GMP+ International

# Comparison between FSMA (USA) and GMP+ B2 standard

## GMP+ D 2.7

Version EN: 1 March 2019

**GMP+ Feed Certification scheme**

Feed Safety Worldwide

gmpplus.org

# Index

# 1. Introduction

## 1.1. General

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focused on feed safety) and GMP+ Feed Responsibility Assurance (focused on responsible feed).

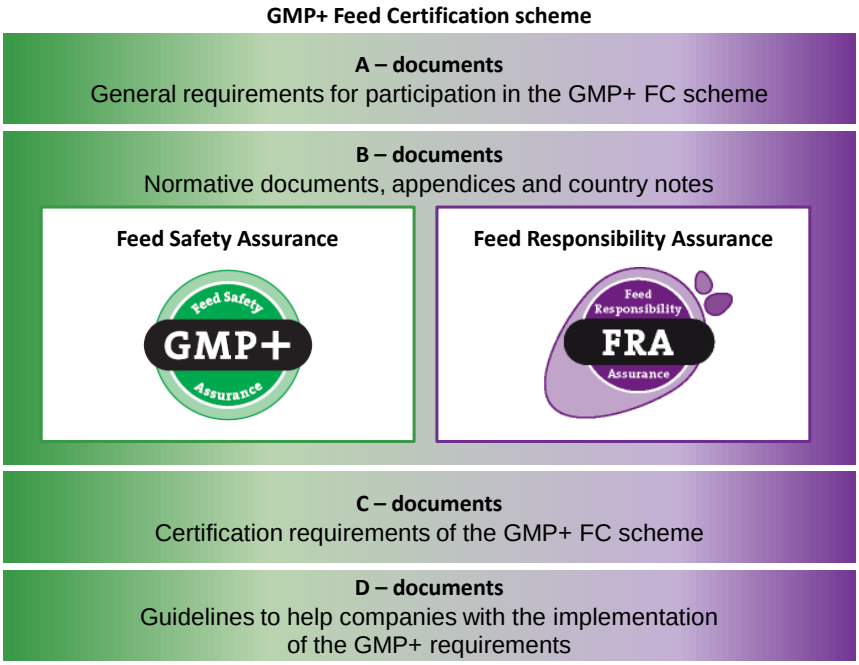
GMP+ Feed Safety Assurance (FSA) is a complete module for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA module, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programs, chain approach and the Early Warning System.

With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sec-tor is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In or-der to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance.
Together with the GMP+ partners, GMP+ International transparently sets clear requirements to guarantee feed safety & responsibility. Certification bodies are able to carry out GMP+ certification independently.
GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

The United States of America Government launch the Food Safety Modernization Act (FSMA) in 2011 with several internationally accepted principles for food and feed safety assurance. There is a substantial overlap between FSMA and GMP+ Feed Safety Assurance standards.

## 1.2. Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:




All these documents are available through the website of GMP+ International (www.gmpplus.org).

The document in the present case is referred to as 'Comparison between FSMA (USA)- and the GMP+ FSA standards (B2)'

It is not a normative document, but it may be useful in case a company has to comply with both regulations (FSMA-USA and GMP+ B2 standard).

# 2. Aim of the document and abbreviations

## 2.1. Aim

GMP+ FSA certified companies which are active in the United States of America (USA) in the production of feed ingredients must comply with the requirements set by national legislation (FDA Food Safety Modernization Act – CFR title 21 part 507). If they are GMP+ FSA certified, they can benefit twofold: (largely) compliance with FSMA requirements and with internationally accepted market principles with regard to feed safety assurance.
This document shows the results of a comparison between the requirements of FSMA and GMP+ Feed Safety Assurance standards.

This comparison could help companies to identify the overlap between the standard GMP+ B2 'Production of feed Ingredients' and the requirements stipulated in the USA feed legislation.

The comparison shows which FSMA-requirements are covered by GMP+ B2 'Production of Feed Ingredients' and which are not. In some cases, additional information is also included to help in better understanding the requirements.

The development of this comparison has been made jointly with SGS North America (SGS Food Services).

## 2.2. Abbreviations

FDA / USFDA: (United States) Food and Drug Administration

CFR: Code of Federal Regulation

FSMA: Food Safety Modernization Act

Chapter 7 also contains information regarding definitions and abbreviations used in this document.

## 2.3. Guidance

| Term used, as conclusion, in the comparison table | Clarification |
|---|---|
| Comply | The GMP+ requirements are in accordance with the FSMA requirements |
| Partially comply | The GMP+ requirements are partially in accordance with the FSMA requirements. In some cases column 'Details or Conformity or Non-conformity' contains more information about the partially coverage. |
| No comply | The GMP+ requirements are not in accordance with the FSMA requirements or the requirement does not exist in the GMP+ standard. |
| Additional | The GMP+-requirement does not exist in the FSMA. |

# 3. Comparison between FSMA (USA) and GMP+ B2 standard

## 3.1. Subpart A—General requirements

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 requirements | Yes / No/ Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.1 Applicability and status** | | | | | |
| *(a)* | The criteria and definitions in this part apply in determining whether an animal food is: | *NA* | *No specific requirement* | | | |
| *(1)* | *Adulterated within the meaning of:* | *NA* | *No specific requirement* | | | |
| *(i)* | *Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or* | *5.2.1* | *The production of feed ingredients must be carried out in an environment where it is not possible for the presence of potentially hazardous substances to lead to an unacceptable level of those substances in feed ingredients.* | Partially comply | General environment clause | |
| *(ii)* | *Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and* | *5.2.1* | *The production of feed ingredients must be carried out in an environment where it is not possible for the presence of potentially hazardous substances to lead to an unacceptable level of those substances in feed ingredients.* | No | | |
| *(2)* | *In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).* | *NA* | *No specific requirement* | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(b)* | The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, E, or F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act. | *D2.1* | *From In Europe, as of 1 January 2006, the Animal Feed Hygiene Regulations (Regulation (EC) 183/2005) has been effective. This Regulation includes requirements relating to hygienic animal feed handling. The Regulation determines that all activities during all stages of animal feed production fall under the scope of the Regulation. The Regulation determines that all animal feed companies shall apply HACCP principles.* | No | No specific requirement to comply with USA regulations. | |
| *(c)* | Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations. | *NA* | *No specific requirement* | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(d)* | Except as provided by § 507.12, if a facility is required to comply with subpart B of part 507 and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food and animal food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control. When applying the requirements of part 117 of this chapter to animal food, the term "food" in part 117 includes animal food. | *NA* | *No specific requirement* | | | |
| | **§ 507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food** | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(a)(1)* | The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and | *5.1.2* | *Personnel who carry out work which may influence feed safety must be competent. Their level of competency is based on suitable courses, training, skills and experience. The participant must have personnel with the skills and qualifications which are required for the production of safe feed ingredients.* | Yes | | |
| *(2)* | *The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part are qualified to perform their assigned duties.* | | | | | |
| *(b)* | Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must: | | | | | |
| *(1)* | *Be a qualified individual as that term is defined in § 507.3, i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties; and* | *5.1.2* | *Personnel who carry out work which may influence feed safety must be competent. Their level of competency is based on suitable courses, training, skills and experience. The participant must have personnel with the skills and qualifications which are required for the production of safe feed ingredients.* | *Partially comply* | GMP+ does not define 'qualified individual' as per FSMA | Qualified individual in FSMA does not refer to HACCP Team; it refers to 'each individual engaged in manufacturing, processing, packing, or holding animal food (including |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | temporary and seasonal personnel)' |
| *(2)* | *Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.* | *5.1.2* | The participant must:<br>a. Establish the necessary skills which the personnel must have if they carry out work which influences feed safety. This also applies to the HACCP Team.<br>b. Offer training or take other measures to meet these needs.<br>c. Maintain personnel records of courses, training, skills and experience.<br>The above also applies to temporary personnel. | *Yes* | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(c)* | *Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.* | *5.1.1* | All personnel must be aware of their responsibility for feed safety. There must be:<br>a. an organizational chart;<br>b. a description of the qualifications (for example diplomas, summary of professional experience) of (also temporary employed) personnel.<br>c. A description of the personnel's tasks, responsibilities and authorities.<br>All relevant personnel must be informed clearly in writing of their duties, responsibilities and powers with regards to the maintenance of safe raw materials and feed ingredients. This information must be updated in the event of any significant changes. | *Partially to yes* | | |
| *(d)* | Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part. | *5.1.2* | *c. Maintain personnel records of courses, training, skills and experience.* | *Yes* | | |
| | **§ 507.14 Personnel** | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(a)* | The management of the establishment must take reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against the contamination of animal food. | 5.1 | No specific requirements | Partially comply | | |
| *(b)* | The methods for conforming to hygienic practices and maintaining cleanliness include: | | | | | |
| *(1)* | *Maintaining adequate personal cleanliness;* | *5.1* | *No specific requirement* | *Partially comply* | General HACCP requirements | |
| *(2)* | *Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination;* | *5.1* | *No specific requirement* | *Partially comply* | General HACCP requirements | |
| *(3)* | *Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;* | *5.1* | *No specific requirement* | *Partially comply* | General HACCP requirements | |
| *(4)* | *Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and* | *5.1* | *No specific requirement* | *Partially comply* | General HACCP requirements | |
| *(5)* | *Taking any other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.* | *5.1* | *No specific requirement* | *Partially comply* | General HACCP requirements | |
| | *No requirement* | *5.1.1* | Protective clothing must be worn wherever contamination of feed ingredients by personnel is identified as a risk by the risk assessment | Additional | General HACCP requirements | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | study. All clothing and equipment must be maintained in hygienic condition. See 5.1 | | | |
| | *No requirement* | *5.1.1* | Clear policies on smoking and eating / drinking on site must be made known to employees and visitors (including personnel from a third party) and must prohibit eating, drinking and smoking in areas where these activities may adversely affect feed ingredients. If necessary, separate facilities must be provided.<br>See 5.1 | Additional | General HACCP requirements | |
| | *No requirement* | *5.1.1* | The participant must ensure that (technical) personnel from a third party working on site are controlled in such a way that maintenance and building works do not adversely affect either raw material or feed ingredient safety. There must be a procedure in place to ensure that appropriate cleaning and tidying has been completed prior to recommencing activities in that area. See 5.1 | Additional | | |
| | **§ 507.7 Requirements that apply to a qualified facility** | | | | | |
| *(a)* | A qualified facility must submit the following attestations to FDA: | *NA* | *No requirement* | No | | |
| *(1)* | *An attestation that the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year* | *NA* | *No requirement* | No | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | *for calculating the adjustment for inflation is 2011; and* | | | | | |
| *(2)(i)* | *An attestation that you have identified the potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or* | *NA* | *No requirement* | No | | |
| *(ii)* | *An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.* | *NA* | *No requirement* | No | | |
| *(b)* | *The attestations required by paragraph (a) of this section must be submitted to FDA by any one of the following means:* | *NA* | *No requirement* | No | | |
| *(1)* | *Electronic submission. To submit electronically, go to http://www.fda.gov/furls and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.* | *NA* | *No requirement* | No | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(2)* | *Submission by mail. (i) You must use Form FDA 3942b. You may obtain a copy of this form by any of the following mechanisms:* | *NA* | *No requirement* | No | | |
| *(A)* | *Download it from http://www.fda.gov/pcafrule;* | | | | | |
| *(B)* | *Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550; or* | *NA* | *No requirement* | No | | |
| *(C)* | *Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.* | *NA* | *No requirement* | No | | |
| *(ii)* | *Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20550. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.* | *NA* | *No requirement* | No | | |
| *(c)(1)* | A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year. | *NA* | *No requirement* | No | | |
| *(2)* | *The attestations required by paragraph (a) of this section must be:* | *NA* | *No requirement* | No | | |
| *(i)* | *Submitted to FDA initially:* | *NA* | *No requirement* | No | | |
| *(A)* | *By December 16, 2019 for a facility that begins manufacturing, processing, packing, or holding animal food before September 17, 2019;* | *NA* | *No requirement* | No | | |
| *(B)* | *Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019; or* | *NA* | *No requirement* | No | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *(C)* | *By July 31 of the applicable calendar year, when the status of a facility changes from "not a qualified facility" to "qualified facility" based on the annual determination required by paragraph (c)(1) of this section; and* | *NA* | *No requirement* | No | | |
| *(ii)* | *Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.* | *NA* | *No requirement* | No | | |
| *(3)* | *When the status of a facility changes from "qualified facility" to "not a qualified facility" based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.* | *NA* | *No requirement* | No | | |
| *(d)* | When the status of a facility changes from "qualified facility" to "not a qualified facility," the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility. | *NA* | *No requirement* | No | | |
| *(e)* | A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for | *NA* | *No requirement* | No | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | domestic facilities, and comparable full address information for foreign facilities) as follows: | | | | | |
| *(1)* | *If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.* | *NA* | *No requirement* | No | | |
| *(2)* | *If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.* | *NA* | *No requirement* | No | | |
| *(f)(1)* | A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section. | *NA* | *No requirement* | No | | |
| *(2)* | *The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.* | *NA* | *No requirement* | No | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | No requirement | 4,1 | Management must be aware of its responsibility for the safety of the feed. Feed is part of the food production chain. Management must:<br>a. Make the organization aware of the importance of feed safety and of compliance with both the requirements of the customer, of this GMP+-standard and the obligations of the feed legislation.<br>b. Demonstrate its responsibility and involvement in the development and introduction of the feed safety management system to achieve safe feed.<br>c. Establish a HACCP Team.<br>d. Ensure that resources are available. Management must determine what resources are required to realize safe feed and ensure that these resources are<br>also available. At least, compliance with this standard is necessary.<br>e. Assess at least once per 12 months whether the feed safety management system is still suitable and effective. See for details about such a management re-<br>view section 8.3. | Additional | | In GMP+ this is the Feed Safety Management System part |

| | | | | | | |
|---|---|---|---|---|---|---|
| | No requirement | 4,3 | The participant must establish, document, implement and maintain a feed safety management system in accordance with the requirements of this standard. The feed safety management system must be adapted to regulatory and other safety related developments, as they occur.<br>The feed safe management system must ensure that all those activities that could impact on the safety of the feed ingredients produced / processed are consistently defined, implemented and maintained in the organization.<br>The participant must determine and record the scope of the feed safety management system by identifying the (categories of) feed ingredients and production sites which are covered by the system and ensuring that the feed safety objectives are established. The scope must in any event include all feed ingredients and all activities related to the feed ingredients for which the participant is responsible. | Additional | | |
| | No requirement | 4,3 | The participant shall determine the following:<br>a. The part of the chain for which the participant is responsible. This begins where the responsibility for the previous link (the supplier) ends and ends where the responsibility for the following link in the feed chain begins.<br>b. All feed ingredients (in specifications) which are produced.<br>c. All activities related to the production of the | Additional | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | feed ingredients, including activities which are outsourced.<br>d. All relevant locations whether these are the property of the company or not, including locations where relevant administrative activities are carried out.<br>If a participant decides to outsource an activity which may have an influence on feed safety then the participant must ensure that this activity is also carried out in accordance with the requirements of this GMP+ standard and is also certified as such. See GMP+ BA10 Minimum Requirements for Purchasing.<br>The participant must also describe all other activities and/or products which are not feed related. The participant must ensure that these activities do not have a negative influence on the safety of the feed ingredients. | | | |

## 3.2. Subpart B—Good Manufacturing Practice

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.17 Plant and grounds** | | | | | |
| *(a)* | *The grounds around an animal food plant under the control of the management of the establishment must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:* | *5.2.1* | *The production of feed ingredients must be carried out in an environment where it is not possible for the presence of potentially hazardous substances to lead to an unacceptable level of those substances in feed ingredients.*<br>*If an environment presents a risk to feed safety then the participant must show by way of a hazard analysis that the risks are controlled.* | *Partially Comply* | *Generic requirements in GMP B2* | |
| *(1)* | *Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;* | | | | | |
| *(2)* | *Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;* | | | | | |
| *(3)* | *Adequately draining areas that may contribute to contamination of animal food; and* | *5.2.2.1* | *Drainage facilities are suitable for the intended purpose. They must be designed and constructed in such a way that any risk of* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *contamination of the feed ingredients is prevented.* | | | |
| *(4)* | *Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.* | *5.2.2.2* | *Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. Spilled feed and dust must be controlled to prevent pest.* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(b)* | The plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials, including that the plant must: | 5.2.2.1 | *Facilities and equipment must be designed, constructed, maintained and managed to ensure that the safety of raw materials and feed ingredients is protected at all times.*<br>*Consideration must be given to preventing both the malicious and accidental contamination of feed ingredients.*<br>*Facilities must be designed and constructed such that, where necessary:*<br>*a. accumulation of dirt is prevented;*<br>*b. condensation and undesired mould is prevented as much as possible;*<br>*c. falling particles and feed remainder are limited;*<br>*d. cleaning, disinfection and maintenance can be carried out properly;*<br>*e. that birds and other animals* | Partially Comply | Generic requirements in GMP B2 | |
| *(1)* | *Provide adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;* | | | | | |
| *(2)* | *Be constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *have the least possible chance of getting in.* | | | |
| *(3)* | *Provide adequate ventilation (mechanical or natural) where necessary and appropriate to minimize vapors (e.g., steam) and fumes in areas where they may contaminate animal food and in a manner that minimizes the potential for contaminating animal food;* | *5.2.2.1 (b)* | Facilities must be designed and constructed such that, where necessary:<br>b. condensation and undesired mould is prevented as much as possible;<br>b. condensation and undesired mould is prevented as much as possible; | *Yes* | | |
| *(4)* | *Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured,processed, packed, or held, and areas where equipment or utensils are cleaned; and* | *5.2.2.1* | The facilities must be provided with proper natural and/or artificial lighting to ensure that cleaning, processing and other activities important to raw material and feed ingredient safety can be undertaken effectively. | *Partially Comply* | GMP+ specified areas which must be provided with adequate ligthing | |
| *(5)* | *Provide shatter-resistant light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against the contamination of animal food in case of glass breakage.* | *5.3.6* | The participant must ensure that glass and breakable materials do not form any hazard to the feed ingredients. All reasonable efforts must be made to minimize the risk of | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | glass breakage and to ensure that no contamination of feed ingredients can take place in the event of glass breakage. | | | |
| *(c)* | The plant must protect animal food stored outdoors in bulk from contamination by any effective means, including: | 7.3.1, 5.3.4 | The participant must control all storage activities with his own feed safety manage-ment system, in accordance with the requirements of this standard. This applies to storage a. at both own and hired sites, and b. both packaged and unpackaged feed ingredients or raw materials | Partially Comply | No specific requirement. However based on the guidance under clause 7.3.1 It required the facilities to store raw material and Feed ingredients in such a manner to prevent cross contamination. | |
| (1) | *Using protective coverings where necessary and appropriate;* | | | | | |
| *(2)* | *Controlling areas over and around the bulk animal food to eliminate harborages for pests; and* | | | | | |
| *(3)* | *Checking on a regular basis for pests, pest infestation, and product condition related to safety of the animal food.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | 5.2.2.1 | The facilities must be such that:<br>a. the chance of errors is limited as much as possible and contamination, cross-contamination, carry-over and any other negative influence on the safety of feed ingredients is prevented as much as possible.<br>c. That a strict and complete physical and organizational separation is imposed between the feed and products that may have an adverse effect on animal health, human health or the environment.<br>This separation is intended with respect to feed safety to prevent feed ingredients coming into contact or being mixed with other product | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | 5.2.2.1 | Ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of moulds and the shedding of particles that may adversely affect the safety of raw materials or feed ingredients. | Additional | | |
| | **§ 507.19 Sanitation** | | | | | |
| *(a)* | Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming adulterated. | 5.3.3 | A participant must ensure that at all relevant stages of the production, storage or handling of raw materials and feed ingredients, standards of cleanliness are operated such that exposure to pests and pathogens is minimised. | Yes | | |
| *(b)* | Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. | 5.3.3 | A cleaning programme must be documented and ensure that feed ingredient production, storage and transport facilities are cleaned to maintain feed ingredient safety at all times. | Partially to yes | GMP+ specified areas which must be provided with adequate ligthing | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | When necessary, equipment must be disassembled for thorough cleaning. In addition: | | | | | |
| *(1)* | *When animal food-contact surfaces used for manufacturing, processing, packing, or holding animal food are wet-cleaned, the surfaces must, when necessary, be thoroughly dried before subsequent use; and* | *5.3.3* | Machines or components which come into contact with dry feeds must be dried after wet cleaning or must be dry before they are used again. | Yes | | |
| *(2)* | *In wet processing of animal food, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.* | *5.3.3* | GMP+ art 5.3.3. (general requirement concerning cleaning and sanitation): A cleaning program must be documented and ensure that feed ingredient production, storage and transport facilities are cleaned to maintain feed ingredient safety at all times.<br>(note: no differences between wet or dry processing feed) | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(c)* | Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use. | 5.3.3 Guidance note | No specific requirement but provided in guidance: Only food-/feed compatible cleaning and disinfectant / sanitizing agents may be allowed to come into contact with feed ingredients and should be used in accordance with manufacturers recommendations and safety data sheet requirements. Where cleaning agents and disinfectants / sanitizers come into contact with feed ingredients, the participant should ensure that control systems provide the correct and effective dilution levels at all times. The participant can make use of the information in the user instructions for the cleaning agent or disinfectant used. | Yes | | |
| (d) | The following applies to toxic materials: | | | | | |
| *(1)* | *Only the following toxic materials may be used or stored in the plant area where animal food is manufactured, processed, or exposed:* | *5.3.3* | Cleaning and disinfection / sanitizing chemicals must be stored, if required by legislation, | Partially Comply | No requirement for lab testing chemicals | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (i) | *Those required to maintain clean and sanitary conditions;* | | separately in clearly identified containers to avoid the risk of (malicious or accidental) contamination. | | | |
| (ii) | *Those necessary for use in laboratory testing procedures;* | | | | | |
| (iii) | *Those necessary for plant and equipment maintenance and operation; and* | | | | | |
| (iv) | *Those necessary for use in the plant's operations.* | | | | | |
| *(2)* | *Toxic materials described in paragraph (d)(1) of this section (e.g., cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials; and* | *5.3.3* | *Cleaning and disinfection / sanitizing chemicals must be stored, if required by legislation, separately in clearly identified containers to avoid the risk of (malicious or accidental) contamination.* | Yes | | |
| *(3)* | *Other toxic materials (such as fertilizers and pesticides not included in paragraph (d)(1) of this section) must be stored in an area of the plant where animal food is not manufactured, processed, or exposed.* | *5.2.2.3* | *Facilities for storage of feed ingredients and potentially hazardous products (e.g. cleaning materials, lubricants, fuels, etc.) must be provided.* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(e)* | Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of pesticides in the plant is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. | 5.3.4 | Everything which is reasonably possible must be done to keep birds, pets and pest away from the production areas and to prevent their presence. The participant must take measures to counter pest and set up, implement and document a pest control program.<br>Personnel must be appropriately qualified and trained to carry out any control treatment required.<br>Activities within the framework of pest control must be planned, carried out and recorded.<br>Records of the control activities must show that there is compliance with the requirements. | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (f) | Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash to become an attractant and harborage or breeding place for pests. | 5.3.5 | All materials which are considered to be waste must be visually designated as such and protected in such way that the chance of errors or unintended use is eliminated.<br>The waste must be collected and stored in separate bins or containers. These must be easily identifiable and must be covered to prevent pest. | Yes | | |
| | **§ 507.20 Water supply and plumbing** | | | | | |
| (a) | The following apply to the water supply: | | | | | |
| (1) | *Water must be adequate for the operations and must be derived from an adequate source;* | *5.2.4.3* | The participant must be sure that the water or the steam which is used during the cleaning or in the production of the feed ingredients is safe for animals. The participant must ensure that the feed ingredients are not contaminated by the use of water of poor quality. | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (2) | *Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities;* | *NA* | *No specific requirement* | *No* | | |
| (3) | *Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use; and* | *5.2.4.3* | *The participant must be sure that the water or the steam which is used during the cleaning or in the production of the feed ingredients is safe for animals. The participant must ensure that the feed ingredients are not contaminated by the use of water of poor quality* | *Yes* | | |
| (4) | *Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.* | *5.2.4.3* | The participant must be sure that the water or the steam which is used during the cleaning or in the production of the feed ingredients is safe for animals. The participant must ensure that the feed ingredients are not contaminated by the use of water of poor quality. | *Yes* | Not specifically outlined but would fall under this clause | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (b) | Plumbing must be designed, installed, and maintained to: | *NA* | No specific requirement | *No* | | |
| (1) | *Carry adequate quantities of water to required locations throughout the plant;* | *NA* | No specific requirement | *No* | | |
| (2) | *Properly convey sewage and liquid disposable waste from the plant;* | *5.2.2.1* | Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. | *Partially Comply* | Not specific to Plumbing design but implies | |
| (3) | *Avoid being a source of contamination to animal food, water supplies, equipment, or utensils, or creating an unsanitary condition;* | *5.2.2.1* | Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. | *Partially Comply* | Not specific to Plumbing design but implies | |
| (4) | *Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and* | *5.2.2.1* | Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. Drainage facilities are suitable for the intended purpose. They must be designed and constructed in such a way that any risk of contamination of the feed ingredients is prevented. | *Partially Comply* | Implies but not to the same extent. | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (5) | *Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.* | *5.2.2.2* | Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. Drainage facilities are suitable for the intended purpose. They must be designed and constructed in such a way that any risk of contamination of the feed ingredients is prevented. | *Partially Comply* | Implies but not to the same extent. | |
| (c) | *Sewage and liquid disposal waste must be disposed of through an adequate sewerage system or through other adequate means.* | *5.2.2.1* | Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feed ingredients in not influenced. Drainage facilities are suitable for the intended purpose. They must be designed and constructed in such a way that any risk of contamination of the feed ingredients is prevented. | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (d) | Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. | *NA* | *No specific requirement* | *No* | | |
| (e) | Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. | *NA* | *No specific requirement* | *No* | | |
| | **§ 507.22 Equipment and utensils** | | | | | |
| (a) | The following apply to plant equipment and utensils used in manufacturing, processing, packing, and holding animal food: | | | | | |
| (1) | *All plant equipment and utensils, including equipment and utensils that do not come in contact with animal food, must be designed and constructed of such material and workmanship to be adequately cleanable, and must be properly maintained;* | *5.2.2.4* | *All equipment used for producing or processing feed ingredients must be fit for the purpose for which it is used.*<br>*Equipment coming into contact with feed ingredients must be designed and constructed to ensure that, where necessary, it can be cleaned, disinfected and maintained to avoid the* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *contamination of the feed ingredients.* | | | |
| (2) | *Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants;* | *5.2.2.1* | *Facilities and equipment must be designed, constructed, maintained and managed to ensure that the safety of raw materials and feed ingredients is protected at all times. Consideration must be given to preventing both the malicious and accidental contamination of feed ingredients.* | *Yes* | | |
| (3) | *Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and adjacent spaces;* | *5.2.2.4* | All equipment used for producing or processing feed ingredients must be fit for the purpose for which it is used. Equipment coming into contact with feed ingredients must be designed and constructed to ensure that, where necessary, it can be cleaned, disinfected and maintained to avoid the contamination of the feed ingredients | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (4) | *Animal food-contact surfaces must be:* | | | | | |
| (i) | *Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds, cleaning procedures, and sanitizing agents;* | *5.2.2.4* | *All equipment used for producing or processing feed ingredients must be fit for the purpose for which it is used.*<br>*Equipment coming into contact with feed ingredients must be designed and constructed to ensure that, where necessary, it can be cleaned, disinfected and maintained to avoid the contamination of the feed ingredients* | Partially Comply | | |
| (ii) | *Made of nontoxic materials; and* | | | | FSMA is more prescriptive | |
| (iii) | *Maintained to protect animal food from being contaminated.* | | | | | |
| (b) | Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way to protect against the contamination of animal food. | 5.2.4.2 | *5.2.4.2 Air movement*<br>*In cases where air is used for conveying or cooling, the participant must evaluate the risk of this becoming a vehicle for pathogens and take any necessary precautions.* | *Partially Comply* | Not specific but implies | |
| (c) | Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device. | 5.3.2 | *Maintenance of measuring equipment*<br>*All inspection, measuring and test equipment used to confirm that feed ingredients meet specified* | *Partially Comply* | Not specific but implies | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *feed safety requirements must be calibrated at intervals not exceeding 12 months.* | | | |
| (d) | Instruments and controls used for measuring, regulating, or recording temperatures, pH, $a_w$, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses. | 5.3.2 | All inspection, measuring and test equipment used to confirm that feed ingredients meet specified feed safety requirements must be calibrated at intervals not exceeding 12 months.<br>Records of the results of calibration and verification must be maintained. | Yes | GMP+ specifies minimum calibration intervals. | |
| (e) | Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way to protect against the contamination of animal food. | 5.2.4.2 | In cases where air is used for conveying or cooling, the participant must evaluate the risk of this becoming a vehicle for pathogens and take any necessary precautions. | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | 5.2.2.4 | Where drying operations result in combustion gases coming into contact with raw materials or feed ingredients, a participant must be able to demonstrate that the levels of undesirable substances are not exceeded beyond the maximum levels prescribed for feed ingredients in the regulations of the country of production and the countries where the participant will place feed ingredients onto the market. | | | |
| | No requirement | 5.2.2.4 | Where mechanical drying is undertaken, procedures must ensure that any adverse effect on the feed ingredients being dried is minimized. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 5.2.2.4 | Magnets and / or metal detectors must be included in production systems where indicated as necessary by the risk assessment study.<br>Critical sieves, screens, filters, separators, magnets and metal detectors must be regularly checked to ensure that they are not damaged and that they continue to operate effectively. | Additional | | |
| | No requirement | 5.2.2.4 | All scales and metering devices which are used in the production of feed must be appropriate for the range of weights or volumes to be weighed or dosed, and their accuracy must be checked regularly. The dosage capacity must also be matched to the quantity of product to be disseminated. The following must be clearly stated and recorded with respect to the weighing equipment:<br>a. the minimum and maximum | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | weight permissible for the weighing equipment or dosage equipment;<br>b. the accuracy of the weighing or dosage equipment.<br>Security must be applied such that the participant is sure that the weighed and/or dosed quantity of component is actually put into the feed (batch) for which it is intended.<br>If the participant makes use during production of dosage silos when filling these silos a proper locking system must be used. | | | |
| | No requirement | 5.2.2.4 | Where screenings (materials separated from the primary production stream by sieves, screens, filters, separators, etc.) are reclaimed or reprocessed for inclusion in feed ingredients, the risk assessment study must consider the potential hazards resulting from such practices. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 5.3.1 | A (written) program of planned maintenance must be drawn up and implemented for all relevant areas and equipment so that safe and hygienic operations are ensured.<br>Records of the maintenance activities must show that there is compliance with the requirements.<br>The participant should record the maintenance which is carried out on all equipment which is critical for the processing of and/or operations with feed ingredients. | Additional | | |
| | **§ 507.25 Plant operations** | | | | | |
| (a) | Management of the establishment must ensure that: | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(1)* | *All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;* | *7.4.1* | *All activities must be carried out in conformity with this standard. Production must be planned, scheduled and controlled by a designated and competent person, to ensure compliance with documented feed ingredient specifications and documented parameters for critical processes. There must be suitable checks during the activities. All process controls relevant to the safety of the feed ingredients being produced must be demonstrably effective and managed in accordance with formal HACCP principles.*<br>*Procedures must include corrective actions to be taken in the event of critical process parameters being breached.* | Yes | | |
| (2) | *Animal food, including raw materials, other ingredients, or rework is accurately identified;* | *5.2.2.1 c* | *There can be no confusion among the various feed ingredients, the feed ingredients are properly identified and no* | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *incorrect use of the feed ingredients can take place.* | | | |
| *(3)* | *Animal food-packaging materials are safe and suitable;* | *5.2.4.5* | *The packaging of the feed ingredients must be suitable for the kind of feed and the chosen method of delivery or transport. The packaging must be designed for the protection of the feed ingredient during normal storage, treatment and delivery conditions.*<br>*Reusable packaging should be sturdy, easy to clean and, if necessary, should be able to be disinfected. The participant should establish a cleaning regime on the basis of a hazard analysis.*<br>*If applicable, special attention should be paid to the recovery from livestock farms of pallets and other reusable packaging material.* | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(4)* | *The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;* | *5.3.3* | Cleaning and disinfection programs must be monitored for their suitability and effectiveness. An authorized person must carry out inspections of cleaning and a record of all inspections must be kept. | *Yes* | | |
| *(5)* | *Adequate precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food-packaging materials;* | *7.4.1* | *As above* | *Yes* | | |
| *(6)* | *Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination;* | *5.3.3* | | *No* | *No specific requirement except that programs be monitored for suitability* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(7)* | *Animal food that has become adulterated is rejected, disposed of, or if appropriate, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and* | *7.4.2* | The participant must establish a documented procedure for dealing with raw materials and feed ingredients that do not comply with specifications. This procedure must include:<br>a. Identification of batches/lots affected.<br>b. Documentation for managing and recording non-conforming products.<br>c. Evaluation of the cause of the non-conformance.<br>d. Segregation of batches/lots affected.<br>e. Communication with relevant parties.<br>f. Preventive or corrective action to avoid repetition of the non-conformance.<br>Responsibility for review and disposal of non-conforming products must be defined. All incidences of non-conforming raw materials or feed ingredients | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | must be recorded and decisions regarding actions to be taken must only be made by authorized personnel.<br><br>Non-conforming feed ingredients must be dealt with in one of the following ways:<br>a. Sent to waste or used as biomass;<br>b. Reworked;<br>c. Accepted by concession (if agreed in writing by the client);<br>d. Downgraded (if meeting the specification of another feed ingredient).<br>Requirements for reprocessing non-conforming feed ingredients must be documented and any affected feed ingredients must be re-evaluated on completion to ensure that the batch / lot concerned subsequently meets specified requirements. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | The approval and use of reworks (e.g. from quality rejects, customer returns or spillage) must be considered within the HACCP Plan. Those that are not ap- proved must become waste and be disposed of accordingly. Feed ingredients that do not fully meet a customer specification must only be supplied if the customer is notified of the problem in writing and confirms in writing that he is prepared to accept them. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(8)* | *All animal food manufacturing, processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms to protect against the contamination of animal food.* | *7.4.1* | Where production processes contain an effective 'kill step' that is critical in maintaining the acceptable micro-organism count in feed ingredients, the participant must ensure that controls are in place to prevent feed ingredients becoming recontaminated with pathogens at subsequent process stages. The participant must pay particular attention to areas where condensation may occur or where material is allowed to bypass the kill step and rejoin the finished goods stream. | *Partially Comply* | | |
| (b) | Raw materials and other ingredients: | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(1)* | *Must be examined to ensure that they are suitable for manufacturing and processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:* | *7.2* | There must be a procedure for the acceptance of receiving of all products. This procedure must prescribe criteria for the proper acceptance of the products including criteria for the approval of transport.<br>Each incoming delivery must be verified on the basis of the specifications. During the entry check all incoming feed ingredients must be released before they can be stored and/or further processed.<br>For the requirements with respect to sampling see section 5.4. | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(i)* | *Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles holding raw materials and other ingredients must be examined upon receipt to determine whether contamination or deterioration of animal food has occurred;* | *7.2* | Note: If any kind of feed is received, the transport to the participant must be GMP+ certified. The participant must then include in his entry check as a minimum: a check on the correct GMP+ certification of the carrier, compliance with the requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes. The LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable. See also Annex 9 of GMP+ BA10 for additional transport regulations. | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (ii) | *Raw materials must be cleaned as necessary to minimize contamination; and* | *7.2* | "There must be a procedure for the acceptance of receiving of all products…". | Partially comply | | If necessary, a cleaning step has to be done |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(iii)* | *Raw materials and other ingredients, including rework, must be stored in containers designed and constructed in a way that protects against contamination and deterioration, and held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated;* | *7.3.1* | The participant must control all storage activities with his own feed safety management system, in accordance with the requirements of this standard. This applies to storage<br>a. at both own and hired sites, and<br>b. both packaged and unpackaged feed ingredients or raw materials<br>Control measures for the storage must be documented. Feed ingredients and raw materials must be transported (internally) and stored in such a way they are and remain easily identifiable. This is to avoid confusion, (cross-) contamination and degradation of the quality.<br>All products produced or stored in the same premises by the participant but not intended for feed use must be clearly | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | segregated from feed ingredients and identified as such during all stages of production, packing, storage, dispatch and supply, unless the hazard analysis demonstrates that non-separated storage does not entail any risks to the feed ingredient.<br>Where applicable, temperatures must be kept as low as possible in order to prevent condensation and spoiling. The presence of (storage) fungus may be detected based on discoloration and a musty smell. The responsible person should examine the batch for the presence of storage fungi (by means of using his senses). | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | *7.3.1* | The participant may only use stock protection agents if: a. they are approved by the competent authorities, and b. they are in accordance with the user instructions, and c. they are applied by qualified persons, (persons who have permission to use the stock protection agent) . The responsible person must document which agent is used, when it is used and for which feed ingredients. It is then important that the prescribed waiting times are taken into consideration. | Additional | | |
| *(2)* | *Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans; and* | BA4 and Aflatoxin Protocol | See all details in BA4 and Aflatoxin Protocol | Yes | | |
| *(3)* | *If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a* | NA | No specific requirements | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *manner that minimizes the potential for the growth of undesirable microorganisms.* | | | | | |
| *(C)* | For the purposes of manufacturing, processing, packing, and holding operations, the following apply: | | | | | |
| *(1)* | *Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;* | *7.4.1* | All activities must be carried out in conformity with this standard. Production must be planned, scheduled and controlled by a designated and competent person, to ensure compliance with documented feed ingredient specifications and documented parameters for critical processes. There must be suitable checks during the activities. All process controls relevant to the safety of the feed ingredients being produced must be demonstrably effective and managed in accordance with formal HACCP principles. | Partially Comply | Clause 7.4 of GMP+ with generic requirements on production control | |
| *(2)* | *Measures taken during manufacturing, processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (e.g., heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling a $_w$) must be adequate to prevent adulteration of animal food;* | | | | | |
| *(3)* | *Work-in-process and rework must be handled in such a way that it is protected against contamination and the growth of undesirable microorganisms;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(4)* | *Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects against the contamination of animal food;* | | Procedures must include corrective actions to be taken in the event of critical process parameters being breached. | | | |
| *(5)* | *Filling, assembling, packaging, and other operations must be performed in such a way that protects against the contamination of animal food and the growth of undesirable microorganisms;* | | | | | |
| *(6)* | *Animal food that relies principally on the control of water activity ($a_w$) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe $a_w$ level;* | | | | | |
| *(7)* | *Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and* | | | | | |
| *(8)* | *When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 5.2.3 | Access arrangements must be established for the production areas. Anyone who is not an employee may only be given access to the production areas under the supervision of or with the permission of an authorized person. | Additional | | |
| | No requirement | 5.2.4.1 | Technical or organizational measures must be taken to prevent or minimize cross-contamination or errors, including contamination by means of carry-over | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 5.2.4.1 | Equipment and procedures must be designed and operated to ensure that cross- contamination between different types of feed (or other) materials is minimized. The processed feed ingredients must be kept separate from the untreated feed ingredients to prevent cross-contamination. The participant must determine based on a risk assessment whether the degree of carry-over for his equipment must be determined. A major item for attention in this is the risk that substances or products can get from one feed ingredient to another through carry-over and may lead to an unsafe feed ingredient. In any event the carry-over must be known for production and transport lines in an installation on which (feed with) feed additives are processed, | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | produced and/or transported, that may have an adverse effect on animal or human health (due to residue build-up).<br>The measurement frequency of carry-over in production and transport lines de- pends on the (feed with) feed additives which the participant processes and whether he processes feed ingredients for which a residue standard has been established. See GMP+ BA2 Control of Residues for this. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 5.2.4.1 | The participant must measure this carry-over by means of a testing procedure established by GMP+ International. See BA2 Control of Residues for this. The carry-over must be re-established in the above situations in the event of major changes to the installation. | Additional | | |
| | | 5.2.4.4 | The participant must ensure that the use of processing aids or (technological) additives does not adversely affect the feed safety. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | 5.2.4.4 | Where processing aids are used during production, a risk assessment must show that the unintentional but technological unavoidable presence of residues of the substance or its derivatives in the feed ingredient do not have any adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed.<br>A participant must ensure that control systems provide the correct and effective dosing levels for processing aids and technological additives at all times.<br>Dosing systems for processing aids and technological additives must be calibrated by a competent person and calibration records maintained. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 5.4.1 | Products (as defined in GMP+ A2 Definitions and Abbreviations) must be traceable at all stages of production, processing and distribution, in order to allow for immediate, targeted and accurate recall of these products if necessary, and/or to allow for adequate information to the users of these products. The participant must, for this purpose, set up and describe an internal traceability procedure.<br>The participant must take suitable measures to ensure that the products can be traced effectively during each of the stages referred to above for which the participant is responsible. He must maintain a register with the relevant details with respect to the purchase, production and sale which can be used to trace the products | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | from reception to delivery.<br>The participant must have the necessary information available within 4 hours unless the competent authorities have established a shorter time.<br>See D2.4 Guideline for Traceability for more information about setting up a internal traceability procedure. | | | |
| | No requirement | 5.4.1 | The participant must record at least the following details of all products and ser- vices:<br>a. name and address details of suppliers and customers;<br>b. date of delivery;<br>c. type of product or service;<br>d. product quantity;<br>e. batch number, where appropriate.<br>f. transport/ distribution details (if the participant is responsible for transport)<br>The participant should himself determine whether the | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | recording of other details is necessary. | | | |
| | **§ 507.27 Holding and distribution** | | | | | |
| *(a)* | *Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:* | 5 | *Transport may not lead to undesired contamination of the feed. To control the risks of contamination of feed ingredients during transport the participant must at least apply the relevant requirements and prescribed working methods specified in section Procedures GMP+ International published on the IDTF website.* | yes | | |
| *(1)* | *Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of animal food; and* | *5.2.4.5* | *The packaging of the feed ingredients must be suitable for the kind of feed and the chosen method of delivery or transport. The packaging must be designed for the protection of the feed ingredient during normal storage, treatment and delivery conditions.* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(2)* | *Animal food held for distribution must be held in a way that protects against contamination from sources such as trash.* | *7.3.1* | *Feed ingredients and raw materials must be transported (internally) and stored in such a way they are and remain easily identifiable. This is to avoid confusion, (cross-) contamination and degradation of the quality. All products produced or stored in the same premises by the participant but not intended for feed use must be clearly segregated from feed ingredients and identified as such during all stages of production, packing, storage, dispatch and supply, unless the hazard analysis demonstrates that non-separated storage does not entail any risks to the feed ingredient.* | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(b)* | The labeling for the animal food product ready for distribution must contain, when applicable, information and instructions for safely using the animal food product for the intended animal species. | *7.6* | *The participant must provide his customer with the necessary information with respect to the feed ingredients supplied so that his customer (the next link in the chain) can carry out his own proper hazard analysis.*<br>*See GMP+ BA6 Minimum requirements for labelling & delivery for additional label- ling requirements.* | *Yes* | | |
| | No requirement | *7.6* | *On delivery the batch must be accompanied by the legally-required product information. The documentation with respect to delivery must be clear.*<br>*The participant must ensure that the feed ingredients which are supplied by him comply with the applicable requirements for both the country in which it was produced or treated and, if applicable, the country in which it is placed on the market.* | *Additional* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(c)* | *Shipping containers (e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the animal food itself or arranges with a third party to transport the animal food. | *7.7.1* | *All means of transport (whether by ship, barge, road vehicle, rail, container or other transport system) whether owned or contracted by the participant to carry either raw materials or feed ingredients, whether in bulk or packed, must be appropriate and controlled with specific regard to hygiene and potential contamination. Cargoes being carried concurrently with raw materials and feed ingredients must not adversely affect the safety of the raw materials and feed ingredients.*<br>*Where transport is used to carry raw materials and feed ingredients, the individual load compartments used must be recorded. For road / rail vehicles this may be the trailer / car number or, where load compartments are split into sections, the individual section* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *must be recorded. For water transport, where load compartments are split into holds, the individual hold numbers must be recorded.*<br>*When the participant is responsible for arranging transport of feed ingredients to purchasers operating under a certified assurance program, he must ensure that the specific transport requirements of that program are met.*<br>*In any event the participant must provide the carrier with information with respect to the nature of the product and of the specific product characteristics including its (chemical) composition, to enable the carrier to determine a correct cleaning regime.*<br>*When the participant is not responsible for the transport and is instructed by a buyer to load a* | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *batch in a means of transport which does not comply with the requirements then the participant must consult with the buyer for further instructions before loading. The results of this consultation must be demonstrable* | | | |
| *(d)* | Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed. | *5,5* | *Recall procedures must include systems for: a. Identifying the non-conforming feed ingredient batch / lot, including conse-quences to other feed ingredients, batches / lots or raw materials. b. Ensuring that where recall of a non-feed product is required, recall of feed ingredients is also considered and, if necessary, implemented; c. Identifying the location of affected batches / lots. d. Management of returned feed ingredients, including segregation from other products.* | Partially Comply | This covers material returned under recall. It does not cover material returned for reasons other than recall. | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *e. Recording the destination of any recalled products.* | | | |
| *(e)* | Unpackaged or bulk animal food must be held in a manner that does not result in unsafe cross contamination with other animal food. | *7.3.1* | participant must control all storage activities with his own feed safety management system, in accordance with the requirements of this standard. This applies to storage<br>a. at both own and hired sites, and<br>b. both packaged and unpackaged feed ingredients or raw materials<br>Control measures for the storage must be documented. | Yes | | |
| | *No requirement* | *5.2.2.2* | Proper areas must be provided for reception, loading and unloading of feed ingredients and potentially hazardous products (such as cleaning agents, lubricants, fuels, etc.). | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | *5.2.2.2* | During reception or loading and unloading the participant must do everything which is reasonably possible to create such conditions that the risk of contamination is avoided and that, for example, bad weather cannot have an influence on the feed ingredients to be loaded. | Additional | | |
| | *No requirement* | *7.5* | Feed ingredient specifications must be agreed between the participant and the purchaser and confirmed in the contract. The participant must ensure that all feed ingredients supplied meet the agreed specifications. The sale of feed ingredients must be clearly recorded. | Additional | | |
| | *No requirement* | *7.7.2.1* | The road transport of feed ingredients must meet the requirements in the GMP+ B4 Transport and be certified as such. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | *7.7.3* | Road transport is carried out by a GMP+ B4 Transport certified transporter, or by a transporter with an equivalent certificate. See for this GMP+ BA10 Minimum Requirements for Purchasing.<br>For some countries it is also possible to make use of non-certified carriers. In this case, the participant must apply the conditions from GMP+ BA10 Minimum Requirements for Purchasing, Annex 9. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | *7.7.3* | Transport of packaged raw materials or feed ingredients<br>If a participant makes use of an external carrier for the transport of packaged raw materials or feed ingredients then this external carrier and / or fright broker does not have to be GMP+ certified or equivalent. Risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination. Transport of packaged raw materials or feed ingredients must take place in a clean and dry loading compartment.<br>Sealed loading units<br>Under certain conditions sealed loading units are considered to be packaged products and therefore non-certified external carriers can be used. This is al-lowed when non-certified | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | external carrier has no influence on the transported raw materials or feed ingredients. The carrier just positions this sealed loading unit on a chassis and brings it to the customer. Additionally to the above requirements this means practically that:<br>a) Management of cleaning and inspection of the loading unit is the responsibility of participant.<br>b) The loading unit must be closed and sealed on the responsibility of the participant immediately after loading. The seal may only be broken at the customer.<br>c) The carrier may not use own loading / unloading equipment (pipes, hoses etc.) unless the participant has agreed this with the customer. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No requirement* | *7.7.4* | Where a third party is responsible for the transport, the participant must take reasonable precautions to avoid potential hazards.<br>Where feed ingredients are to be loaded into transport contracted by the purchaser of the feed ingredients, the participant must ensure that any transport offered is suitable to receive the feed ingredients supplied and cleaned. | Additional | | |
| | *No requirement* | *7.7.5a* | inland waterway transport to GMP+ B1-certified companies<br>If the affreightment of inland waterways transport takes place on the responsibility of the participant, he must be GMP+ B4 certified. If a third party is responsible, then this third party must be GMP+ B4 certified.<br>For the activities below no certification for GMP+ B4 is required, but the participant | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | must demonstrably comply with corresponding sections of GMP+ B4. The participant must guarantee these activities in the feed safety system. | | | |
| | | | Giving the order for affreightment:<br>Approval of the ship before loading:<br>Giving the order for LCI:<br>demonstrable compliance with GMP+ B4 section 7.2.1 and 7.2.2 and guaran- teed activity in the feed safety management system.<br>demonstrable compliance with GMP+ B4 section 7.2.1 and 7.2.2 and guaran- teed activity in the feed safety management system.<br>demonstrable compliance with GMP+ B4 section 7.2.3 to 7.2.5 and guaran- teed activity in the feed safety management system. | | | |
| | | | The carriage (= the actual transportation by inland | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | waterway vessel) must be GMP+ B4.3 Inland Waterway Transport certified. | | | |
| | *No requirement* | *7.7.5b* | Transport by sea or by rail should comply with the requirements of GMP+ B4 Transport (Road & rail transport and affreightment) The principal for the sea transport or rail transport should be certified as such. | Additional | | |
| | *No requirement* | *7.7.5c* | In the event of transport via inland waterway, sea transport and transport per rail, an inspection should take place to check the cleanliness of the loading compartments (LCI = Loading Compartment Inspection) before loading is started. The loading process should also be controlled to be able to guarantee feed safety. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | The participant who himself acts as the affreightment party cannot carry out an LCI.<br>The inspection must be carried out by an inspection agency at EN 17020 level which is specialized in, and is accredited for, feed / grains or liquid agri-bulk and operates internationally on the basis of a certified quality system such as ISO 9001 or equivalent<br>If the participant does not act as the affreightment party, he can carry out the inspection by himself. This can be done by a loading inspector from the company. The 'load inspector' is a function specified in the quality system of the company and must be performed by an employee who - on the basis of training and experience - has the knowledge and skill to assess loading compartments on their | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | suitability for use with feed ingredients.<br>In the event of the transport of GMP+-assured feed ingredients and non-GMP+- assured feed ingredients there must be a strict physical separation of these feed ingredients. | | | |
| | **§ 507.28 Holding and distribution of human food by-products for use as animal food** | | **Additional information:** | | | |
| | | | In GMP+: "by-products from the food industry" are considered as regular feed materials. Example: Wheat middlings generated while processing wheat for flour. The same requirements apply to this type of products. GMP + does not have specific requirements for these types of products<br><br>Another group is "former food stuffs": these products are produced with the intention to be consumed by the human. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | Exemple: cookies (BA10 - annex 6 can be used) | | | |
| *(a)* | Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: | NA | No specific requirements | No | | |
| *(1)* | *Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;* | BA10 Annex 6 | no specific requirements | No | | |
| *(2)* | *Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and* | BA10 Annex 6 | No specific requirements | No | | |
| *(3)* | *During holding, human food by-products for use as animal food must be accurately identified.* | BA10 Annex 6 | No specific requirements | No | | |
| *(b)* | Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. | BA10 Annex 6 | No specific requirements | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(c)* | Shipping containers (*e.g.,* totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food. | BA10 Annex 6 | No specific requirements | No | | |

## 3.3. Subpart C—Hazard Analysis and Risk-Based Preventive Controls

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.31 Food safety plan** | | | | | |
| (a) | You must prepare, or have prepared, and implement a written food safety plan. | 6.1 | The participant must ensure the introduction, implementation and maintenance of one or more written procedures which are based on the HACCP principles | Partially Comply | Risk based VS HACCP based | |
| (b) | One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan. | 4.2 | In order to establish a risk assessment system, the participant must appoint an HACCP Team to produce an effective HACCP Plan.<br>The HACCP Team must include personnel from all of the relevant operations and functions within the company and at least one member with demonstrably HACCP- knowledge and/or HACCP-experience. | Partially Comply | Risk based VS HACCP based | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | 4.2 | The HACCP Team must carry out a hazard analysis with the object of identifying and controlling risks which could have a negative effect on feed safety. See for this Chapter 6.<br>The HACCP Team must have expertise in various disciplines or must be able to make use of expertise for the carrying out of the hazards analysis and the drawing up and maintenance of the required feed safety system.<br>The members of the HACCP Team must be recorded within the HACCP documentation.<br>It is acceptable for individual personnel to fulfil multiple roles in the HACCP Team or for the participant to utilize resources from outside of the company, provided that the role of the team remains effective. | Partially Comply | Risk based VS HACCP based, GMP+ does not define PCQI (preventive controls qualified individuals) | Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system; GMP+ require at least at least one member with demonstrably HACCP- |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | | | | knowledge and/or HACCP-experience, which could be equivalent to PCQI if the person training recognized as adequate by FDA |
| (c) | The written food safety plan must include: | 6,1 | The participant must ensure the introduction, implementation and maintenance of one or more written procedures which are based on the HACCP principles | Partially Comply | See details under 507.33 and 507.34 | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (1) | *The written hazard analysis as required by § 507.33(a)(2);* | *a* | Conduct a hazard analysis | | | |
| (2) | *The written preventive controls as required by § 507.34(b);* | *b* | Determine Critical Control Points(CCP's) | | | |
| (3) | *The written supply-chain program as required by subpart E of this part;* | | | Partially Comply | See details under subpart E | |
| (4) | *The written recall plan as required by § 507.38(a)(1);* | *Section 5.5 and BA5* | | Yes | | |
| (5) | *The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);* | *d* | Set up and implement a monitoring plan for CCP's | Partially Comply | See details under 507.4 | |
| (6) | *The written corrective action procedures as required by § 507.42(a)(1); and* | *e* | Define corrective actions | | | |
| (7) | *The written verification procedures as required by § 507.49(b).* | *f* | Validate and verify the HACCP plan | | | |
| (d) | The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part. | | | | | |
| | **§ 507.33 Hazard analysis** | | - | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (a)(1) | You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and | 6.3.1 | The HACCP Team must identify and record systematically all potential hazards which may have a negative effect on feed safety. | Partially Comply | | The HACCP Manual GMP+ D2.1 does include more details to establish food safety plan, hazard identification and evaluation on severity and likelihood, etc. |
| (2) | *The hazard analysis must be written regardless of its outcome.* | *6.1 a* | Conduct a hazard analysis | Partially Comply | FSMA is more prescriptive | |
| (b) | The hazard identification must consider: | NA | No specific requirement | No | | |
| (1) | *Known or reasonably foreseeable hazards that include:* | NA | *No specific requirement;*<br>*In 6.3.1 of GMP + , there is requirement " The hazard identification is based on: g. the generic risk assessment from the Feed Support Products (if applicable)" specific hazard for the feed ingredients could be available in Feed Support Products.* | No | FSMA does not require use of the generic risk assessment in FSP(Food Safety Plan). Other documents may be used to determine risk. | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (i) | *Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;* | NA | *No specific requirement;*<br>*In 6.3.1 of GMP + , there is requirement " The hazard identification is based on: g. the generic risk assessment from the Feed Support Products (if applicable)" specific hazard for the feed ingredients could be available in Feed Support Products.* | No | FSMA does not require use of the generic risk assessment in FSP(Food Safety Plan). Other documents may be used to determine risk. | |
| (ii) | *Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and* | NA | *No specific requirement;*<br>*In 6.3.1 of GMP + , there is requirement " The hazard identification is based on: g. the generic risk assessment from the Feed Support Products (if applicable)" specific hazard for the feed ingredients could be available in Feed Support Products.* | No | FSMA does not require use of the generic risk assessment in FSP(Food Safety Plan). Other documents may be used to determine risk. | |
| (iii) | *Physical hazards (such as stones, glass, and metal fragments); and* | *NA* | *No specific requirement;*<br>*In 6.3.1 of GMP + , there is requirement " The hazard identification is based on: g. the generic risk assessment from the Feed Support Products (if* | No | FSMA does not require use of the generic risk assessment in FSP(Food Safety Plan). | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *applicable)" specific hazard for the feed ingredients could be available in Feed Support Products.* | | Other documents may be used to determine risk. | |
| (2) | Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons: | *NA* | No specific requirement | No | | |
| (i) | *The hazard occurs naturally;* | *NA* | No specific requirement | No | | |
| (ii) | *The hazard may be unintentionally introduced; or* | *NA* | No specific requirement | No | | |
| (iii) | *The hazard may be intentionally introduced for purposes of economic gain.* | *NA* | No specific requirement | No | | GMP+ has a document with information about fraude (see GMP+ D1.3) |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (c)(1) | The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. | 6.3.2 | The HACCP Team carries out a risk assessment for each identified hazard. This is also done systematically, and with the purpose to establish whether a hazard is of such a nature that elimination or reduction to an acceptable level is essential for the production of safe feed ingredients. | Partially Comply | | The HACCP Manual GMP+ D2.1 does include more details to establish food safety plan, hazard identification and evaluation on severity and likelihood, etc. |
| (2) | *The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.* | NA | No specific requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (d) | The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal: | 6.3.1 | The hazard identification is based on: | Yes | | |
| (1) | *The formulation of the animal food;* | *6.3.1 b & 6.2.2* | the specification of the feed ingredient; | Yes | | |
| (2) | *The condition, function, and design of the facility and equipment;* | *C, e* | the business layout and resources used; the lay-out drawn up; | Yes | | |
| (3) | *Raw materials and other ingredients;* | *a* | raw materials and auxiliary substances | Yes | | |
| (4) | *Transportation practices;* | *6.3.1 b & 6.2.2* | the specification of the feed ingredient; | Yes | | |
| (5) | *Manufacturing/processing procedures;* | *6.2.3* | the process diagram drawn up | Yes | | |
| (6) | *Packaging activities and labeling activities;* | *6.3.1 b & 6.2.2 & 7.6 &BA6* | the specification of the feed ingredient; labelling | Yes | | |
| (7) | *Storage and distribution;* | *6.3.1 b & 6.2.2, 5.2.2.3.* | Facilities for storage of feed ingredients and potentially hazardous products (e.g. cleaning materials, lubricants, fuels, etc.) must be provided. | Yes | | |
| (8) | *Intended or reasonably foreseeable use;* | *6.3.1 b & 6.2.2* | the specification of the feed ingredient; | Yes | | |
| (9) | *Sanitation, including employee hygiene; and* | *NA* | No specific requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (10) | *Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).* | *Na* | No specific requirement | No | | |
| | *No requirement* | *f* | experience, expertise, research and other sources of information (internal/external); | Additional | | |
| | *No requirement* | *g* | the generic risk assessment from the Feed Support Products (if applicable). | Additional | | |
| | *No requirement* | *6.3.1* | For each hazard the HACCP Team also records an acceptable level of presence in the feed whereby there is at least compliance with the statutory norms and those laid down in the GMP+ FSA module. See GMP+ BA1 Specific feed safety limits. | Additional | | |
| | **§ 507.34 Preventive controls** | | - | | | |
| (a)(1) | You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated | *6.4.1* | The HACCP Team must establish, record and implement the measures to control any risk for which it has been established (based on the hazards analysis) that this risk may have a negative effect on feed safety. More than | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | under section 402 of the Federal Food, Drug, and Cosmetic Act; and | | one control measure may be necessary to control a risk and more than one risk may be controlled by a single control measure. | | | |
| (2) | *Preventive controls required by paragraph (a)(1) of this section include:* | | | | | |
| *(i)* | *Controls at critical control points (CCPs), if there are any CCPs; and* | *6.4.2* | The HACCP Team must then determine whether this control measure is the last measure in the process for controlling the risk. If this is the case then there is a critical control point (CCP). The reasons for why there is a critical control point (CCP) must be recorded. | Yes | | |
| *(ii)* | *Controls, other than those at CCPs, that are also appropriate for animal food safety.* | *NA* | *No specific requirement* | No | | |
| (b) | Preventive controls must be written. | 6.1 b | Determine Critical Control Points(CCP's) | Partially Comply | | |
| (c) | Preventive controls include, as appropriate to the facility and animal food: | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(1)* | *Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:* | *6,6* | *A monitoring plan must be drawn up in writing and implemented which includes in particular the control of critical points in the production process. The plan includes all planned measurements, analyses and observations of features which indicate that the critical control points are controlled and applies to processed materials up to and including the produced feed (end products).The monitoring plan must at least be in accordance with the inspections established in this GMP+ FSA module (GMP+ BA4 Minimum Requirements for Sampling and Analysis). The participant must provide the reasoning for the structure of the monitoring plan.* | Yes | *GMP + covers all the CCPs identified and monitoring must be in accordance with the inspection in GMP+ FSA Module; whereas FSMA is specific to process preventive control* | |
| *(i)* | *Parameters associated with the control of the hazard; and* | *6,5* | In order to establish whether a specific control measure is | Yes | *GMP + covers all the CCPs identified ;* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(ii)* | *The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.* | | effective, the HACCP Team must establish for each Critical Control Point (CCP)<br>a. which parameters must be measured, analyzed or observed, and<br>b. which product standards (action and rejection limits) apply for these parameters. | | *whereas FSMA is specific to process preventive control* | |
| | *No requirement in the preventive control section of FSMA* | *6,5* | In establishing the product standards (action and rejection limits) there must be compliance with the relevant feed legislation and the product standards established under this GMP+ FSA module. These product standards must be considered to be (contractual) obligations. | Additional | | |
| *(2)* | Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the | 5.3.3 | A participant must ensure that at all relevant stages of the production, storage or handling of raw materials and feed ingredients, standards of cleanliness are operated such that exposure to pests and pathogens is minimised. | Partially Comply | FSMA is more prescriptive ,GMP + is more general with the same intent. | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | animal food, procedures, practices, and processes for the: | | A cleaning programme must be documented and ensure that feed ingredient pro-duction, storage and transport facilities are cleaned to maintain feed ingredient safety at all times. | | | |
| *(i)* | *Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and* | | | | | |
| *(ii)* | *Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product.* | | | | | |
| *(3)* | *Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart E of this part;* | *7.1.1 - 7.1.2, BA10* | *Purchase* | *Partially Comply* | For GMP+, purchase requirements are under 7.1.1 to 7.1.3; unless hazard analysis identified purchase is used to minimize or eliminate significant hazards and manage as CCP. Other | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | | | requirements are under BA10 see more details in Subpart E supply chain program | |
| (4) | *A recall plan as required by § 507.38; and* | *5.5, BA5* | Refer to Recall Plan | Partially Comply | Recall plan in FSMA only required if risk analysis requires a preventative control. See more details in 507.38 | |
| *(5)* | *Other preventive controls. These include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.* | | | | | |
| | **§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control** | | - | | | |
| *(a)* | If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply: | NA | No requirement | No | | |
| *(1)* | *You determine and document that the type of animal food could not be consumed without application of an appropriate control;* | NA | No requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(2)* | *You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to ensure that the identified hazard will be significantly minimized or prevented; and you:* | NA | No requirement | No | | |
| *(i)* | *Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is "not processed to control [identified hazard]"; and* | NA | No requirement | No | | |
| *(ii)* | *Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard (except as provided in paragraph (c) of this section);* | NA | No requirement | No | | |
| *(3)* | *You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:* | NA | No requirement | No | | |
| *(i)* | *Disclose in documents accompanying the animal food, in accordance with the practice of the* | NA | No requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *trade, that the animal food is "not processed to control [identified hazard]"; and* | | | | | |
| *(ii)* | *Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements;* | NA | No requirement | No | | |
| *(4)* | *You rely on your customer to provide assurance that the animal food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:* | NA | No requirement | No | | |
| *(i)* | *Disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is "not processed to control [identified hazard]"; and* | NA | No requirement | No | | |
| *(ii)* | *Annually obtain from your customer written assurance, subject to the requirements of § 507.37, that your customer:* | NA | No requirement | No | | |
| *(A)* | *Will disclose in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is "not processed to control [identified hazard]"; and* | NA | No requirement | No | | |
| (B) | *Will only sell to another entity that agrees, in writing, it will:* | NA | No requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(1)* | *Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part), except as provided in paragraph (d) of this section, or manufacture, process, or prepare the animal food in accordance with applicable animal food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of this part); or* | NA | No requirement | No | | |
| *(2)* | *Obtain a similar written assurance from the entity's customer, subject to the requirements of § 507.37, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or* | NA | No requirement | No | | |
| *(5)* | *You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food product you distribute and you document the implementation of that system.* | NA | No requirement | No | | |
| *(b)* | You must document any circumstance specified in paragraph (a) of this section that applies to you, including: | NA | No requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(1)* | *A determination in accordance with paragraph (a) of this section that the type of animal food could not be consumed without application of an appropriate control;* | NA | No requirement | No | | |
| *(2)* | *The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;* | NA | No requirement | No | | |
| *(3)* | *The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;* | NA | No requirement | No | | |
| *(4)* | *The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and* | NA | No requirement | No | | |
| *(5)* | *Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the animal food product you distribute.* | NA | No requirement | No | | |
| *(c)* | For the written assurance required by paragraph (a)(2)(ii) of this section, if your customer has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, your customer's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing | NA | No requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | assurance of procedures established and followed that will significantly minimize or prevent the identified hazard. | | | | | |
| *(d)* | For the written assurance required by paragraph (a)(4)(ii)(B) of this section, if the entity in the distribution chain subsequent to your customer is subject to subpart C of this part and has determined that the identified hazard in paragraph (a) of this section is not a hazard in the animal food intended for use for a specific animal species, that entity's written assurance may provide this determination (including animal species and why the identified hazard is not a hazard) instead of providing assurance that the identified hazard will be significantly minimized or prevented. | NA | No requirement | No | | |
| | **§ 507.37 Provision of assurances required under § 507.36(a)(2), (3), and (4)** | | - | | | |
| | A facility that provides a written assurance under § 507.36(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance. | NA | No requirement | No | | |
| | **§ 507.38 Recall plan** | | - | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(a)* | For animal food with a hazard requiring a preventive control you must: | | in GMP+, recall/EWS is part of feed safety system, and not considered as preventive control | | | |
| *(1)* | *Establish a written recall plan for the animal food; and* | *5.5 and BA5* | The participant has a documented procedure for warning at an early stage and for handling these signals which warn that the safety of feed ingredients may not comply with the legal standards the standards set in the GMP+ FSA module or merchantable trading quality, and may lead to damage in subsequent links in the chain. The signals must be assessed on this basis. | *Yes* | | |
| *(2)* | *Assign responsibility for performing all procedures in the recall plan.* | *NA* | No requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(b)* | *The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:* | *5.5and BA5* | If a feed ingredient is found to not comply with:<br>a. legal requirements relating to safety, or<br>b. the usual merchantable quality, or<br>c. the essential requirements of the GMP+ FSA module,<br>then the participant shall undertake the following actions:<br>a. inform the customers:<br>- In case of exceeding the maximum permitted level(s) of undesirable substances in feed as mentioned in legislation or/and GMP+ BA1 Specific feed safety limits, the customers must be informed within 12 hours after confirmation of the contamination.<br>- In case of all other perceived non-conformities and irregularities (others than complaints, see GMP+ BA5) not controlled by the participant, which could have consequences for the customers, the customers | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | must be informed, and<br>b. immediate suspension of the sale of the relevant feed, and<br>c. recall of the feed ingredient and ensuring that the feed ingredient does not enter the feed and cattle farm sector, | | | |
| *(1)* | *Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;* | *5,5* | As above | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(2)* | *Notify the public about any hazard presented by the animal food when appropriate to protect human and animal health;* | *B2-7.4.2 BA5* | BA5: involved company has to inform their clients, GMP+, certification bodies in case of contaminated products and B2-7.4.2: Non-conforming feed a. Identification of batches / lots affected. b. Documentation for managing and recording non-conforming products. c. Evaluation of the cause of the non-conformance. d. Segregation of batches / lots affected. e. Communication with relevant parties. f. Preventive or corrective action to avoid repetition of the non-conformance. | *Yes* | | |
| *(3)* | *Conduct effectiveness checks to verify the recall has been carried out; and* | *5.5and BA5* | The participant must prepare a recall procedure for the above actions. After deter- mining the recall procedure, a recall simulation must be carried out within three months. Subsequently, the recall simulation must be repeated | *Yes* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | annually. The experiences of these recall simulations must be recorded. | | | |
| *(4)* | *Appropriately dispose of recalled animal food, e.g., through reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying the animal food.* | *7.4.2* | Non-conforming feed ingredients must be dealt with in one of the following ways:<br>a. Sent to waste or used as biomass;<br>b. Reworked;<br>c. Accepted by concession (if agreed in writing by the client);<br>d. Downgraded (if meeting the specification of another feed ingredient). | *Yes* | | |
| | *No requirement* | *5.5 and BA5* | unless the participant can demonstrate that the non-conformity does not have any harmful consequences to animal and human health and that the product is still in compliance with legal requirements.<br>The participant needs to notify GMP+ International and the Certification Body in accordance | *Additional* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | with GMP+ BA5 Minimum Requirements EWS. If it is a legal obligation, the participant also needs to notify the non-conformity to the competent authority in the country or region of residence. | | | |
| | **§ 507.39 Preventive control management components** | | - | | | |
| *(a)* | Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.34 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system: | | | | | |
| (1) | *Monitoring in accordance with § 507.40;* | *6,6* | Monitoring- refer to § 507.40 | | Monitoring- refer to § 507.40 | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (2) | *Corrective actions and corrections in accordance with § 507.42; and* | *6,7* | Corrective action, refer to § 507.42 | | Corrective action, refer to § 507.42 | |
| (3) | *Verification in accordance with § 507.45.* | *6.8.2* | Verification, refer to § 507.45. | | Verification, refer to § 507.45. | |
| *(b)* | The supply-chain program established in subpart E of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient: | 7.1.1 - 7.1.2 | Refer to Supply Chain Program | | Refer to Supply Chain Program | |
| *(1)* | *Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;* | 6,7 | Corrective action, refer to § 507.42 | | Corrective action, refer to § 507.42 | |
| (2) | *Review of records in accordance with § 507.49(a)(4)(ii); and* | *Various clauses* | Refer to 507.49(a)(4)(ii) | | Refer to 507.49(a)(4)(ii) | |
| (3) | *Reanalysis in accordance with § 507.50.* | | Refer to § 507.50 | | Refer to § 507.50 | |
| *(c)* | The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section. | 5.5 and BA5 | Under GMP+ Recall is part of the feed safety plan and required to be documented and tested. | yes | | |
| | **§ 507.40 Monitoring** | | - | | | |
| | As appropriate to the nature of the preventive control and its role in the facility's food safety system you must: | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(a)* | Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and | 6,6 | A monitoring plan must be drawn up in writing and implemented which includes in particular the control of critical points in the production process. | Yes | | |
| *(b)* | Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. | 6,6 | The plan includes all planned measurements, analyses and observations of features which indicate that the critical control points are controlled and applies to processed materials up to and including the produced feed (end products). | Yes | | |
| | No requirement | 6,6 | The monitoring plan must at least be in accordance with the inspections established in this GMP+ FSA module (GMP+ BA4 Minimum Requirements for Sampling and Analysis). The participant must provide the reasoning for the structure of the monitoring plan. | *Additional* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 6.6 See also B10 for lab require-ments | The monitoring plan includes:<br>a. the procedures for and the frequency of the sampling;<br>b. the (analysis) methods and equipment to be used. These methods must be suitable to achieve planned results;<br>c. the laboratories that are selected for the analysis concerned;<br>d. the frequencies of the analyses, checks and inspections;<br>e. the compliance with the specifications – and the use, in the event of non-compliance with the specifications;<br>f. all planned inspections and checks and analyses;<br>g. the instructions for the carrying out of inspections and checks;<br>h. the personnel responsible for the carrying out of the monitoring;<br>i. the personnel responsible for the assessment of the monitoring | *Additional* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | results;<br>j. the personnel responsible for releasing the feed ingredients. | | | |
| *(c)(1)* | You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i); | 6,6 | The results of the monitoring must be recorded. | *Partially comply* | See below 507.45 and 507.49 | |
| *(2)(i)* | *Records of refrigeration temperature during storage of animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control; and* | *7,3* | *The participant must control all storage activities with his own feed safety management system, in accordance with the requirements of this standard. This applies to storage*<br>*a. at both own and hired sites, and*<br>*b. both packaged and unpackaged feed ingredients or raw materials*<br>*Control measures for the storage must be documented.* | *Partially comply* | FSMA is more prescriptive ,GMP + is more general with the same intent. | |
| *(ii)* | *Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.* | *NA* | *No specific requirement* | *No* | GMP+ does not have this specific verbage | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.42 Corrective actions and corrections** | | - | | | |
| *(a)* | As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section: | | | | | |
| *(1)* | *You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:* | *6,7* | *The participant must ensure that non-conformities (in the feed ingredient or the process) to the requirements in this standard are recorded and controlled in order to prevent unintentional use or delivery of the product. The controls and associated responsibilities and competences for dealing with non-conformities must be defined in a documented procedure.* | *Yes* | | |
| *(i)* | *The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and* | *6,7* | *The above process of handling non-conformities applicable for all non-conformities in the feed ingredient or the process* | *Yes* | | |
| *(ii)* | *The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).* | *NA* | *No specific requirement* | *No* | *GMP+ does not include environmental pathogen or indicator organism monitoring* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(2)* | *The corrective action procedures must describe the steps to be taken to ensure that:* | | | | | |
| *(i)* | *Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;* | *6,7* | *The participant must deal with non-conforming feed ingredient in one or more of the following manners:*<br>*a. by taking measures to remove the observed non-conformities;*<br>*b. by permitting use, release or acceptance with the approval of a competent authority;*<br>*c. by taking measures to exclude the originally-intended use or application If products are no longer appropriate for feed they must be transported to a destination that is in accordance with the provisions in the applicable feed legislation.*<br>*Records of the nature of non-conformities and any measures taken later, including approvals obtained, must be maintained (see section 4.4).*<br>*If a non-conformity is corrected it must be verified again to show* | *Yes* | | |
| *(ii)* | *Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;* | | | | | |
| (iii) | *All affected animal food is evaluated for safety; and* | | | | | |
| *(iv)* | *All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *that it complies with the requirements.* | | | |
| *(b)(1)* | Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply: | Refer to paragraph (b) (2) of this section | | yes | Refer to paragraph (b) (2) of this section | |
| *(i)* | *A preventive control is not properly implemented and a corrective action procedure has not been established;* | | | | | |
| *(ii)* | *A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or* | | | | | |
| (iii) | *A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.* | | | | | |
| (2) | *If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:* | *6,7* | *The participant must deal with non-conforming feed ingredient in one or more of the following manners:* | *Yes* | | |
| (i) | *Take corrective action to identify and correct the problem;* | | *a. by taking measures to remove* | | | |
| (ii) | *Reduce the likelihood that the problem will recur;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (iii) | *Evaluate all affected animal food for safety;* | | *the observed non-conformities;*<br>*b. by permitting use, release or acceptance with the approval of a competent authority;*<br>*c. by taking measures to exclude the originally-intended use or application If products are no longer appropriate for feed they must be transported to a destination that is in accordance with the provisions in the applicable feed legislation.*<br>*Records of the nature of non-conformities and any measures taken later, including approvals obtained, must be maintained (see section 4.4).*<br>*If a non-conformity is corrected it must be verified again to show that it complies with the requirements.* | | | |
| *(iv)* | *As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and* | | | | | |
| *(v)* | *When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.* | | | | | |
| *(C)* | You do not need to comply with the requirements of paragraphs (a) and (b) of this section if: | | | | | |
| *(1)* | *You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the sanitation controls in § 507.34(c)(2)(i) or (ii); or* | | | | | |
| *(2)* | *You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.* | | | | | |
| *(d)* | All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i). | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.45 Verification** | | - | | | |
| *(a)* | Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system: | | | | | |
| (1) | *Validation in accordance with § 507.47;* | *6.8.1* | | | Refer § 507.47 | |
| *(2)* | *Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);* | *6.8.2* | | | Refer § 507.39 and § 507.40 | |
| *(3)* | *Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);* | *6,7* | | | Refer § 507.39 and § 507.42 | |
| (4) | *Verification of implementation and effectiveness in accordance with § 507.49; and* | *6.8.2* | | | Refer to § 507.49 | |
| (5) | *Reanalysis in accordance with § 507.50.* | | | | Refer to § 507.49 | |
| *(b)* | All verification activities conducted in accordance with this section must be documented in records. | 6.8.2 | Once the HACCP plan has been drawn up, a periodic (at least yearly) verification of (elements of) the system must take place. Verification is carried out and documented by the HACCP team. See also section 8.3. | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | | | | |
| | **§ 507.47 Validation** | | - | | | |
| *(a)* | You must validate that the preventive controls identified and implemented in accordance with § 507.34 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system. | 6.8.1 | An independent validation of the HACCP plan must be carried out. Management must establish a validation team in order to avoid undue influence. The members of the HACCP team can be members of the validation team but the validation team must have independent members. If this is not possible for the participant then he may deviate from this as long as his reasons are given.<br>The composition of the validation team and the activities they carry out must be clearly laid down. | Partially comply | Generic requirements for validation in GMP +. The FSMA requirements highlighted in blue are not specified in GMP+. GMP+ required validation team must have independent members. | |
| (b) | The validation of the preventive controls: | | | | | |
| (1) | *Must be performed (or overseen) by a preventive controls qualified individual:* | | | | | |
| (i)(A) | *Prior to implementation of the food safety plan or;* | | | | | |
| *(B)* | *When necessary to demonstrate the control measures can be implemented as designed:* | | | | | |
| *(1)* | *Within 90 calendar days after production of the applicable animal food first begins;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(2)* | *Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins;* | | | | | |
| *(ii)* | *Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and* | | | | | |
| (iii) | *Whenever a reanalysis of the food safety plan reveals the need to do so;* | | | | | |
| *(2)* | *Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards.* | | | | | |
| (c) | You do not need to validate: | | | | | |
| (1) | *The sanitation controls in § 507.34(c)(2);* | | | | | |
| (2) | *The recall plan in § 507.38;* | | | | | |
| (3) | *The supply-chain program in subpart E of this part; and* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(4)* | *Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.* | | | | | |
| | **§ 507.49 Verification of implementation and effectiveness** | | - | | | |
| *(a)* | You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system: | | | | | |
| *(1)* | *Calibration of process monitoring and verification instruments (or checking them for accuracy);* | *5.3.2* | All inspection, measuring and test equipment used to confirm that feed ingredients meet specified feed safety requirements must be calibrated at intervals not exceeding 12 months.<br>Records of the results of | *Yes* | *GMP+ specify frequency of calibration* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | calibration and verification must be maintained. | | | |
| *(2)* | *Product testing for a pathogen (or appropriate indicator organism) or other hazard;* | *6,6* | *The monitoring plan must at least be in accordance with the inspections established in this GMP+ FSA module (GMP+ BA4 Minimum Requirements for Sampling and Analysis).*<br>*The participant must provide the reasoning for the structure of the monitoring plan.* | *Yes* | *Product testing is included in HACCP section in GMP+. The requirements made reference to GMP+ BA4 with details for sampling, testing methods and tests required for feed materials, compound feed.* | |
| *(3)* | *Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and* | *NA* | *No requirement* | *No* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(4)* | *Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:* | *NA* | *No specific requirements* | *No* | *No specific requirement on timeframe to review records* | |
| (i) | *Monitoring and corrective action records within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and* | | | | | |
| (ii) | *Records of calibration, testing (e.g., product testing, environmental monitoring), and supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and* | | | | | |
| (5) | *Other activities appropriate for verification of implementation and effectiveness.* | | | | | |
| *(b)* | As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | implement written procedures for the following activities: | | | | | |
| *(1)* | *The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section;* | *5.3.2* | All inspection, measuring and test equipment used to confirm that feed ingredients meet specified feed safety requirements must be calibrated at intervals not exceeding 12 months.<br>Records of the results of calibration and verification must be maintained. | Partially comply | | |
| *(2)* | *Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:* | *6.6 & GMP+ BA4* | The monitoring plan must at least be in accordance with the inspections established in this GMP+ FSA module (GMP+ BA4 Minimum Requirements for Sampling and Analysis).<br>The participant must provide the reasoning for the structure of the monitoring plan | Yes | Product testing is included in HACCP section in GMP+. The requirements made reference to GMP+ BA4 with details for sampling, testing methods and tests required for feed materials, compound feed. | |
| *(i)* | *Be scientifically valid;* | | | | | |
| *(ii)* | *Identify the test microorganism(s) or other analyte(s);* | | | | | |
| *(iii)* | *Specify the procedures for identifying samples, including their relationship to specific lots of product;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(iv)* | *Include the procedures for sampling, including the number of samples and the sampling frequency;* | | | | | |
| *(v)* | *Identify the test(s) conducted, including the analytical method(s) used;* | | | | | |
| (vi) | *Identify the laboratory conducting the testing; and* | *6.6 & 3.9 of GMP+ BA 10 also B10* | If measurement and monitoring takes place by way of an analysis this must be carried out by a laboratory approved for this under the GMP+ FSA module. See GMP+ BA10 Minimum Requirements for Purchasing. | *Yes* | GMP + HACCP Section 6.6 required analysis carried out by laboratory approved under GMP+ module, and 3.5 of GMP+ BA 10 detailed the requirements for laboratory | |
| | *(vii) Include the corrective action procedures required by § 507.42(a)(1).* | *6,7* | | | Refer § 507.42(a)(1). | |
| *(3)* | *Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:* | *NA* | *No specific requirement on environmental monitoring* | *No* | | |
| *(i)* | *Be scientifically valid;* | | | | | |
| *(ii)* | *Identify the test microorganism(s);* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(iii)* | *Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;* | | | | | |
| *(iv)* | *Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;* | | | | | |
| *(v)* | *Identify the test(s) conducted, including the analytical method(s) used;* | | | | | |
| *(vi)* | *Identify the laboratory conducting the testing; and* | | | | | |
| (vii) | *Include the corrective action procedures required by § 507.42(a)(1)(ii).* | | | | | |
| | *No requirement* | *8,1* | *The participant must document his procedure for handling complaints from customers. This procedure must in any event describe the registration of relevant aspects of the complaint and the measures taken. A procedure for recording and handling complaints must at least* | *Additional* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *consist of:*<br>*a. The registration of complaints*<br>*b. The examination of the sources of complaints*<br>*c. Registration of the measures which were taken as a result of the complaint*<br>*d. Registration of communication with the customer in question.* | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No specific requirement on internal audit, however, some requirements for internal audit could be similar to verification* | *8,2* | *The participant must have a documented procedure for internal auditing. Internal auditing procedures must require the participant to carry out a program of planned audits to check that internal systems are operating as intended and are also effective. Such internal audits must encompass:*<br>*a. Compliance with the requirements of this standard.*<br>*b. Compliance with the requirements of the participant's HACCP Plan.*<br>*c. Compliance with the participant's formal procedures.*<br>*d. Compliance with legislation pertaining to feed ingredient safety and quality.*<br>*e. Satisfaction of specified customer requirements.*<br>*The program of internal audits must ensure that all relevant activities are audited at least once a year (= every 12 months).*<br>*All personnel carrying out internal* | *Additional* | *No specific requirement on internal audit for FSMA, however, some requirements for internal audit could be similar to verification* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *audits must be competent for this by training or education (internal or external), or experience. Internal audits must be formally reported to those with responsibility for the area audited and record any aspects where the operations are not in compliance with operational requirements. Such areas of non-compliance must be corrected and audit report records signed off by an authorized person to indicate that problems have been corrected satisfactorily.* | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *No specific requirement on management review; however, some requirements for management review could be similar to verification* | *8,3* | *The participant must establish, collect and analyse suitable data at least once per year*<br>*a. in order to show that the feed safety system is suitable and effective, and*<br>*b. to assess whether continuous improvement in the effectiveness of the feed safety system is possible*<br>*A documented procedure must be established up for this. Verification of (elements of) the HACCP plan is part of this review.* | *Additional* | *No specific requirement on management review; however, some requirements for management review could be similar to verification* | |
| | | | *This must be part of the management review (see section 4.1) The input for such a review should in any event contain information on:*<br>*a. Assessment of the prerequisites program*<br>*b. Assessment of analysis results for products*<br>*c. Verification of the hazards analysis.*<br>*d. Assessment of the level of knowledge of the personnel* | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | *e. the results of the supplier evaluation*<br>*f. feedback / complaints from customers*<br>*g. Assessment of the implementation of legislation and regulations*<br>*h. the results of internal and external audits*<br>*i. Changes which have an influence on the feed safety management system.*<br>*This review should in any event contain information about:*<br>*a. the extent to which the feed safety system must or can be modified*<br>*b. the possibilities and chances of improving the feed safety management system*<br>*The results of the management review must be recorded* | | | |
| | **§ 507.50 Reanalysis** | | - | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(a)* | You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years. | 6.8.2 | Once the HACCP plan has been drawn up, a periodic (at least yearly) verification of (elements of) the system must take place. Verification is carried out and documented by the HACCP team. See also section 8.3. | Yes | GMP+ require review of system is done at least annually as part of verification | |
| | | 8,3 | The participant must establish, collect and analyse suitable data at least once per year<br>a. in order to show that the feed safety system is suitable and effective, and<br>b. to assess whether continuous improvement in the effectiveness of the feed safety system is possible<br>A documented procedure must be established up for this. Verification of (elements of) the HACCP plan is part of this review. This must be part of the management review (see section 4.1) This must be part of the management review (see section 4.1) Production of Feed Ingredients - B 2 | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | The input for such a review should in any event contain information on:<br>a. Assessment of the prerequisites program<br>b. Assessment of analysis results for products<br>c. Verification of the hazards analysis.<br>d. Assessment of the level of knowledge of the personnel<br>e. the results of the supplier evaluation<br>f. feedback / complaints from customers<br>g. Assessment of the implementation of legislation and regulations<br>h. the results of internal and external audits<br>i. Changes which have an influence on the feed safety management system.<br>This review should in any event contain information about:<br>a. the extent to which the feed safety system must or can be | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | modified<br>b. the possibilities and chances of improving the feed safety management system<br>The results of the management review must be recorded | | | |
| *(b)* | You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan: | 8,3 | The participant must establish, collect and analyse suitable data at least once per year<br>a. in order to show that the feed safety system is suitable and effective, and<br>b. to assess whether continuous improvement in the effectiveness of the feed safety system is possible<br>A documented procedure must be established up for this.<br>Verification of (elements of) the HACCP plan is part of this review. | Partially comply | The intent is similar but the specific requirements are slightly different between FSMA and GMP+; | |
| *(1)* | *Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;* | | | | | |
| *(2)* | *Whenever you become aware of new information about potential hazards associated with the animal food;* | | | | | |
| *(3)* | *Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(4)* | *Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.* | | This must be part of the management review (see section 4.1) This must be part of the management review (see section 4.1)<br>Production of Feed Ingredients - B 2<br>The input for such a review should in any event contain information on:<br>a. Assessment of the prerequisites program<br>b. Assessment of analysis results for products<br>c. Verification of the hazards analysis.<br>d. Assessment of the level of knowledge of the personnel<br>e. the results of the supplier evaluation<br>f. feedback / complaints from customers<br>g. Assessment of the implementation of legislation and regulations<br>h. the results of internal and external audits | | | |
| *c)* | (You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified: | | | | | |
| *(1)* | *Before any change in activities (including any change in preventive control) at the facility is operative; or,* | | | | | |
| *(2)* | *When necessary to demonstrate the control measures can be implemented as designed:* | | | | | |
| *(i)* | *Within 90 calendar days after production of the applicable animal food first begins; or* | | | | | |
| *(ii)* | *Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | i. Changes which have an influence on the feed safety management system.<br>This review should in any event contain information about:<br>a. the extent to which the feed safety system must or can be modified<br>b. the possibilities and chances of improving the feed safety management system<br>The results of the management review must be recorded | | | |
| *(d)* | You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard, or document the basis for the conclusion that no revisions are needed. | 8,3 | As above. This review should in any event contain information about:<br>a. the extent to which the feed safety system must or can be modified | Yes | | |
| *(e)* | A preventive controls qualified individual must perform (or oversee) the reanalysis. | NA | No specific requirement | No | | |
| *(f)* | You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding. | NA | No specific requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food** | | - | | | |
| *(a)* | If a facility that is solely engaged in the storage of unexposed packaged animal food stores any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls: | GMP B3 | GMP B2 does not cover the scope for facility that is solely engaged in the storage of animal feed materials but under GMP B3 | Partially comply | Same intention but different specific requirements between FSMA and GMP B3 | |
| *(1)* | *Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, pathogens;* | | | | | |
| *(2)* | *Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;* | | | | | |
| *(3)* | *If there is a loss of temperature control that may impact the safety of such refrigerated packaged animal food, take appropriate corrective actions to:* | | | | | |
| (i) | *Correct the problem and reduce the likelihood that the problem will recur;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (ii) | *Evaluate all affected animal food for safety; and* | | | | | |
| *(iii)* | *Prevent the animal food from entering commerce, if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;* | | | | | |
| (4) | *Verify that temperature controls are consistently implemented by:* | | | | | |
| *(i)* | *Calibrating temperature monitoring and recording devices (or checking them for accuracy);* | | | | | |
| *(ii)* | *Reviewing records of calibration within a reasonable time after the records are created; and* | | | | | |
| *(iii)* | *Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days;* | | | | | |
| (5) | *Establish and maintain the following records:* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(i)* | *Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged animal food;* | | | | | |
| *(ii)* | *Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged animal food; and* | | | | | |
| (iii) | *Records documenting the verification activities.* | | | | | |
| *(b)* | The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part. | | | | | |
| | **§ 507.55 Implementation records required for this subpart** | | - | | | |
| *(a)* | You must establish and maintain the following records documenting implementation of the food safety plan: | | | | | |
| *(1)* | *Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance with § 507.36(a);* | *4.4.1, 4.4.2 and other relevant clauses in* | GMP+4.4.1 and 4.4.2 specify documents and records requirements; and records requirements in relevant clauses of standard | Yes | | |
| *(2)* | *Records that document the monitoring of preventive controls;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| *(3)* | *Records that document corrective actions;* | *the standard* | | | | |
| *(4)* | *Records that document verification, including, as applicable, those related to:* | | | | | |
| *(i)* | *Validation;* | | | | | |
| *(ii)* | *Verification of monitoring;* | | | | | |
| *(iii)* | *Verification of corrective actions;* | | | | | |
| *(iv)* | *Calibration of process monitoring and verification instruments;* | | | | | |
| *(v)* | *Product testing;* | | | | | |
| *(vi)* | *Environmental monitoring;* | | | | | |
| *(vii)* | *Records review; and* | | | | | |
| *(viii)* | *Reanalysis;* | | | | | |
| *(5)* | *Records that document the supply-chain program; and* | | | | | |
| *(6)* | *Records that document applicable training for the preventive controls qualified individual and the qualified auditor.* | | | | | |
| *(b)* | The records that you must establish and maintain are subject to the requirements of subpart F of this part. | | | | | |
| | **§ 507.206 Additional requirements applying to the food safety plan** | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | The owner, operator, or agent in charge of the facility must sign and date the food safety plan upon initial completion and upon any modification. | 4.2.2 | Control of documentation and data<br>The documents and (registration) data must be controlled. This means that the documentation:<br>a. must be kept up to date;<br>b. approved, signed and dated, and must be assessed at least annually by a competent person. This assessment must at least consider any changes to the regulations or to the GMP+ FSA module; | Yes | No specific requirement in GMP+ on HACCP must be approved and signed; As part of the feed safety management system, HACCP documents must be approved, signed and dated and assessed at least anually by a competent person | |
| | No requirement | 6,1 | To apply these principles successfully, the participant must first comply with a number of other requirements which are laid in other chapters and sections of this standard:<br>a. Establishing a HACCP-Team(section 4.2);<br>b. Description of product and process, including the intended use (section 6.2)<br>c. Establishing and implementing | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | a prerequisite program (chapter 5) | | | |
| | No requirement | 6.2.1 | The participant must determine all (safety) requirements with respect to the feed ingredients to be produced, including storage and/or transport:<br>a. legal requirements of the feed ingredients, including requirements for storage and transport, and<br>b. all additional feed safety requirements, including those necessary for the specified or intended use, if known. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 6.2.1 | Communication with (potential) customers may result in determining:<br>a. customer requirements relating to the safety of feed ingredients, and/or<br>b. any other special customer requirements. If the customer participates in a certain feed safety program, the participant must ensure he understands, determines and complies with the specific program requirements, including, for example, any specific storage or transport conditions. | Additional | | |
| | No requirement | 6.2.1 | Each type of feed material that is produced must be listed (with its generic risk assessment) in GMP+ International's Feed Support Products. If the participant produces a feed material<br>a. of which no risk assessment is listed in the Feed Support Products; or<br>b. using a manufacturing method that is not in accordance with | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | one of the risk assessments already included in the Feed Support Products.<br>then the participant must guarantee that the risk assessment is listed in the Feed Support Products. The above does not apply to feed materials produced exclu- sively for purposes of feed for non-food producing animals.<br>In Appendix GMP+ BA7 Specific requirements for by-products from Oil and Fat for specific by-products from the oil and fat industry (from certain origins) additional requirements have been laid down. These requirements focus on purchase of raw materials, shipment, transport, monitoring, and labelling. If applicable, the participant needs to comply with these requirements. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 6.2.1 | The participant must determine and specify all (safety) requirements relating to the feed ingredients to be produced. For each feed ingredient, a description must be available based on the above-mentioned requirements.<br>The scope of this specification must include the products used, ranging from the products used in the manufacturing process (feed materials, processing aids and/or (technological) additives) through distribution.<br>If requirements are modified, the participant must ensure that the relevant specification is updated and that the relevant personnel is aware of these changes. This specification must be kept up to date. | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 6.2.2 | The specification must at least – if applicable - include: a. Characteristics of the feed ingredient<br>1. General details (name, code, origin, creation/manufacturing model etc.);<br>2. Composition (chemical, physical, microbiological)<br>3. Used raw materials and processing aids (including any additives and processing aids);<br>4. Requirements (feed legislation; agreements with buyers) and tolerances;<br>Within the GMP+ FSA module, the feed ingredients must at least comply with the relevant product standards as determined in the GMP+ BA1 Specific feed safety limit.<br>5. Other characteristics (including storage, packaging).<br>b. Characteristics of use:<br>1. Intended use;<br>2. Preparation instructions;<br>3. Instructions for feeding to | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | animals<br>4. Storage conditions;<br>5. Shelf life;<br>6. Conditions and agreements relating to transport and place of delivery;<br>7. Legally required information on the packaging and any accompanying documents. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 6.2.3 | The HACCP Team must draw up a description of the production process for each feed ingredient in the form of flow diagrams and a floor plan which enables the organization to identify and assess hazards.<br>The flow diagrams and the layout must be verified by the HACCP Team, and must be kept up-to-date.<br>The flow diagrams must comply with at least the following requirements :<br>a. Representation of all the individual steps in the process (from purchasing through to delivery), including any work outsourced as well as the description of all products used and also any by-products, customer returns and waste which may be produced during the process.<br>b. Clear, accurate and detailed in order to establish possible hazards. The whole infrastructure | Additional | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | of the establishment must be shown in a floor plan, including:<br>a. the production units, storage areas and personnel facilities<br>b. the routing of products<br>c. the areas/rooms where cross-contamination or incidental contacts are possible between raw materials and auxiliary substances, lubricants and cooling agents, semi-produced and other feed ingredients (end products), packaging, pallets, etc. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 6,5 | In order to establish whether a specific control measure is effective, the HACCP Team must establish for each Critical Control Point (CCP)<br>a. which parameters must be measured, analyzed or observed, and<br>b. which product standards (action and rejection limits) apply for these parameters.<br>In establishing the product standards (action and rejection limits) there must be compliance with the relevant feed legislation and the product standards established under this GMP+ FSA module. These product standards must be considered to be (contractual) obligations. | Additional | | |

## 3.4. Subpart E - Supply Chain Program

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.105 Requirement to establish and implement a supply-chain program** | | | | | |
| (a)(1) | Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. | 7.1.2, | Preferable sourcing should be done from GMP+ certified or equivalent companies (equivalents are outlined in BA10 per commodity type). Sourcing materials from companies certified to ISO 22000 or GFSI standards as being equivalent for use in feeds is allowed. If a supplier has one of the equivalent certifications they are allowed to be used and required to undergo evaluation.<br><br>Annexes to BA10 (listed at end of BA10 Appendix) outline the Gatekeeper principal which allows for certain types of feed ingredients, example | Partially Comply | see details below | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | additives, to be purchased from non-certified companies. The basic requirements are 1) a contract must be in place, 2) Specifications must be defined 3) a risk assessment of the material must be performed and documented. 4) material must have a goods inward inspection to confirm compliance to specifications 5) testing may be required depending on the risk assessment 6) supplier must be reevaluated periodically 7) The supplier must have an audit either by the purchaser or by an independent agency.<br><br>If none of the above solutions (GMP+ or equivalent certified or listed as applicable under the gatekeeper principal) the purchaser must apply for a | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | temporary exemption with GMP+ to allow for the use of the material.<br><br>BA 4 outlines specific guidelines for sampling should this be required (quantity/type of sampling) etc.<br><br>Currently if testing is required, currently labs which are ISO 17025 certified for the test required (preferred), ISO 17025 but not for the test required, ISO 9001, and finally participation in a check sample program to confirm proficiency would be allowed to be used. There are new standards (B10 and B11) on the way which take effect next year which will require testing by GMP+ registered labs. | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | Allowable contents are based on EU specifications (Not USA) for heavy metals, pesticides, Dioxins, Salmonella, etc. so a level of one contaminant might be allowed in the USA but that same level may not be allowed in Europe. | | | |
| (2) | *A receiving facility that is an importer, is in compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.* | *No* | *No requirement* | *No* | | |
| (3) | *The requirements in this subpart do not apply to animal food that is supplied for research or evaluation use, provided that such animal food:* | *No* | *No requirement* | *No* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (i) | *Is not intended for retail sale and is not sold or distributed to the public;* | *No* | *No requirement* | *No* | | |
| (ii) | *(Is labeled with the statement "Animal food for research or evaluation use";* | *No* | *No requirement* | *No* | | |
| (iii) | *Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the animal food is used only for this purpose, and any unused quantity is properly disposed of; and* | *No* | *No requirement* | *No* | | |
| (iv) | *Is accompanied with documents, in accordance with the practice of the trade, stating that the animal food will be used for research or evaluation purposes and cannot be sold or distributed to the public.* | *No* | *No requirement* | *No* | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (b) | The supply-chain program must be written. | 7.1.1 | The participant must ensure that the purchasing of raw materials (including processing aids, etc.), services and feed ingredients are in accordance with the GMP+ requirements. The purchase of all raw materials, services and feed ingredients must be clearly recorded.<br>A documented procedure must be drawn up for the whole purchase process. Specifications must be documented and must be part of the purchase documents and contracts. Goods inward inspections must be performed on incoming materials | Yes | | |
| (c) | When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (*e.g.,* when a non-supplier applies controls to certain produce (*i.e.,* produce covered by part 112 of this chapter), because growing, harvesting, and packing | NA | No specific requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | activities are under different management), the receiving facility must: | | | | | |
| (1) | *Verify the supply-chain-applied control; or* | | | | | |
| (2) | *Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.* | | | | | |
| | **§ 507.110 General requirements applicable to a supply-chain program** | | | | | |
| (a) | The supply-chain program must include: | | | | | |
| (1) | *Using approved suppliers as required by § 507.120;* | | | | | |
| (2) | *Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 507.125;* | *Refer § 507.125* | | | *Refer § 507.125* | |
| (3) | *Conducting supplier verification activities as required by §§ 507.130 and 507.135;* | *Refer to § 507.130 and 507.135* | | | *Refer to §§ 507.130 and 507.135* | |
| (4) | *Documenting supplier verification activities as required by § 507.175; and* | *Refer to § 507.175* | | | *Refer to § 507.175* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (5) | *When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 507.175, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 507.175.* | *Refer to § 507.175* | | | *Refer to § 507.175* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (b) | The following are appropriate supplier verification activities for raw materials and other ingredients: | D2.5 Guideline for supplier assessment | Five elements can be distinguished with respect to supplier assessment. As a customer this means:<br>1. that you have detailed specifications which are in accordance with the legislation and with the requirements of the relevant standards for good manufacturing practice<br>2. that you select suppliers on the basis of their ability to:<br>a) deliver the specified product which complies with the legal requirements<br>b) work in accordance with systems for good manufacturing practice<br>3. regularly visit suppliers to assess whether they can meet their obligations in the field of food safety or to assess results of audits which were carried out at the suppliers in | Partially Comply | | |
| (1) | *Onsite audits;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (2) | *Sampling and testing of the raw material or other ingredient;* | | question<br>4. carry out a monitoring program established on the basis of a risk assessment<br>5. record complaints and deviations and handle them correctly | | | |
| (3) | *Review of the supplier's relevant food safety records; and* | | | | | |
| (4) | *Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.* | | | | | |
| (C) | The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. | 7.1.2 | If the participant purchases feed (to which feed ingredients belong) or certain services, the participant must make sure that these feed ingredients or services are:<br>a. from suppliers who are GMP+ certified at the moment of delivery, or<br>b. from suppliers which are certified based on a standard approved in the GMP+ FSA module;<br>c. certain feed ingredients and services may also be bought without one of the above certificates (i.e. from a non-certified supplier). | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | Separate requirements have been established for this.<br>In GMP+ BA10 Minimum Requirements for Purchasing there are more details of the specific feed and services concerned, and further details of the above options.<br>d. Prior to the purchase of products or services that differ from the above meant the participant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and the quality assurance, which is applied by the supplier, the participant must make a selection of suppliers and must adjust his (entry) check accordingly. | | | |
| (d)(1) | Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with | *7.1.3* | *The participant must assess all its suppliers on an annual basis. This requires determining criteria for* | *Partially Comply* | *FSMA is much more prescriptive than GMP+* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | which they are conducted, the following must be considered: | | *selection, assessment, approval and evaluation. The participant must demonstrate that all suppliers always comply with these requirements.* | | | |
| (i) | *The hazard analysis of the animal food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;* | | | | | |
| (ii) | *The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;* | | | | | |
| (iii) | *Supplier performance, including:* | | | | | |
| (A) | *The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;* | | | | | |
| (B) | *Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of animal food and other FDA compliance actions related to animal food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *relevant to the supplier's compliance with those laws and regulations); and* | | | | | |
| (C) | *The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and* | | | | | |
| (iv) | *Any other factors as appropriate and necessary, such as storage and transportation practices.* | | | | | |
| (2) | *Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:* | *NA* | *No requirement* | *No* | | |
| (i) | *A qualified facility as defined by § 507.3;* | | | | | |
| (ii) | *A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or* | | | | | |
| (iii) | *A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (e) | If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or other ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. | NA | No requirement | No | | |
| | **§ 507.115 Responsibilities of the receiving facility** | | | | | |
| (a)(1) | The receiving facility must approve suppliers. | | | | | |
| (2) | *Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.* | | | | | |
| (3) | *An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the* | *7.1.2 AlsoD2.5 Guideline* | *If the participant purchases feed (to which feed ingredients belong) or certain services, the* | *Partially Comply* | *GMP+ require suppliers are GMP+ certified or comply* | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *entity's applicable documentation, and documents that review and assessment:* | *for supplier assessment* | *participant must make sure that these feed ingredients or services are:*<br>*a. from suppliers who are GMP+ certified at the moment of delivery, or*<br>*b. from suppliers which are certified based on a standard approved in the GMP+ FSA module;* | | *with GMP+ BA 10 requirements. In such, suppliers must also comply with GMP+ requirements which are similar to FSMA requirements* | |
| (i) | *Establish written procedures for receiving raw materials and other ingredients by the entity;* | | | | | |
| (ii) | *Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and* | | | | | |
| (iii) | *Determine, conduct, or both determine and conduct, the appropriate supplier verification activities, with appropriate documentation.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (4) | *The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.* | | *c. certain feed ingredients and services may also be bought without one of the above certificates (i.e. from a non-certified supplier). Separate requirements have been established for this.*<br>*In GMP+ BA10 Minimum Requirements for Purchasing there are more details of the specific feed and services concerned, and further details of the above options.*<br>*d. Prior to the purchase of products or services that differ from the above meant the participant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and the quality assurance, which is applied by the supplier, the participant must make a selection of suppliers and must adjust his (entry) check accordingly.* | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (b) | For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity: | NA | No specific requirement | No | | |
| (1) | *A determination by its supplier of the appropriate supplier verification activities for that supplier;* | | | | | |
| (2) | *An audit conducted by its supplier;* | | | | | |
| (3) | *A review by its supplier of that supplier's own relevant food safety records; or* | | | | | |
| (4) | *The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 507.110(b)(4).* | | | | | |
| (c) | The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135. | NA | No Specific requirement | No | | |
| | **§ 507.120 Using approved suppliers** | | | | | |
| (a) | The receiving facility must approve suppliers in accordance with the requirements of § 507.110(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers; | Refer to § 507.110 d | | | Refer to § 507.110 d | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (b)(1) | Written procedures for receiving raw materials and other ingredients must be established and followed; | 7.2 | There must be a procedure for the acceptance of receiving of all products. This procedure must prescribe criteria for the proper acceptance of the products including criteria for the approval of transport.<br>Each incoming delivery must be verified on the basis of the specifications. During the entry check all incoming feed ingredients must be released before they can be stored and/or further processed. For the requirements with respect to sampling see section 5.4.<br>The products must comply with the specifications.<br>Checking on compliance with specification is a major issue.<br>The participant must also verify if the transport complies with the agreed | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (2) | *The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and* | | requirements.<br><br>Note: If any kind of feed is received, the transport to the participant must be GMP+ certified. The participant must then include in his entry check as a minimum: a check on the correct GMP+ certification of the carrier, compliance with the requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes. The LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable.<br>In the case of doubt the specifications must be verified by way of analysis. The frequency of this may differ for the various | | | |
| (3) | *Use of the written procedures for receiving raw materials and other ingredients must be documented.* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | | | parameters. In addition, batches from 'new' suppliers must be checked at a higher intensity.<br>The received products must not be accepted if they do not comply with the specifications unless they are treated to ensure that the batch does comply with the safety specifications. | | | |
| | **§ 507.125 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)** | | | | | |
| | Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 507.110(d). | Refer to § 507.110 (d) | | | Refer to § 507.110(d) | |
| | **§ 507.130 Conducting supplier verification activities for raw materials and other ingredients** | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (a) | Except as provided by paragraphs (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 507.110(b), as determined under § 507.110(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter. | § 507.110(d) | | | § 507.110(d) | |
| (b)(1) | Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals: | 7.1.3 | Assessment of suppliers<br>The participant must assess all its suppliers on an annual basis. This requires determining criteria for selection, assessment, approval and evaluation. The participant must demonstrate that all suppliers always comply with these requirements. | Partially Comply | | |
| (i) | *The appropriate supplier verification activity is an onsite audit of the supplier; and* | | | | | |
| (ii) | *The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.* | | | | | |
| (2) | *The requirements of paragraph (b)(1) of this section do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *supplier provide adequate assurance that the hazards are controlled.* | | | | | |
| (c) | If a supplier is a qualified facility as defined by § 507.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility: | | | | | |
| (1) | *Obtains written assurance that the supplier is a qualified facility as defined by § 507.3:* | | | | | |
| (i) | *Before first approving the supplier for an applicable calendar year; and* | | | | | |
| (ii) | *On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and* | | | | | |
| (2) | *Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (i) | *A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the animal food; or* | | | | | |
| (ii) | *A statement that the facility is in compliance with State, local, county, tribal or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign counties.* | | | | | |
| (d) | If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility: | | | | | |
| (1) | *Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:* | | | | | |
| (i) | *Before first approving the supplier for an applicable calendar year; and* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (ii) | *On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and* | | | | | |
| (2) | *Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).* | | | | | |
| (e) | If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility: | | | | | |
| (1) | *Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:* | | | | | |
| (i) | *Before first approving the supplier for an applicable calendar year; and* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (ii) | *On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and* | | | | | |
| (2) | *Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).* | | | | | |
| (f) | There must not be any financial conflicts of interest that influence the results of the verification activities listed in § 507.110(b) and payment must not be related to the results of the activity. | | | | | |
| | **§ 507.135 Onsite audit** | | | | | |
| (a) | An onsite audit of a supplier must be performed by a qualified auditor. | | | Partially Comply | GMP+ BA10 Gatekeeper protocol | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (b) | If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (*e.g.*, Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). | 7.1.3 , GMP+ BA10 | 7.1.3 Assessment of suppliers and GMP+ B10 Minimum requirements for purchasing | | require audit but no specific requirements to the same level as FSMA | |
| (c)(1) | The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted: | | | | | |
| (i) | *The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (ii) | *For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.* | | | | | |
| (2) | *For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.* | | | | | |
| (d) | If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations. | | | | | |
| | **§ 507.175 Records documenting the supply-chain program.** | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (a) | The records documenting the supply-chain program are subject to the requirements of subpart F of this part. | | | | See details on subpart F Requirements for records | |
| (b) | The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 507.49(a)(4). | NA | No specific requirement | No | | |
| (c) | The receiving facility must document the following in records as applicable to its supply-chain program: | | | | | |
| (1) | *The written supply-chain program;* | 7.1.1 & 7.1.2 | Refer above | Yes | | |
| (2) | *Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;* | *NA* | No specific requirement | No | | |
| (3) | *Documentation of the approval of a supplier;* | 7.1.1 & 7.1.2 | Refer above | Yes | | |
| (4) | *Written procedures for receiving raw materials and other ingredients;* | *7.2* | As above | Yes | | |
| (5) | *Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;* | *7.2* | *As above* | Yes | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (6) | *Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;* | See 7.1.3 and D2.5 | Assessment of supplier and Guide for the supplier assessment | Partially Comply | | |
| (7) | *Documentation of the conduct of an onsite audit. This documentation must include:* | *See 7.1.3 and D2.5* | Assessment of supplier and Guide for the supplier assessment | Partially Comply | | |
| (i) | *The name of the supplier subject to the onsite audit;* | | | | | |
| (ii) | *Documentation of audit procedures;* | | | | | |
| (iii) | *The dates the audit was conducted;* | | | | | |
| (iv) | *The conclusions of the audit;* | | | | | |
| (v) | *Corrective actions taken in response to significant deficiencies identified during the audit; and* | | | | | |
| (vi) | *Documentation that the audit was conducted by a qualified auditor;* | | | | | |
| (8) | *Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:* | See 7.1.3, 7.2 and D2.5 | Assessment of supplier, Verification of received products and Guide for the supplier assessment | Partially Comply | | |
| (i) | *Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;* | | | | | |
| (ii) | *Identification of the test(s) conducted, including the analytical method(s) used;* | | | | | |
| (iii) | *The date(s) on which the test(s) were conducted and the date of the report;* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (iv) | *The results of the testing;* | | | | | |
| (v) | *Corrective actions taken in response to detection of hazards; and* | | | | | |
| (vi) | *Information identifying the laboratory conducting the testing;* | | | | | |
| (9) | *Documentation of the review of the supplier's relevant food safety records. This documentation must include:* | NA | No specific requirement | No | | |
| (i) | *The name of the supplier whose records were reviewed;* | | | | | |
| (ii) | *The date(s) of review;* | | | | | |
| (iii) | *The general nature of the records reviewed;* | | | | | |
| (iv) | *The conclusions of the review; and* | | | | | |
| (v) | *Corrective actions taken in response to significant deficiencies identified during the review;* | | | | | |
| (10) | *Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;* | NA | No specific requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (11) | *Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals;* | NA | No specific requirement | No | | |
| (12) | *The following documentation of an alternative verification activity for a supplier that is a qualified facility:* | *NA* | No specific requirement | No | | |
| (i) | *The written assurance that the supplier is a qualified facility as defined by § 507.3; and* | | | | | |
| (ii) | *The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (13) | *The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:* | NA | No specific requirement | No | | |
| (i) | *The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; and* | | | | | |
| (ii) | *The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);* | | | | | |
| (14) | *The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:* | NA | No specific requirement | No | | |
| (i) | *The written assurance that the shell eggs provided by the supplier are not subject to part* | | | | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | *118 of this chapter because the supplier has less than 3,000 laying hens; and* | | | | | |
| (ii) | *The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);* | | | | | |
| (15) | *The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;* | NA | No specific requirement | No | | |
| (16) | *Documentation of actions taken with respect to supplier non-conformance;* | NA | No specific requirement | No | | |
| (17) | *Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and* | NA | No specific requirement | No | | |

| | FSMA - Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (18) | *When applicable, documentation of the receiving facility's review and assessment of:* | NA | No specific requirement | No | | |
| (i) | *Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;* | | | | | |
| (ii) | *Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;* | | | | | |
| (iii) | *Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;* | | | | | |
| (iv) | *Applicable documentation, from its supplier, of:* | | | | | |
| (A) | *The results of sampling and testing conducted by the supplier; or* | | | | | |
| (B) | *The results of an audit conducted by a third-party qualified auditor in accordance with §§ 507.130(f) and 507.135; and* | | | | | |
| (v) | *Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.* | | | | | |

## 3.5. Definitions (part of subpart A)

| | FSMA - Sub Category | | | | Additional information |
|---|---|---|---|---|---|
| | **§ 507.3 Definitions** | | | | |
| | See FSMA document | | | | For definitions and abbreviations in GMP+ see document GMP+ A2 |

## 3.6. Exemptions (part of subpart A)

| | FSMA -Sub Category | Additional information |
|---|---|---|
| | **§ 507.5 Exemptions** | If – due to an exceptional situation – a GMP+ participant is unable to meet (one of) the GMP+ requirements, it is possible to request an (temporary) exemption from GMP+ International. This is possible based on article 11.3 of GMP+ A1 General Regulations of the GMP+ FC scheme. More information: https://www.gmpplus.org/media/1924/criteria-for-exemption-en.pdf |
| | (a) This part does not apply to establishments, including "farms" (as defined in § 1.227 of this chapter), that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act. | |
| | (b)(1) Subparts C and E of this part do not apply with respect to activities that are subject to § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at an animal food facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to those activities. | |
| | *(2) The exemption in paragraph (b)(1) of this section is applicable only with respect to those microbiological hazards regulated under part 113 of this chapter.* | |
| | (c) Subparts C and E of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety). | |
| | (d) Except as provided in subpart D of this part, subparts C and E of this part do not apply to a qualified facility. Qualified facilities are subject to the requirements in § 507.7. | |

| | FSMA -Sub Category | Additional information |
|---|---|---|
| | (e) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm packing or holding of processed animal food, and § 507.7 does not apply to on-farm packing or holding of processed animal food by a very small business, if the only packing or holding activities subject to section 418of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations—*i.e.*, packing (or repacking) (including weighing or conveying incidental to packing or repacking); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of: | |
| | *(1) Roughage products (e.g., alfalfa meal, entire plant meal, stem meal, pomace, and pulp);* | |
| | *(2) Plant protein meals (e.g., algae, coconut (copra), guar, and peanut);* | |
| | *(3) Grain by-products and processed grain products (e.g., bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal);* | |
| | *(4) Oilseed products (e.g., oil and meal of safflower, soybean, or sunflower);* | |
| | *(5) Molasses (e.g., processed sugar cane, sugar beets, and citrus).;* | |
| | *(6) Animal protein meals (e.g., blood, feather, meat, meat and bone, and marine (e.g., crab, fish, shrimp));* | |
| | *(7) Milk products (e.g., casein, cheese rind, and lactalbumin);* | |
| | *(8) Animal tissue-derived products (e.g., fat);* | |
| | *(9) Vitamins, minerals, and concentrates;* | |
| | *(10) Processing aids (e.g., enzymes, preservatives, and stabilizers); and* | |
| | *(11) Any other processed animal food that does not require time/temperature control for safety.* | |

| | FSMA -Sub Category | Additional information |
|---|---|---|
| | (f) For a farm mixed-type facility that is a small or very small business, subparts C and E of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and § 507.7 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following low-risk manufacturing/processing activity/animal food combinations: | |
| | *(1) Chopping or shredding hay;* | |
| | *(2) Cracking, crimping, flaking, pearling, peeling, shelling, or wafering—grain (e.g., barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (e.g., beans, canola, cottonseed, linseed, soybeans, and sunflowers);* | |
| | *(3) Crushing, dry rolling, grinding, milling, pulverizing—grain, oilseed, grain by-products and processed grain products, oilseed products, hay, ensiled material, culled fruits and vegetables, roughage (e.g., cobs, hulls, husks, and straws), or roughage products;* | |
| | *(4) Ensiling (including chopping, shredding, mixing, storing, or fermenting), that is, making silage or haylage from forage (e.g., sorghum (milo), corn (maize), alfalfa, and grass), grain, culled fruits and vegetables, or roughage;* | |
| | *(5) Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;* | |
| | *(6) Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety; and* | |

| | FSMA -Sub Category | Additional information |
|---|---|---|
| | *(7) Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.* | |
| | (g) Subparts C and E of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. | |
| | (h) Subpart B of this part does not apply to any of the following: | |
| | *(1) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;* | |
| | *(2) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); and* | |
| | *(3) Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).* | |

## 3.7. Subpart F - Requirements for Records

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | **§ 507.200 Records subject to the requirements of this subpart** | | | | | |
| (a) | Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart. | NA | No specific requirements | | | |
| (b) | Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter. | NA | No specific requirements | | | |
| (c) | All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request. | NA | No specific requirement | | | |
| (d) | The requirements of § 507.206 apply only to the written food safety plan. | NA | No specific requirements | | | |
| (e) | The requirements of § 507.202(a)(2), (4), and (5) and (b) do not apply to the records required by § 507.7. | NA | No specific requirements | | | |
| | **§ 507.202 General requirements applying to records** | | | | | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (a) | Records must: | 4.4.2 | Control of documentation and data<br>The participant must ensure that all documentation and data required under this standard are:<br>a. kept for a period of at least 3 years unless a longer retention period is prescribed by law;<br>b. stored in a way that any degradation in the condition of or damage to the documentation and data is prevented;<br>c. stored in such a way that the documentation and data is complete and easy to retrieve;<br>d. clearly legible. | Partially comply | FSMA is more prescriptive | |
| (1) | *Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;* | | | | | |
| (2) | *Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;* | | | | | |
| (3) | *Be accurate, indelible, and legible;* | | | | | |
| (4) | *Be created concurrently with performance of the activity documented; and* | | | | | |
| (5) | *Be as detailed as necessary to provide history of work performed.* | | | | | |
| (b) | All records must include: | | | | | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (1) | *Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);* | *NA* | No specific requirement | No | | |
| (2) | *The date and, when appropriate, the time of the activity documented;* | *NA* | No specific requirement | No | | |
| (3) | *The signature or initials of the person performing the activity; and* | *NA* | No specific requirement | No | | |
| (4) | *Where appropriate, the identity of the product and the lot code, if any.* | *NA* | No specific requirement | No | | |
| (c) | Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter. | *NA* | No specific requirement | No | | |
| | **§ 507.208 Requirements for record retention** | | | | | |
| (a)(1) | All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared. | 4.4.2a | kept for a period of at least 3 years unless a longer retention period is prescribed by law; | Comply | GMP + require longer retention period | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| (2) | *contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;* | *6.6.*<br>*6.8.2* | art. 6.6. The results of the monitoring must be recorded.<br>art 6.8.2 : Once the HACCP plan has been drawn up, a periodic (at least yearly) verification of (elements of) the system must take place. Verification is carried out and documented by the HACCP team. See also section 8.3. | Comply | | |
| (b) | Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (*e.g.,* because the facility has updated the written food safety plan (§ 507.31) or records that document validation of the written food safety plan (§ 507.45(b))). | NA | No specific requirement | No | | |
| (c) | Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are | 4.4.2 b & c | stored in a way that any degradation in the condition of or damage to the documentation and data is prevented; stored in such a way that the documentation | Partially comply | GMP + requirements are more generic | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | considered to be onsite if they are accessible from an onsite location. | | and data is complete and easy to retrieve; | | | |
| (d) | If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request. | NA | No specific requirement | No | | |
| | **§ 507.212 Use of existing records** | | | | | |
| (a) | Existing records (*e.g.,* records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart. | NA | No specific requirement | No | | |
| (b) | The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be | NA | No specific requirement | No | | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | kept either separately or combined with the existing records. | | | | | |
| | No requirement | 4,4 | Documentation and registration | Additional | | |
| | No requirement | 4.4.1 | Quality documentation and manual | Additional | | |
| | | | A participant must produce and implement procedures and instructions that incor-porate the requirements of this standard. | Additional | | |
| | | | The feed safe management system documentation must include, or refer to | Additional | | |
| | No requirement | a | The documented Quality Policy, including feed safety objectives | Additional | | |
| | No requirement | b | Description of the scope of the feed safety management system as required in section 4.3; | Additional | | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | c | All relevant records or approvals in accordance with national and international legislation; | Additional | | |
| | No requirement | d | The HACCP documentation; | Additional | | |
| | No requirement | e | All procedures, instructions, registration forms, etc. required by this standard, and/or necessary for the operating of the feed safe management system; | Additional | | |
| | No requirement | f | All records of treatment, audits and inspections and all other records which are required under this standard. This register must be set up and maintained as evidence of compliance with the requirements and of the effective operation of the feed safety management system; | Additional | | |
| | No requirement | | There must be a clear, unambiguous structure applied to these documents, instructions, forms, etc. | Additional | | |

| | Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|---|
| | No requirement | 4.4.2 | Control of documentation and data | Additional | | |
| | | | The documents and (registration) data must be controlled. This means that the documentation: | Additional | | |
| | No requirement | a | must be kept up to date; | Additional | | |
| | No requirement | b | approved, signed and dated, and must be assessed at least annually by a competent person. This assessment must at least consider any changes to the regulations or to the GMP+ FSA module; | Additional | | |
| | No requirement | c | always be accessible and understandable to those members of the personnel who implemented the requirements of the procedure | Additional | | |
| | No requirement | d | be revised and updated if the process undergoes a relevant change so that it is always up to date. | Additional | | |

## 3.8. Modified requirements (part of subpart A)

| Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|
| **§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food** | | | | | In GMP+: "by-products from the food industry" are considered as regular feed materials. Example: Wheat middlings generated while processing wheat for flour.<br>The same requirements apply to this type of products. GMP + does not have specific requirements for these types of products<br><br>Another group is "former food stuffs":<br>these products are produced with the intention to be consumed by the human. Example : cookies (BA10 - annex 6 can be used) |
| (a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production, or the off-farm packing and holding of raw agricultural commodities, that are packed or held by that human food facility for distribution as animal food if: | NA | No specific requirement | No | | |

| Sub Category | GMP+ B2 Clause | GMP+ B2 Requirements | Yes /No/Partially comply | Details or Conformity or Non-conformity | Additional information |
|---|---|---|---|---|---|
| (1)(i) The human food facility is subject to and in compliance with subpart B of part 117 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; or | NA | No specific requirement | No | | |
| (ii) For the off-farm packing and holding of produce (as defined in part 112 of this chapter), the human food facility is subject to and in compliance with § 117.8 of this chapter and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and | NA | No specific requirement | No | | |
| (2) The human food facility does not further manufacture or process the by-products intended for use as animal food. | NA | No specific requirement | No | | |
| (b) The human food by-products for use as animal food identified in paragraph (a) of this section must be held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter. | NA | No specific requirement | No | | |

GMP+ International

**GMP+ International**
Braillelaan 9
2289 CL Rijswijk
The Netherlands
t. +31 (0)70 – 307 41 20 (Office)
+31 (0)70 – 307 41 44 (Help Desk)
e. info@gmpplus.org