all (future) GMP+ companies when setting up their company-specific HACCP system. The Feed Safety Database is a tool which the companies can use to make easier the setting up and implementation of their company-specific HACCP system. The responsibility for use and implementation remains with the GMP+ certified companies, the Feed Safety Database can offer support in this process.

The following diagram shows which GMP+ products in the Feed Safety Database can offer support for which part of the company-specific HACCP analysis.



2 Risk assessments

2.1 What is the purpose of including a risk assessment in the FSD?

The following are the four objectives of including a risk assessment in the FSD:

a) which feed materials are considered to be controllable and can therefore be safely used in the feed sector;
b) An aid to GMP+ companies in the drawing up of their company-specific risk assessments.

c) the feed sector makes clear to interested parties how the production processes are assessed.
d) The risk assessments serve as a reference for the auditors within the framework of GMP+ certification.

2.2 Which products can be included in the FSD?

The FSD is currently intended for all feed materials which are fed to food-producing animals.

2.2.1 Feed materials?

Use can be made of the ‘Feed Materials ‘Decision Tree'. as an aid when categorizing a product. The decision tree uses the answers to a number of questions to categorize the product in question.

2.2.2 Target animals?

With the arrival of the new trade regulation EC/767/2009 there is a new definition for productive livestock, namely food-producing animals. FSD 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 FSD 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 FSD. This is not a requirement of the GMP+ FSA scheme.

2.3 Is it mandatory to include a feed material in the FSD?

The obligation applies to all standards with the scope production / trade of feeds for productive livestock. The 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 Safety Database (FSD).

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

2.4 Is the information in a risk assessment binding?

The risk analyses in the 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.

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.

Also, when estimating the **likely occurance** the situation is assumed where no control measures have been taken yet. The likely occurence estimation is a guide-line. Each individual GMP+ company should determine and enter the likely occurence itself.

The estimation of the **severity** is the same for all the hazards in all the risk as-sessments. It is a characteristic of the substance (for example a chemical contami-nant) or the product (bacteria, glass, etc.).

2.5 What are the sections of a risk assessment?

Each risk assessment consists of four parts:

1. Data sheet
2. A global flow chart
3. A detailed flow chart
4. The risk analysis

An explanation of the various sections is to be found in appendix x.

2.6 Estimation of the Severity

The estimation of the severity is the same for all the hazards in all the risk assess-ments. It is a characteristic of the substance (for example a chemical contaminant) or the product (bacteria, glass, etc.).

The severity is determined by both the effect on the animal and the effect on hu-mans. The effect on all farm animals is included as it is not known or which type of animal a raw material will be used). The degree of severity is determined by the most sensitive species and the sum of the severity (effect on humans and animals) is determined by the greatest effect on humans and animals.

The degree of severity is determined on the basis of scientific data. This data is laid down in fact sheets. Please refer to the Fact Sheets button in the database.

2.7 Estimation of the Likely occurence

The likely occurence estimation is worst case which means that in this situation no control measures have been taken yet. And the likely occurence estimation is ge-neric and a guideline. A GMP+ certified company can use this information a part of

its company-specific lik ely occurence estimation. See the other questions for more information.

2.8 What has changed compared to the old risk assessments?

The structure of the current risk assessments is in accordance with the most recent HACCP system as described n the HACCP manual 2008. Compared to the old risk assessments, this mean that no information is now included about the risk classes (1,2,3 and 4) and the conclusion POA/CCP.
The control measures (and the associated hazards) as specified in the GMP+ pre-requisites programme will also no longer be part of risk assessment. This means there is more attention for product-specific hazards.

2.9 Why are the names of producers mentioned next to the mineral feed materials?

With mineral feed materials the name of the manufacturer and his registration number is mentioned next to the product name. The reason for this is that it turned out to be impossible to provide a generic risk assessment when the risk assessment of these mineral feed materials is provided. GMP+ International has therefore consented (provisionally) to the provision of company-specific risk assessments. These are not published because they constitute sensitive information about the company.

At this moment it is only possible to purchase mineral feed materials which originate from manufacturers which are mentioned next to the mineral feed material concerned.
Names and registration numbers of new manufacturers of mineral feed materials may be included on the basis of an approved company-specific risk assessment. See the 'Risk assessment' button for more information about submitting new risk assessments.

If the name of your company is mentioned with an old company name next to a mineral feed material, then please send an E-mail to FSDDOS@gmpplus.org. In this E-mail please state clearly the name of the mineral feed material as included in the 'Products list', your registration number, your old company name and your current data.

Companies which, when supplying a new risk assessment, are not yet in possession of GMP+ registration numbers should indicate this clearly in the application. In this situation, the production location will be included in the FSD in addition to the company name. Once the registration is granted, the company must inform the FSD. Note that these rules also apply to companies which are or will be approved under other accepted quality systems (see GMP+ BA10 Minimum Requirements for Purchasing).

** The registration numbers will be added soon for mineral feed materials which are already included*

3 Fact Sheets

3.1 What are fact sheets?

Fact Sheets are information sheets with background information. There are fact sheets for undesirable substances and processing aids.
The undesirable substances are called hazards in the risk assessments. Information is provided in the fact sheets about the hazard and the reason for the 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.

There is not yet a complete fact sheet for every hazard with the section More Facts. These will be supplemented in the coming period.

3.2 Which new style fact sheets are available in FSD?

Fact sheets are available with regard to undesirable substances and technical auxiliary substances which are used in the production of feed materials.

A new style fact sheet is available for the following **undesirable substances**:

Mycotoxin

1. Aflatoxin
2. Don
3. Fumonisin B1
4. Ergot of rye (second version)
5. Orchratoxin
6. Zealarenon

Crop protection agents (Pesticides which are not permitted in the EU)

7. Camphechloor
8. Chlordane
9. DDT (second version)
10. Endosulfan
11. Endrin
12. Heptachlor
13. Hexachlorobenzene (HCB)
14. Hexachlorecyclohexane (HCH)

Toxic substances

15. Dioxins Furans Dioxin like PCB's
16. Hydrocarbons (C10-C40)

Heavy Metals

17. Arsenic
18. Cadmium
19. Fluorine
20. Mercury
21. Lead
22. Nickel

Antinutritional factors / Botanical impurities

23. Ricinus-Ricinus commuc L.
24. Datura Stramonium L.
25. pyrrolizidine alkaloids
26. Theobromine
27. Vinylthiooxazolidon/various mustard seeds

Others

28. Antibacterial inhibition/antibiotics
29. Biogenic Amines
30. Cyanogen compounds
31. Animal Protein
32. Melamin
33. Radioactivity (as soon as possibles added in FSD)

Fact sheets are available for the following groups **of technical auxiliary substances**:

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

The use of technological auxiliary substances is allowed in GMP+ if it is demonstrated on the basis of a risk analysis that the unintended, but technically unavoidable presence of residues of these technical auxiliary substances or their derivatives in the end product do not have adverse consequences for the health of humans or animals or for the environment and do not have any technological effect on the end product.

For the above groups of technological auxiliary substances the FSD includes fact sheets with information about the group of technological auxiliary substances concerned which can be used by the GMP+ certified companies as input for the realisation of the above-mentioned risk analyses.

3.3 Are the old Fact Sheets still available?

The old Fact sheets can be found under the History button. These are only those fact sheets for which no new style Fact Sheet is available yet in FSD. These fact sheets are only available in Dutch.

4 Standards

The appendix to be downloaded here is that which applies in the GMP+ FSA schema, GMP+ BA1.

Appendix 1: 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 FSD 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:

8. Organic solvents
9. Mineral salts
10. Inorganic acids
11. Hydroxides
12. Coagulants and flocculants
13. Catalysts
14. 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:

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

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 occurence that a hazard may occur and of the consequences (severity) involved. Where necessary suggestions are made for the control measures to be taken.

The new 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 estimation

Th risk estimation comprises the two elements Likely occurence 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, moderate and great. (Source: HACCP manual 2008)

Likely occurence

The likely occurence 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 occurence is based on measurements, observations or expectations in a company-specific situation and it is divided into three levels: small, moderate and great. (Source: HACCP manual 2008)

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 Safety Database.

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