BT-03

Ver 0.2

Purchase :

Specific provisions

Feed Chain Alliance
together for safety and quality

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DOCUMENT HISTORY

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BT-03: Purchase: Specific provisions

1. Preamble

When a ~~GMP certified~~ company certified for Feed Chain Alliance , purchases from a supplier, they must comply with the provisions mentioned in document 'BT-02: Purchase: General provisions'.

For some very specific feed materials (or non downgraded food which can be considered as such) , it appears to be impossible to find a supplier complying integral with all the requested qualifications. In this case, and provided certain specific conditions are met, there is a possibility through application of this document to purchase from this supplier.

In other cases it may concern foodstuffs[1] destined for human consumption, but were unexpectedly downgraded accidentally, for example due to marketing reasons or technical problems. These products should therefore find a rapid market. In view of the exceptional and unique nature of these events, it will take too long to obtain a certification. A protocol was developed to enable ~~GMP certified~~ companies certified for FCA to acquire this product while at the same time safeguarding the entire chain.

A few examples
A ~~GMP certified~~ company certified for FCA buys carrot powder for use in its production. The ~~GMP~~ FCA supplier reports that he no longer distributes this product. The ~~GMP~~ FCA company finds only one more supplier in Belgium, but this supplier only supplies to food and pharmaceutical industries. For just a few hundred kilos per month, the supplier does not want to invest in a quality system specifically for animal feed, such as ~~GMP~~ FCA Standard. He has already developed other systems. He already has a « Food » certification and the « Feed » market is not of interest to him at the moment. Provided compliance with the conditions set out in this document, the ~~GMP certified~~ company certified for FCA may purchase from this supplier, in order to secure its production.
A food company decides to relocate a production line from one site to another. A few tons of coconut fat remain at the first production site,. Given the transfer costs, the company board prefers to find a buyer and get rid it. Provided application of a specific procedure , a ~~GMP certified~~ company certified for FCA could purchase this « Food » fat, even if it is not covered by a ~~GMP~~ FCA certificate.
A food company manufactures foodstuffs (e.g. dehydrated aromatic herbs (thyme, oregano, etc.)). (This concerns a non-downgraded foodstuff). A compound feed manufacturer decides to use these foodstuffs in animal feed. The producer does not wish to obtain a ~~GMP~~ FCA certification immediately. Provided compliance with this document the compound feed manufacturer is allowed to purchase from this supplier.

2. Scope

[1] *See 'AC-00 : Introduction', point « Definitions »*

The requirements contained in this document are specific to the ~~GMP Regulation~~ Feed Chain Alliance and are applicable to all ~~GMP certified~~ companies certified for FCA who:

- wish to purchase small quantities of feed materials or (for reprocessing) (or non-downgraded foodstuffs that may be considered as such) by-products originating from the food industry (point 3 is applied)
- Wish to purchase occasionally downgraded foodstuffs (§ 4).

In order to be able to determine exactly if this document can be applied, the participant shall observe the following decision tree:

1	**a**	The product to be purchased is an additive, a pre-mixture or a compound feed	
	b	The product to be purchased is a 'feed material'[2] or a non-downgraded foodstuff (or marketed as such by e.g. a chemical, pharmaceutical of food company)	**2**
	c	The product to be purchased is a by-product for reprocessing originating from a food company	**3**
	d	The product to be purchased is an occasionally downgraded foodstuff	**6**
2	**a**	The tonnage to be purchased is higher than 10 000 kg/month	
	b	The tonnage to be purchased is lower than 10 000 kg/month	**4**
3	**a**	The tonnage to be purchased is higher than 2 000 kg/month and higher than 20 000 kg/year	
	b	The tonnage to be purchased is lower than 2 000 kg/month and 20 000 kg/year	**4**
4	**a**	The supplier does not possess a quality system certified by an independent third party	
	b	The supplier possesses a quality system certified by an independent third party and the HACCP study is conducted	**5**
5	**a**	For this specific product, there is another supplier fulfilling the requirements stated in the document «BT-02: Purchase: General provisions »	
	b	For this specific product, there is no other supplier fulfilling the requirements stated in the document «BT-02: Purchase: General provisions »	**Application of point 3**

[2] *This term also includes products intended for human food (not downgraded as foodstuff) which the ~~GMP~~ FCA company wishes to use, e.g. carrot powder for baby food.*

6	**a**	It concerns multiple supplies of more than one batch within a 6-month period.	
	b	This relates to an occasional (once) supply of one (or several) batch(es) within a 6-month period	**Application of point 4**

Animal by-products, processed products and animal feed containing these products

Depending on the composition and the nature of the products, additional requirements may apply for animal by-products, processed products and animal feed containing these products (cfr. 'AT-01: Legislation' and 'AT-11: Animal by-products').

Important remarks

The application of a particular protocol does not discharge the company from its obligation to proceed with the assessment of its suppliers, service providers, bodies and laboratories. They will be assessed at least once a year.

Given the exceptional nature of these two protocols, therefore they cannot be integrated into a sectorial sampling plan or a sectorial feed analysis scheme.

3. Purchase of small quantities of feed materials

3.1. Application requirements

This purchase protocol for small quantities applies to all ~~GMP certified~~ companies certified for FCA, if all of the following requirements are met:

1. The purchase concerns exclusively a feed material, a non-downgraded foodstuff destined for animal feed, or a by-product originating from a food sector company.
2. The supplier has implemented a quality system (ISO 9000, ISO 22000, GMP Pharmacy, Auto control System (ACS), etc.), also valid for feed materials, which is certified by an independent certification body. He applies the HACCP principles in his company. The ~~GMP certified~~ company certified for FCA needs to have proof that this supplier, was in possession of a valid certificate at the moment of supply (e.g. copy of the certificate).
3. the purchased quantity is :
    a. lower than 10 000 kg/month for a feed material or a non-downgraded foodstuff (except for by-products originating from the food sector)
    b. lower than 2 000 kg/month, with maximum 20 000 kg/year for a by-product originating from the food sector industry
4. The supplier does not comply with any of the requirements set in document 'BT-02: Purchase: General provisions'. Moreover, the ~~GMP certified~~ company certified for FCA cannot purchase animal feeds with the same required characteristics from any other supplier based in Belgium or in the European Union.

Important remarks
The requirements relating to products, transport or storage, mentioned in document 'BT-02: Purchase: General provisions', still apply as a whole.
This document does not apply to the purchase of additives, pre-mixtures or compound feed (including milk replacers, mineral feed, dietary supplements, etc.) A non downgraded foodstuff for human consumption, used in animal feed, must comply with the definition of a feed material.

Example
A ~~GMP certified~~ producer certified for FCA uses feed material of mineral origin. For its intended use in the pharmaceutical sector, the feed material has undergone an additional treatment on top of the usual crushing following the extraction, whereby the feed material has a better solubility and a lighter color compared to the unprocessed product. The extra treatment justifies an adapted use by the manufacturer, at a rate of 1500 to 2000 kg/month. This product can only be obtained from an international group. This group, having developed the product as a "carrier" in the pharmaceutical industry, has an ISO 9001 quality system. According to the supplier, and although no complete definition of this concept exists, this product is of « pharmaceutical » quality. The international management of this company does not want to invest in a quality system specifically for feed, but complies with all the legal obligations. There is no other supplier with this specific product available in Belgium. In this case the protocol can be applied.
The producer is in the same situation as described above, but there is another supplier in Belgium, complying with the requirements set out in document 'BT-02: Purchase: General provisions'. The latter markets the same feed material, but is 25% more expensive than the supplier not complying with the requirements set out in document 'BT-02 : Purchase : General provisions'. In this case, the application of the protocol is not authorized.

3.2. Validation of a protocol by OVOCOM

If the requirements are met, the ~~GMP certified~~ company certified for FCA introduces, prior to any purchase, a validation request for a purchase protocol to OVOCOM VZW/ASBL. It is only after its evaluation, validation and registration by OVOCOM, that it can be applied by the company.

The protocol is to be sent per mail to the address info@ovocom.be, by means of the attached form A.

The request must contain at least the following:

- The name and certificate number of the ~~GMP~~ FCA company ;
- he name of the feed material, non-downgraded foodstuff or by-flow ;
- The category of the feed material and number (see European catalogue of feed materials. For a foodstuff or a by-product, the company will also mention the category to which the purchased product belongs;
- The quantity received (monthly and annually); the number of batches, if applicable

- The CCPs and Points of Attention for feed material, non-downgraded foodstuff or by-product were identified.
- The monitoring plan

Within two weeks following reception of the protocol, OVOCOM sends:

- either a request for additional information to the company that has introduced the protocol
- Or an acknowledgement of receipt, stating that the file is complete.

Within a reasonable period after the sending of the acknowledgement receipt indicating the file is complete OVOCOM will respond to the company, when the answer is positive the certification organization will also be informed.

Since such a protocol is based on the achievement of the HACCP study of the purchased product, this study is to be revised at least once a year, the validity period of a protocol is 12 months. A new application file will be introduced at least one month before the end of the validity period.

Since this is per definition a temporary protocol, the ~~GMP certified~~ company certified for FCA must encourage its supplier to obtain a qualification in conformity with document 'BT-02: Purchase: General provisions'. The certification body will assess during each audit, the actions taken by the ~~GMP~~ FCA participant.

Only when obtaining a qualification, accepted in document 'BT-02: Purchase: General provisions', can an additional safeguard be provided that the ~~GMP~~ FCA participant can count on a constant supply.

3.3. Principles

The protocol is based on two principles:

- The ~~GMP certified~~ ~~compan~~company certified for FCA (purchaser) must assess the hazard analysis sent by the supplier or, failing that they must perform themselves a hazard analysis of the feed material, the foodstuff or by-product concerned. This analysis is based on the HACCP method. The company must have sufficient documents demonstrating that they sufficient knowledge of the production processes, of its supplier and of the product that it purchases (e.g. production diagrams, site evaluation reports, tolerance limits, monitoring plan and frequency of the sampling and analysis, technical sheets, analysis certificates, etc.).
- The purchaser applies an individual Level 1 monitoring plan (sampling and analyses) specifically for the product in question mentioned in the protocol, developed via this document. This monitoring plan must be in conformity with document 'AT-05: Monitoring', with the exception of the sampling and analysis frequency (see the following table 1).

3.4. Frequency

The yearly frequency for monitoring and analysis depends on the number of batches . This frequency is mentioned in table 1. In this document the number of batches (L) at least equals the anticipated number of supplies, except for the application of the remarks mentioned below.

Number of batches (L)	Level 1 (individual)	
	CCP	PA
$L \leq 2$	Per batch	1
$2 < L \leq 8$	Per batch	2

Number of batches (L)	Level 1 (individual)	
	CCP	PA
8 < L ≤ 15	Per batch	2
15 < L ≤ 25	Per batch	3
25 < L ≤ 50	Per batch	5
50 < L ≤ 90	Per batch	8
90 < L ≤ 150	Per batch	13
L > 150	Per batch	20

Table 1 : Minimum number of samples to be taken per year for an individual monitoring plan (see ISO 2859-1, Table I & II-C)

Remarks: Practical application of the batch concept

- A supply of bags (or in any other packaging (e.g. cubitainers or barrels) can be composed of two or more different batches. In this case, the protocol has to be applied for each single batch that is part of the supply.
- Bags (or any other packaging (e.g. cubitainers or barrels)) of one and the same supplier's batch may be divided into multiple deliveries. In this case, the protocol shall be applied only once for the batch, namely upon the first delivery.
- Every bulk delivery is to be considered as a different batch, even if it concerns one and the same supplier's batch number. When several loading compartments are used, their capacity shall be allocated to the same number of different batches. It is not authorized to group the batches.

3.5. Sampling for Analyses

Sampling shall take place on reception of the product by the ~~GMP~~ FCA Company applying the protocol.

Document 'BT-11: Sampling and analyses' applies here.

3.6. Analyses

Analyses are operated in conformity with the modalities mentioned in document 'BT-11: Monitoring and analyses'.

It is the company's responsibility to decide whether the feed material concerned is to be blocked pending the analysis results.

3.7. Control

The certification body shall exercise the control over the application of the purchase protocol for small quantities, as described in this document, at each company audit (surveillance audit and renewal audit).

4. Purchase of a single supply of a downgraded foodstuff

4.1. Preconditions

This purchase protocol for a single supply applies to all ~~GMP certified~~ companies certified for FCA, if all of the following conditions are met:

1. The purchase relates exclusively to one single supply of downgraded foodstuff. It is authorized to divide the purchase into multiple deliveries when this particular purchase is the subject of a well-determined total amount and of a given number of deliveries. This information shall be contractually mentioned prior to the first supply. The delivery period may not exceed 7 days starting from the date of the first delivery.
2. The foodstuff, packed or not, respects any legislation with regards to its safe use in foodstuffs for human consumption, but does not satisfy all of the internal quality requirements, imposed by the producer (color, taste, package printing, etc.) or is put on the market after a loss or damage. As for packaged products, the packaging must not be faulty or damaged in such a way that the product could no longer be intended for human consumption, in terms of e.g. insuring the microbiological quality (presence of micro-cracks, rupture of the cold chain, etc).
3. The supplier must be either the producer of the downgraded foodstuff, or, in the case of an accident or insurance claim, the institution (insurance company) that has to upgrade the downgraded foodstuff.
4. The producer of the feed material or the insurance company must dispose of a quality system (ISO 9000, ISO 22000, BRC, IFS, etc.), which is certified by an independent certification body, and apply the HACCP principles within his company. The ~~GMP certified~~ company certified for FCA shall hold a copy of the certificate and verify its validity. This copy is to be kept together with the documents relating to the purchase.
5. The Belgian or European supplier does not satisfy any of the requirements stated in document 'BT-02: Purchase – General Provisions'.

If it concerns a packaged food, the accompanying documents must specify that the package must to be removed before any use in animal feed.

If all of the requirements are met, the ~~GMP certified~~ company certified for FCA shall have the product controlled by a certification body in accordance with the following modalities.

Compliance with document 'BT-02 : Purchase : General provisions'
The requirements for products, transport or storage mentioned in document 'BT-02: Purchase: General provisions' remain fully applicable, unless the transport or storage facility falls under the responsibility of the owner (producer or insurance company) of the downgraded foodstuff.

Examples
Due to an operating error, a green food colorant is used instead of pale pink, which is generally used for biscuit glazing. These biscuits may not be put into circulation, since they do not correspond to consumer expectations. In an isolated case and if the product can be considered as a foodstuff, the application of the protocol is authorized.
A roll of preprinted wrapping paper for foodstuffs was wrongly introduced in the wrapping installation, so that the inscriptions were printed upside down and became illegible. The manufacturer wants to upgrade the batch in animal feed. Provided the other requirements are

respected, the protocol may be applied by the ~~GMP~~ FCA purchaser.
Due to a road traffic accident, a milk collector slips into a ditch. The milk tank is intact and another lorry arrives to pump the milk. Although this milk can still be used in foodstuffs for human consumption, the dairy processing company decides to use it in animal feed. Provided that the other requirements are met, the protocol can be applied by the ~~GMP~~ FCA purchaser.
Upon loading, a pallet of milk cartons fall from the lorry. Some of the cartons were ripped open, while others were damaged but not leaking. Here and there, a few drops are visible. All of the cartons that appear intact are put together. Provided the other requirements are met, only those cartons completely intact are admissible for the application of this protocol. The other cartons must be accompanied by a reprocessing sheet (the treatment to be applied shall also control the microbiological risk).

4.2. Principals

The protocol is based on the following three principles:

- As it concerns an occasional flow, the supply of which cannot be planned, the ~~GMP certified~~ company certified for FCA (purchaser) needs to perform a risk analysis, before delivery. The latter is based on the HACCP method.
- The company shall possess a sufficient number of documents demonstrating that it has a good knowledge of the producer's manufacturing processes and of the foodstuff bought (e.g. production diagrams, assessment reports on the premises, tolerance limits, monitoring program and frequency of the monitoring activities, technical sheets, analysis certificates, etc.). On the basis of the information gathered, and on the reasons why this foodstuff is offered for sale, the ~~GMP certified~~ company certified for FCA determines the specific CCPs and Points of Attention for that product.
- The purchaser applies a level 1 monitoring plan on an individual basis (sampling and analyses) specifically for that feed material concerned by the protocol. This monitoring plan shall be in conformity with document 'AT-05: Monitoring', except for the frequency of monitoring and analysis (see point 4.3).
- A visual control of each batch that is part of the product delivery, with a representative monitoring (see BT-11: Sampling and analyses) and a product analysis are to be carried out by the certification body of the ~~GMP certified~~ company certified for FCA.

This protocol, that relates to the same producer, can only be applied once every 6 months and maximum twice in the same calendar year.

Example

A company produces various dairy products. In January, it has to downgrade a batch of natural yogurt. In August, this happens again, this time with a batch of yogurt with fruit. In December, there is a problem with a batch of sweetened yogurt.

The protocol can be applied for the first two batches, but not for the third one. The first and the second batch concerns the two productions from the same producer within the same calendar year. Although the third batch relates to a downgrading of another foodstuff, it does not satisfy the requirements set out and thus cannot benefit from this protocol. The ~~GMP certified~~ company certified for FCA can however continue to buy from this yogurt producer, provided that the latter satisfies the requirements set out in document 'BT-02: Purchase: General provisions'.

Certification body : Product control and analysis
If, for practical reasons (availability, distance, etc), the buyers certification body is not able to perform the requested control within an acceptable period, they have the possibility to outsource the control to a certification or inspection body of their choice. However, the final control will remain their responsible . The certification body describes in details the subcontracting modalities as well as the linked guarantees in their own quality system (cf. 'CC-01: Certification Rules').

4.3. Frequency

All production batches, determined by the producer and constituting the delivery, must be:

- Controlled visually;
- Monitored, and
- Analyzed, regarding the CCPs and Points of Attention, determined in the previous HACCP study, according to the frequency set out in table 2.

These operations are carried out at the same time and by the company (purchaser) and by the certification body responsible for ~~GMP~~ FCA certification.

The monitoring and analysis frequency are depending on the number of batches. They are mentioned in table 2. For this document, the number of batches (L) is at least equal to the number of deliveries, unless the following remarks apply.

Number of batches (L)	Level 1 (individual)	
	CCP	AP
L ≤ 2	Per batch	1
2 < L ≤ 8	Per batch	2
8 < L ≤ 15	Per batch	2
15 < L ≤ 25	Per batch	3
25 < L ≤ 50	Per batch	5
50 < L ≤ 90	Per batch	8
90 < L ≤ 150	Per batch	13
L > 150	Per batch	20

Table 2 : Minimum number of samples to be taken for an individual monitoring plan (see ISO 2859-1, Table I & II-C)

Remarks: Practical application of the batch concept

- A delivery in bags (or any other packaging (e.g. containers or barrels) can exist of two or more different batches. In this case, the protocol must be applied for each single batch that is part of the delivery.
  Bags (or any other packaging (e.g. containers or barrels)) of one and the same suppliers' batch may be divided into multiple deliveries. In this case, the protocol shall be applied only one time for the batch, namely upon first delivery.

- Every delivery in bulk is to be considered as a different batch, even if it concerns one and the same supplier's batch number. When several loading compartments are used, their capacity shall be allocated to the same number of different batches. It is not authorized to group the batches.

Example

A producer of frozen vegetables packs the equivalent of a days' production in a packaging showing a printing error. The decision is made to exceptionally upgrade the quantity produced in animal feed.

This case concerns two different production batches, put in sealed containers. This is done in 3 refrigerated trucks and are delivered. The first and second truck is loaded with the same batch (batch 1); whereas batch number 2 is placed in the 3rd vehicle.

The sample from batch 1 is taken from the load of the first or the second truck and analyzed for the CCPs and Points of Attention. The same reasoning must be applied at the level of batch number 2 from the third vehicle.

4.4. Monitoring of analysis

Monitoring will be performed upon receipt of the product or at the latest within 24 hours following the receipt.

The batch(s) constituting the delivery shall be stored separately and may not be used before monitoring. Pending the monitoring, all the necessary measures must be taken in order to preserve the intrinsic quality of the downgraded foodstuff (e.g. no rupture of the cold chain; dry storage in a dark place).

Here document 'BT-11: Sampling and analyses' are applicable.

The certification body will take a representative sample in three specimens of 500 grams.

Each specimen of the sample, sealed and labeled by the certification body, must be kept in storage conditions excluding any modification of the composition or any other abnormal alteration.

The first sample is for the buyer, whereas the second is kept by the certification body during one year. If necessary, the third sample will be sent to the laboratory for analysis. The ~~GMP~~ FCA Company will be responsible for the sending.

The certification body drafts a report of their visit. This report shall contain at least:

- The name and coordinates of the certification body (responsible for certification of the participant)

- Where appropriate, the name and coordinates of the body that performed the control (+sampling) under the responsibility of the participants' certification body
- The name of the inspector
- The name of the ~~GMP~~ FCA company and the inspection location
- The date of delivery
- The inspection date
- The name of the supplier
- The name of the producer (when different from the supplier)
- The name of the downgraded foodstuff (feed material)
- The category of the raw material and its number (cf. part B or C of the annex to the Belgian Royal decree of 8/02/1999 or of the European Directive 96/25/EG)
- The product description
- The quantity received
- The internal entry batch number of the ~~GMP~~ FCA company
- The identification number of the samples
- The analysis possibly based on the CCP's and the Points of attention, identified by the ~~GMP certified~~ company certified for FCA

The purchaser adds a copy of the analysis result which he received along with the report from the certification body

If the HACCP study did not reveal any CCPs or Points of Attention, the certification body will limit their assessment to an organoleptic control of the product conformity. The samples are not sent for analysis.

4.5. Analyses

The analyses are performed in a laboratory satisfying document 'BT-11: Sampling and analyses.

The company is responsible for deciding whether the product concerned is to be blocked pending the analysis results.

4.6. Control

The ~~GMP certified~~ company certified for FCA will keep various inspection and analytical reports readily available for the certification body.

Form A: validation request of a protocol « Purchase of a small quantity » by OVOCOM

Company name : ----------

~~GMP~~ FCA certificate No ----------

☐ Feed material	☐ Foodstuff	☐ By-product
Name :		
Number of the raw material (see European catalogue of feed materials)		
Product description :		
Supplier located :	☐ in Belgium	
	☐ in the European Union	
Maximum receipt quantity planned (/month) :		
Maximum receipt quantity planned (/year) :		
Total amount of batches (for all deliveries)		
Identified CCP		
Identified Attention Point(s)		
Motivation for request		
Enclosure(s) :		

Sending date : ----------

Read and approved by (name + ----------

function) :

Reserved to OVOCOM VZW / ASBL			
Date of receipt of 1st request :		Date of receipt of complete file :	
Date action completed :		Examined and approved by (name + function) :	