



GMP+ BA 10

**GMP+ Feed Certification scheme** 



Feed Safety Worldwide

## History of the document

Revision no. /	Amendment	Concerns	Final implemen-
<b>Date of approval</b> 0.0 / 01-2010	Previous versions can be found in		tation date 01-01-2010
0.1 / 03-2010	History		01-07-2010
0.2 / 07-2010			09-07-2010
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1.0 / 06-2014	Editorial changes: All editorial changes are put together in a factsheet	Entire Document	01-10-2014
	Accepted certification schemes for growers are deleted. Gatekeeper protocol for growers must be applied.	3	01-10-2015
	The GMP+ B6 will be removed from the Feed Certification scheme per 31-12-2015	3	01-10-2014
	Gatekeeper protocol for purchase of unpro- cessed agricultural products from the grower is adapted	Annex 4	01-10-2015
	Gatekeeper protocol (former) foodstuff is added	Annex 6	01-01-2015
	Gatekeeper protocol for transport is adapted.	Annex 9	01-10-2014
	Gatekeeper protocol for storage and transshipment is added.	Annex 10	01-01-2016
	Mutual recognition with TP, EFISC and Gafta have been implemented	3.4.1/ appendix 1	1-10-2014
	Purchase requirements for mineral feed materials are adjusted	3.4.1	1-10-2014
1.1 / 06-2014	Rename GMP+ BA1 Specific Feed Safety Limits	Entire document	01-01-2015
1.1 / 04-2015	By mistake not corrected term <i>untreated</i> into <i>unprocessed</i>	Annex 5 Annex 9	01-01-2015
2.0 / 11-2015	France is included in the list of the A-countries.	Annex 9	01-01-2017
	Editorial correction of the table.	Annex 9 3	01-04-2016
	Clarification that the period of 90 days may also concern 90 non-consecutive days.	Annex 9 5.1	01-01-2017
3.0 / 09-2016	Gatekeeper protocol for purchase of unpro- cessed agricultural products from the grower is also applicable for purchase of hay and straw from a grower-collector	Annex 4	01-03-2017
	With amendment of Annex 4, Annex 8 has become redundant and shall be deleted.	Annex 8	01-03-2017
	Gatekeeper protocol for transport of hay and straw:  - The list of A-countries is not relevant - inspection of whether the loading compartment is clean and dry can be carried out at the loading site	Annex 9 A 5.2	01-03-2017
	Gatekeeper protocol for inland waterway transport is added	Annex 9 Section B (new)	01-03-2017



Revision no. /	Amendment	Concerns	Final implemen-
<b>Date of approval</b> 4.0 / 05-2018	Additional requirements FAMI-QS added	3	tation date 01-07-2018
4.0 / 03-2010	Additional requirements I Awir-QO added	3	01-07-2010
	Mutual recognition with and AMA-Marketing (pastus+) has been implemented	3	01-07-2018
	Mutual recognition with Oqualim (OQUALIM-RCNA) has been implemented	3	01-07-2018
	Requirements for laboratories are amended. This is related to introduction of Registered Laboratories.	3.9	01-07-2019
	Italy is deleted from the list of original countries of origin	Annex 5	01-10-2018
	Monitoring parameters are adapted		
	Link is added to GMP+ BA10, chapter 3.9 related to the changed requirements for laboratories.		01-07-2019
	Definitions and scope are updated	Annex 6	01-10-2018
	Requirements are adapted or laid down in more clear way for suppliers evaluation, sampling and monitoring, witness audit and resell		
	Several editorial changes	Annex 7	01-07-2018
	The max. FFA level is slightly increased		
	Link is added to GMP+ BA10, chapter 3.9 related to the changed requirements for laboratories.		01-07-2019
	Gatekeeper protocol for purchase of straw is deleted	Annex 8	01-07-2019
	Several editorial changes	Annex 9	01-01-2019
	Austria is added to the list of A-countries	Section A and B	
5.0 / 03-2019	By mistake the FAMI-QS Letter of Approval was mentioned for purchase of additives.	3.3	01-04-2019
	GTAS is deleted as accepted scheme.	3.4/3.6/3.7 Annex 1	
	Use of external 'for foodstuffs only' loading compartments is added.	3.7	
	Annex 6: Annex 2 FSDS is moved to GMP+D2.6 Guidance documents for specific GMP+application	Annex 6	
	Annex 9: Annex hay/straw is moved to GMP+ D2.6 Guidance documents for specific GMP+ application	Annex 9	
	Mutual recognition with Oqualim (OQUALIM-RCNA) has been adapted	3	



Revision no. / Date of approval	Amendment	Concerns	Final implemen- tation date
6.0 / 06-2019	Requirements for Laboratory testing of critical contaminants has been amended.	3.9	01-07-2019
7.0 / 06-2019	Annex 4; introduction of the possibility of benchmarking schemes	Annex 4	27-06-2019
7.1 / 10-2019	Clarification scopes EFISC – GTP	Chapter 3	23-10-2019

#### **Editorial note:**

All changes in this version of the document are made visible. This is how you can recognize:

- New text
- Old text

The changes must be implemented by the participant latest at the final implementation date.



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#### 1. Introduction

#### 1.1 General

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

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

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

With the development of the <u>GMP+ Feed Responsibility Assurance module</u>, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market

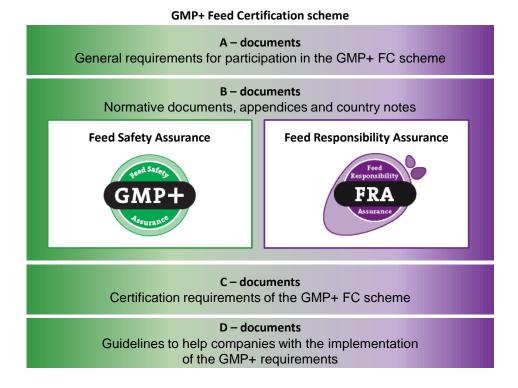
Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

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

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





All these documents are available via the website of GMP+ International (www.gmp-plus.org) .

This document is referred to as GMP+ BA10 *Minimum Requirements for Purchasing* and is part of the GMP+ FSA module.



## 2 Purchasing requirements <sup>1</sup>

A number of GMP+ standards require that a participant may purchase products or services if they

- a. are covered under a GMP+ certificate, or
- b. are covered under a certificate which is accepted as being equivalent In addition, specific feeds may be purchased under so-called Gatekeeper conditions.

This appendix shows further requirements for each of these options.

The following tables show for each product or service to be purchased the required GMP+ certificates with any additional requirements.

These products and services may only be purchased if

- a. the specified certificate is available, and
- b. the additional requirements have been met.

Some products and services are not specified in the table. These products or services can be purchased by a GMP+-certified participant on the condition that the participant carries out his own risk assessment based on HACCP principles and, on the basis of this risk assessment and also the quality assurance implemented by the participant, makes a supplier selection and matches his (entry) check to this.

<sup>&</sup>lt;sup>1</sup>This refers to purchasing by a company that participates in the GMP+FSA module.



Version EN: 27 June 2019

## 3 Overview of GMP+ and equivalent certificates

## 3.1 Purchase of compound feed and semi-manufactured products

Accepted certificates - scopes	Additional requirements
GMP+ B1 - production of compound feed GMP+ B1 - trade in compound feed GMP+ B3 - trade in compound feed	
FCA <sup>2</sup> -BC-02 - MP, production of compound feed FCA -BC-03 - MH, trading of compound feed	
QS-certified producers of compound feed QS-certified traders of compound feed	QS company is listed in the GMP+ companies database, tab <i>Other certification schemes</i> .
UFAS Compound Feed UFAS Merchants - trading of compound feeds	See annex 2.
FAMI-QS - production of Specialty Complementary Feed FAMI-QS - production of Specialty Complementary Dietetic Feed FAMI-QS - trading of Specialty Complementary Feed FAMI-QS - trading of Specialty Complementary Dietetic Feed	<ul> <li>These products are not meant to cover basic animal nutrition.</li> <li>A FAMI-QS Letter of Approval for the scope is required with the FAMI-QS certificate</li> </ul>
OQUALIM-RCNA - certified producers of compound feed OQUALIM-RCNA - certified distributors / traders of compound feed	Oqualim company is certified under the OQUALIM annex 1 "Purchase requirements for goods and services".
pastus+ - certified producers of compound feed pastus+ - certified traders of compound feed	pastus+ company is listed in the GMP+ companies database, tab Other certification schemes.

### 3.2 Purchase of premixtures

Accepted certificates - scopes	Additional requirements
GMP+ B1 - production of premixtures	
GMP+ B1 - trade in premixtures	
GMP+ B3 - trade in premixtures	
FCA -BC-02 - VP, production of premixtures	
FCA -BC-03 - VH, trading of premixtures	
FAMI-QS - production of Premixtures	
FAMI-QS - trading of Premixtures	

<sup>&</sup>lt;sup>2</sup> FCA = Feed Chain Alliance (previous: Ovocom-GMP)



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Accepted certificates - scopes	Additional requirements
QS-certified producers of premixtures	QS company is listed in the GMP+
QS-certified traders of premixtures	companies database, tab Other
	certification schemes.
UFAS Compound Feed	
UFAS Merchants - trading of premixtures	See annex 2.
OQUALIM-RCNA - certified producers of premix-	Oqualim company is certified un-
tures	der the OQUALIM annex 1 "Pur-
OQUALIM-RCNA - certified distributors / traders of	chase requirements for goods and
premixtures	services".

## 3.3 Purchase of feed additives

Accepted certificates - scopes	Additional requirements
GMP+ B1 - production of additives	
GMP+ B1 - trade in additives	
GMP+ B2 - production of additives	
GMP+ B3 - trade in additives	
FCA -BC-02 - TP, production of feed additives	
FCA -BC-03 - TH, trading of feed additives	
FAMI-QS - production of Feed Additives	
FAMI-QS - trading of Feed Additives	
UFAS Merchants - trading of feed ingredients	
FEMAS Core standard	
FEMAS Intermediate Supplier	
QS-certified producers of additives	QS company is listed in the GMP+
QS-certified traders of additives	companies database, tab Other certification schemes.
OQUALIM-RCNA - certified distributors / traders of	Oqualim company is:
feed additives	<ul> <li>producer or distributor of com- pound feed or premixtures, certified under the OQUALIM annex 1 "Purchase require-</li> </ul>
	ments for goods and services".
	or belongs to a group of com- panies of which at least one company is certified as above
See also 3.5 Purchase of feed and other products from non-certified suppliers.	



#### 3.4 Purchase of feed materials

#### 3.4.1 General

The GMP+ participant must verify and make demonstrable that:

- A generic risk assessment for the feed material is included in the GMP+ FSP Product list or in the Positivliste für Einzelfuttermittel, when purchased from QS certified companies. If the product is only included in the Positivliste für Einzelfuttermittel, resale is not permitted.
- If the name of the original manufacturer is listed in the FSP Product list next to a
  mineral feed material, the feed material in question may only be purchased when
  produced by the listed manufacturer. The manufacturer must be certified under
  one of the schemes below.

Accepted certificates - scopes	Additional requirements
GMP+ B1 - production of feed materials GMP+ B1 - trade in feed materials GMP+ B2 - production of feed materials GMP+ B3 - trade in feed materials FCA -BC-02 - GP, production of feed materials FCA -BC-03 - GH, trading of feed materials	
QS-certified producers of feed materials QS-certified traders of feed materials	QS company is listed in the GMP+ companies database, tab <i>Other certification</i> schemes.
FEMAS Core standard FEMAS Intermediate Supplier UFAS Merchants - trading of feed ingredients	See annex 2
IFSA Standard for the Production of Feed Ingredients (IFSA)	Transport to the GMP+ certified company takes place under the GMP+ transport certificate (or transport which has been declared to be equivalent).
EFISC-GTP - Trade/collection of feed materials of vegetable origin.  GTP - Trade/collection of feed materials of	
vegetable origin.	
FAMI-QS - production of Functional Feed Ingredients FAMI-QS - trading in Functional Feed Ingredients	<ul> <li>These products are not meant to cover basic animal nutrition.</li> <li>A FAMI-QS Letter of Approval for the scope is required with the FAMI-QS certificate</li> <li>These products must be registered in the GMP+ FSP Product list .</li> </ul>
<ul> <li>EFISC-GTP</li> <li>Products of the oilseeds crushing and vegetable oil refining industry</li> <li>Products of the starch industry</li> <li>Glycerine (crude and refined) from production of biodiesel</li> </ul>	



Accepted certificates - scopes	Additional requirements
<ul> <li>EFISC</li> <li>Products of the oilseeds crushing and vegetable oil refining industry</li> <li>Products of the starch industry</li> <li>Glycerine (crude and refined) from production of biodiesel</li> <li>pastus+ -certified producers of feed materials pastus+ -certified traders of feed materials</li> </ul>	pastus+ company is listed in the GMP+ companies database, tab Other certification schemes.
OQUALIM-RCNA - certified distributors / traders of feed materials	Oqualim company is:  • producer or distributor of compound feed or premixtures, certified under the OQUALIM annex 1 "Purchase requirements for goods and services".  • or belongs to a group of companies of which at least one company is certified as above
OQUALIM-RCNA – processing of feed materials	Oqualim company is producer of compound feed, certified under the OQUALIM annex 1 "Purchase requirements for goods and services".
See also 3.4.2 Purchase of feed materials from companies with specific certificates.  See also 3.5 Purchase of feed and other products from non-certified suppliers.	



#### 3.4.2 Purchase of feed materials from companies with specific certificates

Some feed materials can also be purchased from a company with a specific certificate. By this is meant:

Feed materials	Approved certificates / special requirements
Combinable crops (grains, (oil-)seeds and legumes	Certificate under the Charte Sécurité Alimentaire (Certification CSA)
-	TASCC Merchants (trading of whole unprocessed combinable crops for food and feed use)
	Note: see annex 2
	QS- Guideline Service Package for agriculture production
	QS company is listed in the GMP+ companies database, tab <i>Other certification schemes</i> .
Bakery waste products	Certificate under the Hygiene Code for the Bread and Confectionery Sector incl. Animal feed expansion module (Netherlands Bakery Centre/ISACert)
Graded consumption potatoes	Certificate under the NAO Hygiene Code small packagers of unpeeled potatoes (Netherlands Potato Organisation)
Whey from farmers	The farmer needs to be admitted to the list of accepted farmers found on www.boerenkaas.nl.

### 3.5 Purchase of feed from non-certified suppliers

Some feeds can also be purchased from a non-certified company, when there is compliance with some additional requirements. By this is meant:

Feeds / Products	Special requirements
Feed additives and silage agents	<ul> <li>Feed additives may be purchased under so-called gatekeeper conditions from companies who are not certified in accordance with one of the specified options. See annex 3 of this appendix GMP+ BA10 Minimum requirements for purchasing.</li> <li>Silage agents may be purchased from not certified suppliers. Only silage agents may be used which are legally permitted.</li> </ul>
Unprocessed agricul- tural products directly from the grower	These products may be purchased with some additional requirements from growers who are not certified in accordance with one of the specified options. See annex 4 to this document.
Unprocessed grains, seeds and legumes	See annex 5 for purchase of unprocessed grains, seeds and legumes.



Feeds / Products	Special requirements	
Intervention grain	See annex 5 for purchase of unprocessed grains, seeds and leg-	
	umes.	
(Former) foodstuff	See annex 6 for the purchase of (former) foodstuff.	
Palm oil	See annex 7 for the purchase of palm oil.	
Dairy raw materials (food grade)	The product is supplied under Dir. (EC) 853/2004 (previously Directive 92/46/EG)	
Intervention skimmed milk powder	-	

## 3.6 Purchase of storage and transshipment

Accepted certificates -scopes	Additional requirements	
GMP+ B1 - storage and transshipment of animal feed		
GMP+ B3 -storage and transshipment of animal feed		
FCA -BC-04 - storage and transshipment of		
animal feed		
TASCC Storage		
EFISC-GTP - storage of feed materials of vegetable		
origin.		
GTP - storage of feed materials of vegetable origin.		
QS-certified companies - storage and transshipment	QS company is listed in the	
	GMP+ companies database, tab	
	Other certification schemes.	
pastus+ -certified companies - storage and transship-	pastus+ company is listed in the	
ment	GMP+ companies database, tab	
	Other certification schemes.	
See also annex 10 of this document for purchase of storage under gatekeeper conditions.		

## 3.7 Purchase of transport

Accepted certificates and scopes	Additional requirements
GMP+ B4 - transport of animal feed, road transport	
GMP+ B4.3 - transport of animal feed, inland waterway	
transport	
FCA -BC-05 - TVWE, road transport of animal feed	
FCA -BC-08 - Hygiene Code for inland	
waterway transport	
TASCC Road Haulage - road transport	See annex 2
Qualimat - road transport	



Accepted certificates and scopes	Additional requirements
QS-certified companies -road transport	QS company is listed in the GMP+ companies database, tab Other certification schemes.
EFISC-GTP transport of feed materials of vegetable origin	Only accepted in combination with EFISC-GTP trade scope.
GTP transport of feed materials of vegetable origin	Only accepted in combination with GTP trade scope.
pastus+ -certified companies -road transport	pastus+ company is listed in the GMP+ companies database, tab Other certification schemes.

- As an exception to the requirement for GMP+-certified transport, GMP+ allows that external carrier for the transport by road of packaged products (including sealed loading units) does not have to be GMP+ certified. Sealed loading units are never the property of or hired by a transport company.
- If "for foodstuffs only" loading compartments are used for transport of vegetable foodstuffs<sup>3</sup> to a feed company, then this external carrier does not have to be GMP+ certified. Such loading compartments are to be marked in a clearly visible and indelible fashion to show that they are used only for the transport of foodstuffs. "For foodstuffs only" loading compartments must be covered by a certification, where application of the HACCP principles is included.

See also annex 9 of this document for purchase of transport under gatekeeper conditions.

#### 3.8 Purchase of affreightment

Accepted certificates - scopes	Additional requirements
GMP+ B4 - affreightment of inland waterway transport	
GMP+ B4 - affreightment of short sea shipping	
GMP+ B4 - affreightment of road transport	
GMP+ B4 - affreightment of rail transport	
GMP+ B4 - affreightment of sea transport	
FCA -BC-07 - TVM, Chartering of animal feed via	
marine transport	
FCA -BC-06 - TVWA, Chartering of animal feed via inland	
waterway	
FCA -BC-09 - TVOR, Transport organization of feed or by	
rail	
QS-certified companies with scope affreightment of rail,	QS company is listed in the
inland waterway and sea ship transport	GMP+ companies data-
	base, tab Other certification
	schemes.

<sup>&</sup>lt;sup>3</sup> Vegetable foodstuffs are all vegetable "substances and products, processed, partially processed or unprocessed, which are intended for consumption by humans or where it may be reasonably expected that they will be consumed by humans" (Re (EC) No 178/2002). This does not include by-products of food industry.



#### **Accepted certificates - scopes**

#### **Additional requirements**

As an exception to the requirement for GMP+-certified freight broker, GMP+ allows that:

- external freight broker for the affreightment of packaged products (including sealed loading units) does not have to be GMP+ FSA-certified or equivalent.
- external freight broker or the principal for the transport of oils and fats and derived products for direct processing in animal feed which demonstrably takes place under a FOSFA contract and where the EU 1 list of acceptable previous loads is used as compulsory, is excluded from mandatory certification for GMP+ B4.

#### 3.9 Laboratory testing

If measurement and monitoring takes place by way of an analysis, the GMP+ participant ensures this is done by a laboratory approved for this under the GMP+ FSA module. The table below shows which laboratory is approved for which analysis

Analysis	Accepted certificates - scopes	Additional requirements
A) Critical contaminants:  - Aflatoxin B1  - Dioxin  - Dioxin-like PCBs  - Non-dioxin-like PCBs  - Heavy metals	GMP+ B11 Registered Laboratory or a laboratory that has applied for registration at a certification body <li>k *</li>	<ul> <li>As long as the GMP+         Registered Laboratory         is registered for the         analysis in question.</li> <li>The use of GMP+ Registered Laboratories is         compulsory as from 1-         7-2019</li> <li>* Laboratory that has         applied for a registration, for the analysis in         question, is accepted         until 1 January 2020.</li> </ul>
B) Other contaminants	GMP+ B10 certified laboratory  ISO17025 accredited laboratory for the analysis in question	The concerning analysis must be under the scope of the GMP+ B10 certificate
	ISO17025 accredited laboratory for another analysis than the one in question  ISO 9001 certified laboratory	Only if the GMP+ participant can motivate why it is not possible to make use of a laboratory which is ISO17025 accredited for the analysis in question.  This motivation must be documented.



Analysis	Accepted certificates - scopes	Additional requirements
	Other quality assurance system	As long as the laboratory produces results in a reliable fashion and that an independent third party has assessed this positively.
		Only if the GMP+ participant can motivate why it is not possible to make use of a laboratory which is ISO17025 accredited for the analysis in question.
		This motivation must be documented.
	TASCC Facilities Testing	-

## 3.10 Purchase of other services

Services	Accepted certificates - scopes	Additional requirements
Production or processing on a contract basis	GMP+ B1 - production of feed materials GMP+ B1 - production of additives GMP+ B1 - production of premixtures GMP+ B1 - production of compound feed GMP+ B2 - production of feed materials GMP+ B2 - production of feed additives	
	FCA, QS, FEMAS, UFAS or FAMI-QS certificate with the corresponding scope	

# ANNEX 1: Additional requirements with respect to GTAS (Gafta)



# ANNEX 2: Additional requirements with respect to UFAS / TASCC /FEMAS

During the process of agreement on compatibility between the British UFAS/TASCC/FEMAS scheme and the GMP+ FSA module the following was agreed with respect to:

#### a. UFAS / FEMAS /TASCC Merchants

GMP+-certified companies may only obtain feed materials from participants in the AIC scheme if a generic risk assessment has been published in the FSP Risk assessments. Further to this, compound feeds may only be obtained if the feed materials used in their processing have a generic risk assessment in the FSP Risk assessments.

#### b. TASCC Road Haulage

The TASCC Road Haulage certificate will be accepted within the GMP+ FSA module on the following conditions

- The transport to the GMP+ company will be carried out by a transport company which is <u>itself</u> TASCC Road Haulage certified and not by a transport company which carries out transport <u>on behalf of</u> a TASCC Road Haulage certified company (a so-called subcontractor).
- The TASCC-certified transport company which carries goods to a GMP+ company will apply the cleaning regimes recorded in the International Database Transport for Feed
  - Reciprocally, the GMP+ FSA certified company will, when transporting goods to participants in the AIC scheme, demonstrably apply the requirements and cleaning regimes recorded in the *TASCC Code of Practice for Road Haulage of Combinable Crops and Animal Feeds*, in particular Section H2, the Exclusion List (Appendix 1) and the Sensitive List (Appendix 2).



## ANNEX 3: Gatekeeper protocol for purchase of additives

The participant may purchase or receive feed additives from a fixed, known supplier who

- a. is not GMP+-certified, or
- is not certified in accordance with an approved standard in the GMP+ FSA mod-

as long as the participant guarantees the feed additive which he introduces into the GMP+ chain complies with the GMP+ requirements from the moment of production.

#### These requirements are:

#### General:

The participant may purchase or receive non-GMP+-feed additives<sup>4</sup> from a regular, well-known supplier as long as the participant guarantees the feed additive which he introduces into the GMP+ chain, complies with the GMP+-requirements. The participant acts in fact as the representative of the supplier of the feed additive.

The participant has entered into a contract with the supplier about the rights and obligations for guaranteeing the GMP+ requirements.

#### HACCP risk assessment and dossier

The participant must carry out a HACCP-based risk assessment per feed additive per supplier. This risk assessment includes at least the following steps:

- Specification of the feed additive including its origin and method of production.
- Process diagram (global/detailed) from the original production of the feed additive up to and including delivery to the gatekeeper. Note: In the risk analysis also all the steps after the original production must be included, like transport, (intermediate) storage, repacking etc.
- Hazard identification + risk assessment per process step.
- Summary of the available general and specific control measures to control the identified risks.
- Monitoring plan + results. Compliance with minimum monitoring requirements if established in the GMP+ FSA module – is necessary.
- The written agreement with the supplier (contract).
- Results of audits by or on behalf of the participant at the supplier/producer. The audits may be carried out by:
  - 1. the participant himself
  - 2. an accredited inspection or certification body commissioned by the participant or supplier

The frequency of monitoring and auditing depends on the risk profile of the feed additive, and the quality assurance, which is applied and demonstrated by the supplier. From an efficiency point of view, the risk assessments of several feed additives, produced in one production process, may be combined.

The participant must further compile a dossier with at least the mentioned items. This dossier must be part of the GMP+-documentation, and must be controlled and updated as such.

<sup>&</sup>lt;sup>4</sup>This includes feed additives with one or more carriers and/or technological additives.



# ANNEX 4: Gatekeeper protocol for purchase of unprocessed agricultural products from the grower / grower-collector

This refers to the purchase of unprocessed agricultural products (such as grains, seeds and legumes) for animal feed and by-products of harvest (e.g. straw). These are purchased from the grower. Besides this, the participant may purchase hay and straw from a grower-collector.

The table below shows schematically the scope of this gatekeeper protocol

Product	Purchased from	This GK protocol applies
Unprocessed agricultural products, including hay and straw	Grower	Yes
Unprocessed agricultural products, <b>including</b> hay and straw	Collector	No
Unprocessed agricultural products, <b>excluding</b> hay and straw	Grower-collector	No
Hay and straw	Grower-collector	Yes

Grower-collector is a grower himself with own harvest equipment and own storage facilities, who collects hay/straw from a group of nearby located growers. The grower-collector takes responsibility for the feed safety of the delivered hay/straw in accordance with the instructions from the GMP+ participant who acts as gatekeeper.

#### General:

The participant should carry out an intensive entry check programme which is based on the implemented risk assessment by him and the quality assurance applied by the grower / grower-collector.

This means, among other things:

- a. Carrying out of a risk assessment from sowing up to and including harvesting including any processing such as own storage and/or transport from the grower. When the grower / grower-collector participates in a certification scheme for growers verified by an independent third-party certification body, the intensity and the size of the entry check can probably be decreased. Examples of such certification schemes for growers are mentioned in the table below. A certification scheme for growers can apply for the benchmark procedure by GMP+ International in order to demonstrate which level of feed safety it guarantees.
  - The results of this benchmark are published on the GMP+ website (see Collaborations Growers schemes) and can be used by the participant as input for the above-mentioned risk assessment.
- b. Making clear how these risks are assured.



c. If the grower / grower-collector contracts out storage and transport then this may only be contracted out to GMP+-certified companies (or those with an equivalent certificate). An exception to this can be contracting out of transport to an agricultural contractor.

If transport by the agricultural contractor takes place

- under responsibility of the grower / grower-collector, and
- immediately following the harvesting, and
- as a part of assignment "harvesting including transport to the storage" then the GMP+ certificate for transport (or equivalent) is not required.

#### Quality assurance agreement

The participant enters into a quality assurance agreement with the grower / grower-collector. The following must be covered:

- a. the control measures which the grower / grower-collector should take
- b. All deliveries of unprocessed agricultural products comply with the maximum levels for undesirable substances<sup>5</sup> (e.g. poisonous plants as Colchium automnale or molds) applicable law and regulations for feed and they do not contain any forbidden products, such as: fertilizer, urine, pesticides, animal products, sludge.
- c. The grower / grower-collector will timely inform the participant in writing in the event that batches of unprocessed agricultural products fail to meet the information and specifications provided, for instance as a result of a calamity, so that the participant can take timely action and block batches.
- d. If any changes occur at the grower / grower-collector causing the above-mentioned to be incorrect, the grower / grower-collector must immediately notify the participant.

In addition to the above-mentioned items, the participant must agree at least the following specific requirements with the grower-collector:

- e. If products are also bought from growers in the area, the grower-collector takes the responsibility to coordinate these requirements with all relevant growers. Demonstrable evidence is provided by the GMP+ participant about the education provided to the grower-collector to assure the risks.
- f. Of all batches, retention samples are taken and retained, that, on request, are available for analysis in case of calamities.

The check on compliance should take place by or on behalf of the participant. Which growers / grower-collectors should be audited depends on the risk assessment of the participant.

#### **Guidance**

It may be decided for reasons of effectiveness to form groups of growers. i.e. growers delivering similar feed materials.

Such a group can be assessed all as one. It is important that:

- a. specific differences between the individual feed materials are examined critically;
- b. the production, storage and transport conditions are equivalent;
- c. no major aspects relating to feed safety are forgotten.

<sup>5</sup> Directive 2002/32/EC

GMP+ International

During the GMP+ audit at the participant both the documentation of the risk analysis and the agreements made with the grower / grower-collector in the form of a contract and its supervision should be clear.

Examples of certification schemes for growers		
Unprocessed agricultural product	Certification scheme	
Consumption potatoes directly from	VVAK Consumption potatoes module	
the growers	VVA Consumption potatoes certificate	
Industrial vegetables directly from	VVAK Industrial vegetables module	
the growers	VIGEF Industrial vegetables certificate	
Grains, seeds and legumes and straw directly from the growers	VVAK Grains, seeds and legumes	
Starch potatoes	VVAK Starch potatoes module	
Sugar beets	VVAK Sugar beets module	
Primary unprocessed products of vegetable origin, directly from the	IKKB Standard for Primary Vegetable Production	
grower	The grower needs to be admitted to the list of certified	
	growers found on	
	http://www.primaryproduction.be/index.php?id=	



# ANNEX 5: Gatekeeper protocol for purchase of grains, seeds and legumes

#### 1. Target group

- a) GMP+ FSA certified companies which purchase the feed materials specified in section 2 originating in a new or other country of origin from a non–GMP+ FSA certified company which is established in a new or other country of origin as specified below.
- b) The GMP+ FSA certified company purchasing intervention grain

#### 2. Feed materials

Grains, (oil-) seeds and legumes in unprocessed form in as far as these appear in the FSP Product list.

#### 3. General requirements

If the feed materials referred to above demonstrably originate from a fully GMP+-FSA certified chain then this is a desirable situation (see also section 9). Each link (from the 1<sup>st</sup> collector through to the final processor) provides the required guarantee in this situation and is therefore certified. In this case the requirements of this protocol do not apply.

lf

- a GMP+FSA certified company purchases the feed materials specified above originating in a new or other country of origin from a non– GMP+ FSA certified company established in a new or other country (see the following schedule), or
- b) a GMP+FSA certified company purchases intervention grain from a non-GMP+FSA certified intervention agency, then he must comply as a minimum with this protocol.



Term	Description	
Countries of origin	a) original countries of origin:  - The Netherlands - UK  - Belgium - Denmark  - Luxembourg - Austria  - Germany - Ireland  - France - Greece  - Canada	The feed materials in question may not be purchased from the specified countries of origin on the basis of this protocol.
	b) other countries of origin. These are all the countries which do not belong to the original countries of origin.	The feed materials in question may be purchased from these countries of origin on the basis of this protocol until a date to be determined.
With respect to the purchase of intervention grain:		
	c) EU countries	Intervention grain can, until a date to be determined, be purchased from EU countries on the basis of this protocol.

Each year (end of September, beginning of October), GMP+ International evaluates together with interested parties which new countries are eligible to be qualified as 'new countries of origin' and an end date for the use of this protocol is established for these countries.

#### Hazard analysis and batch control

The GMP+-certified company carries out its own hazard analysis for the complete preliminary process (cultivation, harvest, collection, transport). On the basis of this hazard analysis and the guarantees which are be provided by the previous links in the chain, the GMP+ FSA certified company makes a selection of the supplier and draws up a monitoring programme which at least complies with the requirements of this protocol. Special attention should be paid to new origins or suppliers. Mycotoxin levels can vary greatly from season to season and should be given special attention especially at the beginning of each season.

N.B. The generic risk assessments published on the website of GMP+ International show that the following risks can be well controlled but do require the necessary attention:

- a. residues of crop protection agents
- b. residues of pesticides
- c. microbiological quality
- d. mycotoxins
- e. heavy metals.
- f. dioxins and dioxin-like PCBs

#### Shipper

If the GMP+ FSA certified company specified above purchases a batch of feed materials from a non-GMP+ FSA certified company and sells this on f.o.b. to a GMP+ FSA certified client (= shipper), then this client (shipper) must observe the obligations arising from this protocol. The initial buyer should makes this known to his client (shipper) in writing.



#### 4. Inspection frequency

#### 4.1 General

Monitoring must be according the requirements as laid down in GMP+ BA4 *Minimum requirements for Sampling and Analysis*, with as a minimum the requirements in the next sections.

#### 4.2 Frequency of sampling and inspection

A representative (end) sample should be put together per specified unit (at the latest during loading).

Transport	Sampling	Inspection
Ship	1 per hold	Each sample
Lighter/coaster:	1 per lighter/coaster	Each sample
Train	1 per train	Each sample
Vehicle.	1 per vehicle	Every 20 <sup>th</sup> sample

#### Ex storage location – direct delivery final recipient (prior to loading)

It is possible to separate a batch at a storage location within the framework of direct transport per road vehicle or train. An independent sample-taker can then, at the request of the manufacturer/supplier, take a representative sample from this batch. This sample can be examined and the results of the sample be considered representative for this batch. Direct delivery of this batch to the final recipient may then take place by road vehicle or train.

The following requirements apply:

- a. In the event of transport by road vehicle the batch may be a maximum of 1000 tons and in the event of transport by train a maximum of 5000 tons
- The batch should be kept in quarantine (separate and identifiable) at the storage location.
- c. The location must be set up in such a way that representative (cross-section) samples can be taken.

#### 4.3 Monitoring

Parameter	Rejection limit	Remarks/explanation			
The samples will in any event be analysed for the parameters which are summarised below. If the hazard analysis shows that other parameters deserve attention then these					
shoujld be analysed. Parameters for which a statutory norm has been established deserve particular attention. Refer to GMP+ BA1 Specific Feed Safety Limits.					
Crop protection agents and pesticides	See, among others, Directive 91/414/EC and Reg. (EC) 396/2005 as amended.	The inspection must be particulary focused on materials for which within the framework of EU foodstuff legislation or national legislation or regulations an MRL value has been established for			
Hoavy motals (Arso	See Dir. 2002/32/EC or	meat, milk or eggs.  Inspection is not always required for			
Heavy metals (Arse- nic, Lead, Mercury,	GMP+ BA1 Specific	(all) heavy metals. If a heavy metal is			
Cadmium)	Feed Safety Limits	not included in the monitoring programme then this should be supported by the hazard analysis.			



Devenueter	Dejection limit	Demontro/explanation
Parameter	Rejection limit	Remarks/explanation
In the event of artificial direct drying using another fuel than gas: analysis for contamination with toxic components.  - Dioxins - Dioxin-like PCBs - Non-dioxin like PCBs - PAHs	See Reg. (EC)2002/32 or GMP+ BA1 Specific Feed Safety Limits	The inspection for dioxin and PCBs is especially important if there is direct drying using certain fuels. Maize is dried a lot in particular.  In case the gatekeeper has a written statement from the drying company that proves - natural gas is used, or - Indirect drying is applied, the 100% monitoring can be reduced (in accordance with HACCP / core standard).  The whole batch must be kept segregated from the other batches, unless these are tested and approved  Dioxins: A screening using the Calux method is also permitted if (according to the applicable requirements) analy-
Salmonella	Absent in 25 grams	sis is continued if the Calux method indicates that limits are exceeded.  If the product is defined as Salmonella -critical. See GMP+ BA4 Minimum, Requirements for Sampling and Analysis (Protocol P4) for a list of Salmonella -critical feed materials.  At this time none of the feed materials in question (grains, (oil)seeds or legumes) is Salmonella-critical.
HCN	See Dir. 2002/32/EC or GMP+ BA1 Specific Feed Safety Limits	Linseed
Free gossypol	See Dir. 2002/32/EC or GMP+ BA1 Specific Feed Safety Limits	Cotton seed
Rye ergot	See Dir. 2002/32/EC or GMP+ BA1 Specific Feed Safety Limits	Wheat, rye and triticale



Mycotoxins <sup>6</sup>	DON⁴	ОТА	ZEA	AFLA B1
All cereals includ-	X	X	X	
ing rice				
Maize	X	Х	X	X <sup>7</sup>
Soy beans			X	

Other (oil-bearing) seeds and legumes: on the basis of a hazard analysis.

#### 5. Sampling method

In accordance with GAFTA Sampling Rules No. 124. Extra requirements in addition to these rules are:

Sampling position: - As close as possible to the receiving hold (preferably

in the flow)

Instructions to personnel: - As much as possible direct from the flow.

- Use disinfected sampling scoop (alcohol)

- If the scoop is not used then store in protective bag.

- Personal hygiene: use sterile gloves.

- Store interim samples in PE (polyethylene) bags

Equipment: - Scoop – of stainless steel.

- Alcohol 95% to clean scoop in the flame

- Bottles: Sterile glass or PET (Polyethylene tubes) of

500 CC or

- Bags: PE bags of 1.5 litres.

Samples: - Store interim samples as above.

- Mix in sterile location and in sterile conditions.

- Send in sterile bottle or bag as described above.

- Avoid contact with heat / sunlight / damp / equipment.

- Send samples immediately.

During the loading of inland waterway vessels, coasters, trains or road vehicles:

 Per inland waterway vessel, train, coaster at least 20 random sub-samples, via 'grabs/scoops' of max. 1 kg.

b. by vehicle at least 10 random sub-samples, via 'grabs/scoops' of max. 1 kg.

The other working methods to be derived from the sampling method described above. The basic principle should be that a representative sample is taken. In addition, the sampling requirements in the GMP+ Feed Safety Assurance module apply (see GMP+ BA13 *Minimum Requirements for Sampling*).

#### 6. Analysis method

The analyses will be carried out by a laboratory approved for this under the GMP+ FSA module. See section 3.9 in GMP+ BA10 *Minimum requirements for Purchasing*.

#### 7. Corrective actions

In accordance with the GMP+ FSA requirements.

<sup>&</sup>lt;sup>7</sup> Note: Beside batch by batch monitoring, overall requirements from Aflatoxin B1 protocol must be fulfilled



<sup>&</sup>lt;sup>6</sup> DON= Deoxynivalenol; OTA=Ochratoxin A; ZEA=Zealarenon; AFLA B1 = Aflatoxin B1

#### 8. Reporting analysis results

The results of the determinations should be provided at least once per month to the GMP+ Monitoring database. Results from the analysis must be shared with the GMP+ Community in the GMP+ Monitoring database.

#### 9. Informing customers

A participant who applies this protocol must on request inform his customer of the results of the tests on the delivered batch. Should several certificates of analysis relate to a certain batch (compound batch), all these certificates must be delivered to the customer.

#### **Explanation**

#### General

A prerequisite in the GMP+ FSA module is that feed materials may only be obtained from GMP+-certified companies. The opportunity is created for each feed material to obtain it from a non-GMP+ FSA certified company because of special market conditions. The buyer must then meet a number of additional requirements. For the purchase of grains, (oil)seeds and legumes an exception has been established to the prerequisite (this protocol).

#### **Application**

This protocol is intended to be used during the purchase of grains, (oil)seeds and legumes from a not fully (GMP+ FSA) certified chain from outside the original countries of origin.

- a. This protocol cannot be used if the feed materials in question come from the socalled original countries of origin. The purchase of the specified feed materials from these countries can only be done from a fully (GMP+ FSA)-certified chain.
- b. A GMP+ FSA certified trading company should, if his purchaser (as shipper) applies this protocol, comply with all other GMP+ FSA requirements except the purchasing.

#### **Transport**

The transport of a batch once the (final) samples have been taken must comply with the relevant GMP+ FSA transport requirements. The following GMP+ FSA standards have been adopted with respect to the guaranteeing of various forms of transport:

- a. GMP+ B4 Transport (Road & rail transport and affreightment)
- b. GMP+ B4.3 Inland Waterways Transport

These standards can be found on the GMP+ International's website ( www.gmpplus.org ) .

The GMP+ transport requirements apply during purchase according to this protocol.



## ANNEX 6: Gatekeeper protocol for purchase of (former) foodstuffs

### 1. Objective

This gatekeeper protocol gives requirements for purchasing foodstuff and former foodstuff, intended for use as feed, from a non-GMP+ FSA (or equivalent) certified food company.

### 2. Definitions

Term	Description
Foodstuff (intended for use as feed)	Finished food products, which were manufactured for human consumption in full compliance with relevant national legislation and labelled as foodstuff by the food company, but which
	are no longer intended for human consumption due to practi- cal, logistical or commercial reasons and do not present any health risks when used as feed.
Former foodstuff (intended for use as feed)	Finished and semi-finished foodstuff and food ingredients, which were manufactured for human consumption, but not labelled as foodstuff by the food company and no longer intended for human consumption due to problems of manufacturing or packaging defects or other defects and do not present any health risks when used as feed.
Semi-finished food- stuff	A product which has already been processed, but which requires further processing into a finished food product.
Food ingredients	Any substance that as such or in a mixture is used in the manufacture or preparation of a foodstuff and present in the final product.
Raw material for foodstuff	Products used for manufacturing or processing of a food ingredient or semi-finished foodstuff.
By-products	Feed materials that are produced as a by-product from the food production and which are neither intended nor suitable as food.
Feed additives	Substances, micro-organisms and preparations which are not feed materials or premixtures and which are added deliberately to animal feed or water with the intention of achieving one or more of the following functions. The additive must:  a) favourably influence the characteristics of the animal feed, b) favourably influence the characteristics of animal products, c) favourably influence the colours of decorative fish and birds,
	d) comply with the nutritional requirements of animals, e) favourably influence the environmental effect of animal production, f) favourably influence animal production, performance or welfare especially by working on the stomach and intestinal bacteria or on the digestibility of the animal feeds, or g) bring about a coccidiostatic or histomonostatic effect.
Prohibited products	Products which are neither intended nor suitable for human consumption and/or products of which the circulation and use in animal feed is prohibited as specified in GMP+ BA3 <i>Minimum Requirements Negative List</i> .



#### 3. Scope and application

#### 3.1 Products and origin

This protocol applies to:

- foodstuff (intended for use as feed) as defined in 2 from any country of origin
- former foodstuff (intended for use as feed) as defined in 2 from any country of origin.

This protocol <u>cannot be used</u> for the purchase of the following products:

- raw material for foodstuff, as defined in 2
- By-products originating from the food industry (e.g. beet pulp, brewers' grain, etc) and manufactured for animal feed.
- feed additives, as defined in 2
- prohibited products, as defined in 2.

#### Guidance

Note: this protocol is not meant to be used for the purchase of products for which already purchase requirements have been established elsewhere in GMP+ BA10 *Minimum Requirements for Purchasing*, e.g. dairy raw materials (food grade) and palm oil.

#### 3.2 Companies

This protocol applies to the participant that:

- purchases (former) foodstuff intended for use as feed <u>directly</u> from a non-GMP+ FSA (or equivalent) certified food company. This food company has at least a written HACCP plan, which is based on HACCP principles and includes the control of hazards related to the (former) foodstuff that is being purchased, and
- is certified for a production scope in order to process the (former) foodstuff into a feed.

The protocol may also be applied by the participant who is certified for a trade scope under conditions. See 4.7.3 for the conditions.

#### Guidance

Meant is the food company, which is not certified in accordance with GMP+ International or one of the following schemes: FEMAS, FCA, EFISC-GTP and QS.

This protocol <u>is not applicable</u> when (former) foodstuff demonstrably originates from a GMP+ FSA (or equivalent) certified food company. The GMP+ FSA certified food company must bring the production of (former) foodstuff intended for use as feed under the scope of his GMP+ FSA certificate in case he wants to sell the (former) foodstuff to participants.

Note: the purchase of (former) foodstuff is only possible with approval from GMP+ International. The participant must apply for an exemption for the purchase of (former) foodstuff.

Only when this exemption is provided by GMP+ International, the participant may purchase (former) foodstuff from a non-GMP+ FSA (or equivalent) certified food company.



#### Guidance

The approval can be applied for by filling in the Exemptions Form on the GMP+ Portal.

#### 4. Requirements for the gatekeeper

#### 4.1 General

(Former) foodstuff, intended for use as feed must comply with relevant animal feed legislation and GMP+ FSA requirements. It is up to the participant that purchases (former) foodstuff to guarantee compliance with all relevant feed legislation and GMP+ FSA requirements.

#### <u>Guidance</u>

All (former) foodstuff used in feed are considered feed materials. The participant must ensure the former foodstuff which is purchased or received is included in a (generic) risk assessment (FSP).

This requirement does not apply to foodstuff.

If the participant wants to purchase a former foodstuff for which there is no (generic) risk assessment in the Feed Support Products (FSP) of GMP+ International or the participant is not sure whether the above mentioned requirement is applicable to the product it wants to purchase, GMP+ International (info@gmpplus.org) must be contacted for further information.

#### 4.2 Application of HACCP principles

The participant carries out a risk assessment per supplying food company per (former) foodstuff (or group of (former) foodstuffs). The risk assessment is based on HACCP principles as laid down in the B-standard applicable to the participant who applies this protocol.

The risk assessment encompasses all operations and activities, from original production of the (former) foodstuff, including the ingredients/raw materials, up to delivery to the participant purchasing the (former) foodstuff, and must result in addressing and controlling all hazards related to the (former) foodstuffs.

Results of this risk assessment must be laid down in a Feed Safety Data Sheet (FSDS), see section 4.6 below.



#### 4.3 Supplier evaluation

#### 4.3.1 Desk study

A desk study is carried out per supplying food company per (former) foodstuff (or group of (former) foodstuffs).

The gatekeeper must gather and assess as much as possible information about:

- the supplier
- the (former) foodstuff: a complete specification/FSDS
- the production process:
  - o a clear process description/process diagram
  - o which raw materials and processing aids are used
  - o other activities or circumstances (transport, storage)

#### Guidance:

Information should at least be focussed on safety aspects and must encompass

- the pre-production phases of the (former) foodstuff insofar these are relevant for identifying and assessing possible hazards. This may concern (production of) raw materials, use of processing aids and technological additives used in the production of the feed material.
- all post-production activities of the (former) foodstuff phases until delivery to the gatekeeper, including transport, (temporary) storage, repackaging etc.

Questionnaires can be very helpful to obtain information in a structured way.

- the results of the supplier's risk assessment
  - o The risks: What are the identified risks of the production process?
  - o The controls: What control measures have been taken?
  - o The monitoring: What monitoring is carried out?
- guarantees:
  - o Is there a safety standard implemented?
  - o What certification does supplier have?
- other relevant information.

#### 4.3.2 Supplier audit

Each year, the participant performs a supplier audit at the food company. In case the food company is certified for BRC including Module 9, 1 audit / 2 year is sufficient.

The participant performs in any case an audit prior to any initial delivery of (former) foodstuffs (or group of (former) foodstuffs) and in case of significant changes in the product and/or production process.

The participant who wishes to conduct the supplier audit but does not have qualified supplier auditors, may delegate the conduction of these audits. See Annex 1 for the qualifications of the supplier auditor.



#### 4.4 Sampling and monitoring

Samples of (former) foodstuff must be taken in sufficient quantity by a procedure preestablished by the participant and be retained. Sampling is done in accordance with the requirements as laid down in the GMP+ B-standard applicable to the participant who applies this protocol.

A monitoring plan must be drawn up in writing and implemented which includes in particular the control of critical points in the production process. Monitoring is done in accordance with HACCP principles as laid down in the GMP+ B-standard applicable to the participant who applies this protocol.

#### 4.5 Witness audit (third party audit)

The participant gives full cooperation to the verification of the supplier audit by his certification body.

The auditor of the certification body is independent with respect to the audited supplier.

No witness audit will be performed during the initial supplier audit by the participant at the supplier.

Minimum number of witness audits per year depends on number of suppliers that are assured by the participant and is calculated as follows:

- 1-10 suppliers = 1 witness audit / 3 years
- 11- 50 suppliers = 1 witness audit /2 years
- 51-100 suppliers = 1 witness audits / year
- Over 100 suppliers = 2 witness audits / year

The auditor of the certification body selects, risk-based and in consultation with the participant, which suppliers are visited. Logistical reasons should be an important selection criterion.

No witness audit is required in case the supplier audit is conducted by a qualified auditor of a certification body.

#### 4.6 Records

The participant creates a feed safety data sheet (FSDS) in cooperation with the supplier per product and per supplier. This can also be another document (e.g. a specification or agreement), provided that it includes the same elements as the FSDS. See GMP+ D2.6 Guidance documents for specific GMP+ application and website for an example of an FSDS.

The FSDS or equivalent document is completed under the responsibility of both the participant and the non-GMP+ FSA (or equivalent) certified food company and has to be signed by both parties. In case of changes in the product and/or production process, but at least once per three years, the FSDS is being reviewed and updated.

#### Guidance

The Feed Safety Data Sheet is meant to give information about the (former) foodstuff in order to assess possible risks and to decide about proper use in feed.



The FSDS gives a description and specification of the (former) foodstuffs intended for feed (including data of identification and production, including information from the HACCP analysis, used ingredients, indication of chemical composition, relevant product standards, instruction about storage and transport, labelling, monitoring, etc.).

The FSDS includes a statement that the (former) foodstuff was produced under a HACCP-system; a quality system that is HACCP certified or at least is based on a written HACCP plan. This may be a self-declaration from the food company but preferably accompanied by independent evidence, like a certificate. Another important element of the FSDS is a statement about the reason for placing the (former) foodstuff on the feed market.

The participant has a written agreement (contract) with the food company about the rights and obligations for guaranteeing the requirements as specified in this protocol.

#### 4.7 Other

#### 4.7.1 Information

Each purchased batch of (former) foodstuff intended for use as feed must be accompanied by a trade document, which refers to the FSDS or equivalent document.

#### 4.7.2 Processing

The participant purchasing (former) foodstuff that is not yet suitable as feed material must process the product into a feed material first. A validated treatment or cleaning must be performed to remove physical contaminants (e.g. glass, plastic, metal) before the (former) foodstuffs can become intended for feed. The treatment or cleaning must be in accordance with scheme requirements.

#### <u>4.7.3 Resell</u>

Resell of (former) foodstuff that has to receive a validated treatment or cleaning to remove physical contaminants (e.g. glass, plastic, metal) before becoming suitable for feed is possible (by exception) under the next conditions:

- Under the scope Trade;
- To a company with a Production scope for further processing into a feed material;
- There is a clear agreement between this 'gatekeeper' and the final producer; this agreement gives guarantees about the responsibilities for buying according to the requirement of this protocol, and about correct processing into a feed material;
- All relevant information about the necessary processing of the (former) foodstuff into a feed material must be provided (=the (former) foodstuff is accompanied with the FSDS and all the necessary information in accordance with the requirements as laid down in Annex VIII of Regulation (EC) No. 767/2009.)
- The processor of the (former) foodstuff must be involved in the supplier audit of the food company concerned.



## Annex 1 Qualifications of the supplier auditor

r	T=
Element	Requirements for the supplier auditor
Education/training	Relevant agricultural or foodstuffs education/training.
	Training for internal auditor or another, equivalent, auditor
	training with respect to methods and techniques aimed at
	the assessment of feed safety management systems.
Knowledge	Knowledge about:
	- HACCP feed and HACCP food (control of risks)
	- Prerequisites programs (PRP's) related to (former)
	foodstuffs intended for feed; and
	- Own feed certification scheme; and
	- Feed legislation and/or food legislation
Work experience	Minimum 1 year working experience of in the feed / food
	sector in a relevant position (for example quality assurance
	or purchase of (former) foodstuffs.
Independence/ impar-	The supplier auditor must have an independent position in
tiality	relation to the supplier and to commercial activities of the
	feed company. This should be reflected in the job descrip-
	tion of the supplier auditor and the organization chart of
	the company. The supplier auditor conforms to the strict
	implementation of the gatekeeper protocol.
Outsourcing of	A gatekeeper who wishes to conduct a supplier audit but
supplier audits	does not have qualified supplier auditors, may delegate
	the conduction of these audits.



# ANNEX 7: Gatekeeper protocol for purchase of GMQ Palm Oil

#### 1. Scope

The Palm Oil Gatekeeper Protocol can be used for buying normal, main stream, Good Merchantable Quality (GMQ) Crude, Refined and/or Fractionated Palm Oil and Palm kernel Oil, (as defined in the EU Feed Catalogue 68/2013 under No. 2.20.1) from a non-GMP+ FSA certified origin.

#### 1.1 Companies

This protocol applies to companies which receive CIF shipments of crude, refined and/or fractionated palm (kernel) oil.

#### 1.2. Products

Crude, refined and/or fractionated palm (kernel) oil, referred to hereafter by the term 'palm oil'. See also paragraph 2.

#### Guidance:

This means the fats and oils from the palm (kernel) oil industry. These may be the crude oils and fats or also fractionated (olein and stearin fraction) and refined oils and fats. This protocol cannot be used for the remainder fractions such as palm acid oils - fatty acid distillates.

#### 2. General conditions

The palm oil which falls under this protocol must be of Good Merchantable Quality (GMQ) as laid down in FOSFA contracts. The protocol applies to CIF contract numbers 53, 54, 80 and 81 of FOSFA.

GMQ must be proved and verified (via FFA% and documentation evidence; see for this resp. paragraph 3 and 4)

- 1. When FOB in port of loading max 7 %
- 2. When CIF in port of arrival max 10%.

If FFA level is above 10% in port of arrival, this protocol cannot be used



### 3. Specific conditions

The safety of palm oil for feed must be guaranteed by compliance with the requirements laid down in this protocol.

### 3.1. Requirements regarding safety

During sea transport the rules apply as laid down in the manual "FOSFA qualifications and procedures for vessels engaged in the carriage of oils and fats in bulk for edible and oleo chemical use".

The rules from the FOSFA manual are the basis for the FOSFA-53, 54, 80 and 81 contracts for CIF delivery of palm oil. With respect to quality, these rules include, among other things:

- a. the obligation that the batches supplied must be of good merchantable quality ("GMQ")
- b. the use of steam and hot water as a heating agent
- c. effective cleaning of ships tanks, according to the FOSFA qualifications and operational procedures for ships engaged in the carriage of oils and fats in bulk
- d. loading and unloading inspection by FOSFA Recognized Superintendents
- e. sampling according to section 3.5.
- f. tracing back to land tanks in the export ports
- g. previous cargoes in sea vessels:
  - in loading compartments of stainless steel or which are covered with epoxy resin or with a technically equivalent coating, then the last cargo which is transported in the tank should be a foodstuff or should appear on the EU list of acceptable previous cargoes (see EU Directive 852/2004, amended by EU Commission Directive 579/2014);
  - if the palm oil is transported in a vessel with tanks of materials other than specified above then the previous three loads transported in the tank should be foodstuffs or should appear on the EU list of acceptable previous cargoes (see EU Directive 852/2004, amended by EU Commission Directive 579/2014);

#### 3.2 Documentation evidence

The company that have imported palm oil under this protocol should be able to provide documentation evidence for auditing and certification purposes that the palm oil is imported under FOSFA contracts and requirements. The following documents as stipulated in the FOSFA contracts that must be available:

- FOSFA (short form) contract
- Bill of Lading
- FOSFA Certificate of Compliance, Cleanliness and Suitability of Ship's Tank
- Certificate of Analysis, both at time of shipment and in port of arrival, in country of destination

#### Guidance:

See for examples of this documentation GMP+ D2.6 'Guidance documents for specific GMP+ application',



# 3.3 Analysis in port of loading

GMQ must be demonstrated by a FFA analysis. For each seagoing vessel in port of loading, each batch is analysed for FFA. At time of shipment, FFA must not exceed 7.

# 3.4 Analysis in port of arrival

Of a seagoing vessel in port of arrival in country of destination, the following substances must be analysed:

Substance	Gasoil		
Rejection limit	25 mg/kg (ppm) total hydrocarbon compounds (C10-C24) calculated as diesel oil	or	400 mg/kg (ppm) total hydrocarbons (C10-C40)
Analysis method	GC-MS		GC-FID
Inspection frequency	Each batch		Each batch

Substance	Pesticides residues
Rejection limit	Maximum residue limits for pesticides as laid down in Regulation (EC) No. 396/2005 and Directive 2002/32/EC
Inspection frequency	Every half year

Substance	Dioxin and dioxin like PCB's
Rejection limit	0.75 ng WHO-PCDD/F-TEQ/kg for dioxin 1.5 ng WHO-PCDD/FPCB-TEQ/kg for dioxin like PCB's
Inspection frequency	Once in 3 months, varied origins

Substance	Heavy metals	
Rejection limit	Lead: 10 mg/kg	
	Cadmium: 1 mg/kg	
	Arsenic: 2 mg/kg	
	Mercury: 0.1 mg/kg	
Inspection frequency	On the basis of a hazard analysis but at least once per	
	year	

Substance	Free Fatty Acids (FFA)
	In port of arrival max. 10%
Inspection frequency	Each batch



# Minimum Requirements for Purchasing - BA 10

## 3. 5 Sampling method

Sampling in accordance with NEN-EN-ISO method 5555.

## 3.6. Analysis method

All analysis must be carried out by a laboratory approved for this under the GMP+ FSA module. See section 3.9 in GMP+ BA10 *Minimum requirements for Purchasing*.

# 3.7 Provision of results

The results of the determinations should be provided at least quarterly to the GMP+ Monitoring database. Results from the analysis must be shared with the GMP+ Community in the GMP+ Monitoring database.



# ANNEX 9: Gatekeeper protocol for transport

#### 1. Introduction

This protocol applies to GMP+ certified producers and traders (referred to hereafter as participants) which intend to use non-certified transport companies for transport of the GMP+ products specified in section 2 by road or by inland waterways.

This protocol give requirements for assuring non-certified transport outside so-called A-countries. See for more information sections A and B.

Note: This protocol does not apply to transport of unprocessed agricultural products by the grower himself. The relevant requirements for this situation are laid down in Annex 4 of this document.

### 2. GMP+ products

GMP+ assured feed and feed ingredients intended for GMP+ certified companies.

### 3. Application

In a number of European countries, a large number of transporters are certified via participation in the GMP+ FSA module, but also via participation in equivalent, approved schemes. In these so-called A-countries (see the sections A and B) only certified transport can be used for the transport of GMP+ products, and this protocol cannot be applied.

Also transport must be certified, if the origin is located outside one of these A-countries, but the destination is a GMP+ certified company within one of these A-countries.

### Section A: Gatekeeper protocol for road transport

This protocol can only be applied to assure road transport outside these A-countries.

### A-countries for road transport

- Austria (from 01.01.2019)
- Belgium
- Czech Republic
- Germany
- France
- Poland
- The Netherlands
- United Kingdom

As an exception, this protocol can also be applied within these A-countries for the transport of <u>unprocessed agricultural products during harvest</u> and the transport of <u>hay</u> and straw. Specific conditions must be met, which are laid down in this protocol.



The requirements for road transport are summarized in the following table.

Origin	Destination	Transport	An exemption for	Sections applicable
A-countries	A-countries	Certified	Harvest period, gatekeeper protocol section A	§A4; §A5.1; §A6
			Hay and straw, gate- keeper protocol sec- tion A	§A4; §A5.2; §A6
A-countries	Other countries	Certified	Harvest period, gatekeeper protocol section A	§A4; §A5.1; §A6
			Hay and straw, gate- keeper protocol sec- tion A	§A4; §A5.2; §A6
Other countries	A-countries	Certified	Harvest period, gatekeeper protocol section A	§A4; §A5.1; §A6
			Hay and straw, gate- keeper protocol sec- tion A	§A4; §A5.2; §A6
Other countries	Other countries	Certified or Gatekeeper (this protocol, section A4)		

Each year GMP+ International evaluates together with involved parties how road transport certification is progressing in various countries and an end date may be established for the use of this protocol in those countries.

## A4. General requirements

The participant guarantees that non-certified transport companies, which transport GMP+ products, comply with the GMP+ requirements.

When making use of non-certified transport companies the participant must apply the requirements of this section.

#### A 4.1 General

- The participant enters into a quality assurance agreement with the non-certified transporter which covers the rights and obligations relating to the guaranteeing of the GMP+ requirements.
- b. Assured transport company must be thoroughly instructed in the relevant transport requirements (cleaning and/or disinfection in accordance with the IDTF, keeping records as part of T&T, what to do in the event of the determination of aberrant load etc.). This should offer guarantees equivalent to GMP+ with respect to the transport of GMP+ products.
- c. Compliance with the agreements made will be checked by the participant by way of an inspection.



#### A 4.2 Initial inspection

The participant should have insight into the following details relating to the loading compartments to be used:

- a. A record for each loading compartment with details of at least 3 previous loads. If prohibited loads have been transported, the loading compartment must be released for the transport of animal feed products in accordance with the release procedure.
- b. Details for each loading compartment about the cleaning and disinfection procedures which are carried out. Cleaning and disinfection must at least comply with the requirements in the IDTF).

The participant carries out an initial inspection to verify the above. If the result of the inspection is positive then the loading compartment is approved for the transport of GMP+ products.

If the required data are not available, the loading compartment must be released in accordance with the release procedure specified in section *Procedures* on the IDTF website, before transport of GMP+ assured feed and feed ingredients.

This inspection must be carried out by a loading inspector. A 'loading inspector' is a position for which the details are specified in the quality system of the participant. This role is fulfilled by an employee who, on the basis of training and experience, has the knowledge and skills required for the inspection of a loading compartment for its suitability for the loading of feeds. If a participant does not have his own loading inspector then he may be hired from an independent certification body or inspection agency. The loading inspector must of course meet the criteria set.

The loading compartments used will be unambiguously recorded in the documentation of the feed safety management system.

#### A 4.3 Periodic inspection

During the assurance period the participant must periodically carry out a check of the following details with respect to the transporters:

- a. Details for each loading compartment about the cleaning and disinfection procedures which are carried out.
- b. Details of the cleaning inspection which was carried out prior to the loading of the loading compartment.
- c. Details of the inspections carried out for each loading compartment.

#### A 5. Additional requirements

In addition to the general requirements, the participant must also meet specific requirements when assuring transport of unprocessed agricultural products during harvest (A 5.1) and transport of hay and straw (A 5.2).

### A 5.1 Transport of unprocessed agricultural products during harvest

It is permitted to use non-certified transport for transport of unprocessed agricultural products during harvest with a maximum of 90 days in sum per year, which can also be non-consecutive, in the event of:

- a. transport directly from the grower;
- b. internal transport between storages.



#### A 5.2 Transport of hay and straw

For the transport of hay and straw remains permitted to use non certified transport under the following conditions:

- Only flatbed / curtain siders trucks are used. The loading compartment must be clean and dry, completely emptied and free of load remains and odour from previous loads.
- b. The delivery address can only be a GMP+ certified company, where a qualified employee checks the products and the loading, and/or,
  - the GMP+ certified participant who applies this gatekeeper protocol makes sure that, when loading the hay/straw, the inspection of the vehicle is carried out by the loader (loading site). This assessment is documented by means of a written agreement (see GMP+ D2.6 Guidance documents for specific GMP+ application & website for an example of a written agreement. In case of deviations, the loading process is halted and the GMP+ certified participant is informed.

The signed written agreement must be kept in the administrative records of the participant for at least three years.

### A 6. Registration of the assured transport companies<sup>8</sup>

A GMP+ certified participant who applies this protocol registers the name, address and registered offices of all transporters assured by him in the GMP+ Companies database. The participant is responsible for keeping the details up to date.

<sup>&</sup>lt;sup>8</sup>For technical reasons, at this moment registration of assured transporter in the GMP+ Companies database is not possible. This requirement will come into force in due time. Companies and CB's will be informed.



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## Section B: Gatekeeper protocol for inland waterway transport (NEW)

This protocol can only be applied to assure transport by inland waterways outside these A-countries.

### A-countries for inland waterway transport

- Austria (from 01.01.2019)
- Belgium
- Czech Republic
- Germany
- France
- Poland
- The Netherlands

The requirements for transport by inland waterway are summarized in the following table:

Origin	Destination	Barges
A-countries	A-countries	Certified
A-countries	Others	Certified
Other countries	A-countries	Certified
Other countries	A-countries	Certified
Other countries	Other countries	Certified or Gatekeeper (this protocol, section B)

### **B4. General requirements**

The participant guarantees that non-certified barges, which transport GMP+ products, comply with the GMP+ requirements.

When making use of non-certified barges the participant must apply the requirements of this section.

## **B4.1 General**

- a. The participant enters into a quality assurance agreement with the owner of the non-certified barge which covers the rights and obligations relating to the guaranteeing of the GMP+ requirements.
- b. Assured barge must be thoroughly instructed in the relevant transport requirements (cleaning and/or disinfection in accordance with the GMP+ B4.3 Short Sea Shipping and Inland Waterways Transport, Annex 1, keeping records as part of T&T, what to do in the event of the determination of aberrant load etc.). This should offer guarantees equivalent to GMP+ with respect to the transport of GMP+ products.
- c. Compliance with the agreements made will be checked by the participant by way of an inspection.



#### **B4.2 Initial inspection**

The participant should have insight into the following details relating to the loading compartments to be used:

- a. A record for each loading compartment with details of at least 3 previous loads. If prohibited loads have been transported, the loading compartment must be released for the transport of animal feed products in accordance with the release procedure for inland waterway transport, specified in section *Procedures* on the IDTF website.
- b. Details for each loading compartment about the cleaning and disinfection procedures which are carried out. Cleaning and disinfection must at least comply with the requirements in the GMP+ B4.3 *Short Sea Shipping and Inland Waterways Transport*, Annex 1).

The participant sees to it that the initial LCI is carried out by the CO [Control Organisation] certified (ISO 17020 or equivalent) for that purpose, in accordance with the GMP+ requirements. If the result of the inspection is positive then the loading compartment is approved for the transport of GMP+ products.

If the required data are not available, the loading compartment must be released in accordance with the release procedure for inland waterway transport before transport of GMP+ assured feed and feed ingredients.

The loading compartments used will be unambiguously recorded in the documentation of the feed safety management system of the participant.

#### B5. Registration of the assured barges<sup>9</sup>

A GMP+ certified participant who applies this protocol registers the name, address and registered offices of all owners of barges together with names of barges assured by him in the GMP+ Companies database. The participant is responsible for keeping the details up to date.

<sup>&</sup>lt;sup>9</sup>For technical reasons, at this moment registration of assured transporter in the GMP+ Companies database is not possible. This requirement will come into force in due time. Companies and CB's will be informed.



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# ANNEX 10: Gatekeeper protocol for storage and transshipment

#### 1. Introduction

This protocol applies to GMP+ certified producers and traders (referred to hereafter as participants) which intend to use non-certified companies for storage and transshipment of the GMP+ products specified in section 2.

This protocol give requirements for assuring non-certified storage and transshipment outside so-called A-countries. See for more information section 3.

## 2. GMP+ products

GMP+ assured feed and feed ingredients intended for GMP+ certified companies.

#### 3. Application

In a number of European countries, a large number of storage and transshipment companies are certified via participation in the GMP+ FSA module, but also via participation in equivalent, approved schemes. In these so-called A-countries (see the table below) as from 1-1-2016 only certified companies can be used for storage and transshipment of GMP+ products, and this protocol cannot be applied.

#### A-countries

- The Netherlands
- Belgium
- Germany
- United Kingdom

So, this protocol can only be applied to assure storage and transshipment outside these A-countries.

As an exception, this protocol can also be applied within these A-countries in the following cases:

- a. Bulk storage <u>at the grower</u> immediately following the harvesting of vegetable primary products.
- b. Temporary (less than 6 consecutive months) bulk storage or transshipment immediately following the harvesting of vegetable primary products.
- c. Storage and transshipment of packaged feeds.

Specific conditions must be met, which are laid down in chapters 4 and 5 of this protocol.

Each year GMP+ International evaluates together with involved parties how certification of storage and transshipment is progressing in various countries and an end date may be established for the use of this protocol in those countries.



#### 4. General requirements

The participant guarantees that non-certified companies, which store and tranship GMP+ products, comply with the GMP+ requirements.

When making use of non-certified storage and transshipment companies the participant must apply the requirements of this section.

#### 4.1 General

- The participant enters into a quality assurance agreement with the non-certified storage and transshipment company which covers the rights and obligations relating to the guaranteeing of the GMP+ requirements.
- b. The participant should establish that the storage and transshipment company complies with all the applicable legal obligations relating to feed.<sup>10</sup>
- c. Assured storage and transshipment company must be thoroughly instructed in the relevant requirements (hygiene, keeping records as part of T&T, pest control, what to do in the event of the determination of aberrant feed product etc.). This should offer guarantees equivalent to GMP+ with respect to the storage and transshipment of GMP+ products.

### 4.2 Initial inspection

The participant carries out an initial inspection at the non-certified storage and transshipment company to verify the above. If the result of the inspection is positive then the location is approved for storage and transshipment of GMP+ products.

This inspection must be carried out by an employee who demonstrably, on the basis of training and experience, has the knowledge and skills required for the inspection of locations for their suitability for storage and transshipment of feeds. Also an inspector may be hired from an independent certification body or inspection agency. The inspector must of course meet the criteria set.

#### 4.3 Periodic inspection

During the assurance period the participant must periodically carry out a check of compliance with the agreements made.

### 5. Registration of the assured storage and transshipment companies<sup>11</sup>

A GMP+ certified participant who applies this protocol registers the name, address and registered offices of all storage and transshipment companies assured by him in the GMP+ Companies database. The participant is responsible for keeping the details up to date.

<sup>&</sup>lt;sup>11</sup> For technical reasons, at this moment registration of assured storage and transshipment companies in the GMP+ Companies database is not possible. This requirement will come into force in due time. Companies and CB's will be informed.



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<sup>&</sup>lt;sup>10</sup> For Europe, for example, there is a duty of registration under Reg. (EC) 183/2005.



#### **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

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