

BC-01

Ver 0.9

General Provisions





DOCUMENT HISTORY

Revision and approval date	Reason for revision	Revision scope	Ultimate date for application
0.0 03/07/2008	Start of the new GMP	Entire document	01/01/2009
0.1 22/12/2008	Decision by the OVOCOM Board of Directors of 27/11/2008 as regards the use of filtration substrate.	Point 1 Point 4.c	01/01/2009
	The moving of requirements from document AC-02 on the proper locking of raw materials and auxiliary agents upon storage	Point 5.e	
0.2 23/12/2010	Modification to the structure of the document Clarification concerning the controls	Points 5 and 6	08/02/2011
0.3 19/12/2012	Update due to the approval of the Auto-control Guide G-001 – ver2.0	Points 2, 4, 5, 6, 10 et 11	1/01/2013
	Obligation to inform OVOCOM and the certification body of any notification.	Point 3	
0.4 19/03/2013	Introduction of the temporary monitoring principle and reference to document BT-16	Point 7	20/03/2013
0.5 12/08/2013	Changes made in the context of a mutual recognition Addition of certain provisions in connection with conditioning.	Points 12	12/11/2013
	Addition of a recommendation related to IT systems and data.	Point 13	
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	Duty to inform OVOCOM and the certification body regarding any incident.	Point 3	
0.7 21/10/2016	New lay-out	Entire document	21/10/2016
0.8 10/01/2018	Supplier and service provider evaluation based on the supplier/product and service / service provider combinations	Point 6	1/04/2018
0.9 15/03/2018	Precisions on the form that can take the evaluation of suppliers and service providers	Point 6	01/04/2018



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BC-01 : General Provisions

1. Definitions

Raw materials (≠ feed materials)

In the framework of the documents from part B, a substance not meeting the definition of animal feed, nor the definition of processing aids, but is used in the production process of an animal feed implemented by a participant to the Feed Chain Alliance Standard (e.g. a product, delivered by the chemical industry, not listed as a feed material, supplied to a FCA company to serve as a basis for the production of an additive).

'By-products for reprocessing' are excluded from this definition.

Processing aids

Substances, not consumed as an animal feed or food ingredient, but intentionally used in the processing of animal feed or feed materials, raw materials, foodstuffs or food ingredients, to fulfill a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues from these substances or derivatives in the finished product, provided these residues do not have an adverse effect on animal health, human health or the environment and do not have a technological effect on the finished feed [Regulation (EC) 1831/2003-Art. 2-2-h) and the Belgian 'Gedragscode met betrekking tot het gebruik van chemische producten in de voedings- en de diervoederindustrie' / 'Code de Conduite concernant l'emploi, dans l'industrie alimentaire et l'industrie de l'alimentation animale, de produits chimiques'].

2. Scope

- a. These provisions apply to companies performing activities such as services or productions of animal feed or 'by-products for reprocessing';
- b. Companies, located in the European Union, must, in the context of activities inherent to the application of Feed Chain Alliance Standard, comply both with the European Legislation as well as with the specific Legislation of the member state, in which the exploitation unit is located. This is also applicable to requirements from documents of the A and B series, which are not explicitly mentioning a national application. (e.g. for medicated feed where the only system applied in Belgium is described in document AC-02).

3. Standards

- a. Any participant certified for Feed Chain Alliance should be able to demonstrate compliance with the legal provisions regarding the animal feed applicable to his activities, and to animal feed which he produces. The products must comply with the legislation of the country of destination. If the country of destination cannot be determined, or if there is no applicable legislation, the European legislation is to be applied;
- b. Any participant certified for Feed Chain Alliance should be able to demonstrate that his products and/or services meet the relevant requirements included in the following documents:

Activities	Documents
Production of animal feed or 'by-products for reprocessing'	'BC-02: Production of animal feed or 'by-products for reprocessing': additional provisions'
Trade in animal feed or 'by-products for reprocessing'	'BC-03: Trade in animal feed or 'by-products for reprocessing': additional provisions'
Storage and transshipment of animal feed or 'by-products for reprocessing'	'BC-04: Storage and Transshipment of animal feed or 'by-products for reprocessing': additional provisions'
Road transport (including chartering)	'BC-05: Road transport of animal feed or 'by-products for reprocessing': additional provisions'
Chartering of inland water transport	'BC-06: Chartering of inland water transport for animal feed or 'by-products for reprocessing''
Chartering of sea transport	'BC-07: Chartering of sea transport for animal feed and 'by-products for reprocessing''
Organization of transport via Rail	'BC-09: Organization of transport of animal feed or 'by-products for reprocessing' by rail (specialized wagons)'



Exception: Inland waterway companies

Inland waterway companies may obtain an attestation after verification of the inland waterway vessel by an inspection body, approved by OVOCOM (see OVC-04 Regulation). These companies should only apply 1 document of the parts A and B, namely 'BC-08: code of hygiene for Inland waterway transport'.

- c. Participants must respect the requirements included in the most recent version in force as regards the documents in parts A and B.

The participant must also:

- Keep documents, in paper or digital version;
- Respect the rights linked to the "copyright" of these documents;
- Be in order with the OVOCOM contributions;
- Dispose of a login and password allowing access to the document series A and B, applicable to their activities. The login and password are specifically intended for the participant. The company management, disposing of a login and password, commits itself, through participation in the FCA system, to not pass this password on to a third party, or anyone else (consultant, other company, etc.). This is also applicable to all Belgian companies certified for Feed Chain Alliance using these codes for the application of the Auto-control Guide G-001. The conditions for obtaining a login and password can be found on the website: www.ovocom.be;

- d. Every participant certified for Feed Chain Alliance must demonstrate that his products and/or services comply with the requirements for food safety and quality, as has been agreed with his customer;
- e. In case a participant provides services or delivers products from different legal entities, whether or not located on the same, the services and products of these legal entities must comply with the requirements of the FCA Standard;
- f. All standards for feed materials and requirements linked to the transformation of trade, storage, transshipment and road transport of feed materials mentioned in the documents of parts A and B, are applicable to the 'by-products for reprocessing' (with the exception of the criteria justifying the reprocessing of these by-products);
- g. OVOCOM (info@ovocom.be) and the body responsible for the FCA certification of a company must be informed:
 - simultaneously with the competent authority, of all communication to the competent authority if a company suspects or has reason to believe that a feed which they place on the market does not satisfy the feed safety requirements (see Regulation (EC) 178/2002 art.20) (e.g. exceeding of a standard or a intervention threshold, shall be subject to a notification requirement;
 - As soon as possible, and maximum 48 hours following the initial determination, when a company has been informed of the existence of an incident concerning his activities or has an impact on the latter (cf. 'BT-17: Incident and crisis management: communication to OVOCOM and the certification body') (e.g. a non compliant result during control by the competent authority, involved in a recall, etc.).

4. Documentary system

- a. Any participant in the FCA system should keep a document registry for a period of at least 5 years. Only for documents relating to formulations of feed, and the sequence of productions, has an exception been made as these should be kept for 10 years;
- b. These documents should be available at the exploitation unit of the participant. In case of a multisite it is possible to centralize the documents in the head office.

5. Staff

- a. An overview of trainings, attended by each staff member, in the context of food safety, should be maintained and updated;
- b. Working with additives and pre-mixtures (medicated pre-mixtures) should, if necessary, be included in the training programs for staff;
- c. The person performing internal audits should be independent from the person responsible for the controlling activities.

6. Evaluation of suppliers and service providers

- a. A company should define the qualifications as to which its suppliers and service providers should comply. In the company there is a list available with all the suppliers and service providers compliant with these qualifications. ~~This list must be elaborated based on the principle of the 'supplier / product' or 'service provider / service' combination.~~ At any time, a clear link should be established between the supplier / service provider and the product / service purchased by the company. The company is free to define how the link must be demonstrated (list of suppliers / products, contracts, etc.).



Link between 'supplier' and 'product' or 'service provider' and 'service' combination

Does the supplier or service provider meet all the requirements?

It is to provide an answer to that question, that a clear link must be established between the animal feed or the purchased by-product for reprocessing (or service) and its supplier (or its service provider). ~~The 'supplier/product' and 'provider/service' combinations provides an answer to this question. Indeed, having a certification may not always suffice.~~

A supplier may e.g. have a qualification recognized for one type of feed (e.g. a cereal) but not for another (a byproduct of the oil manufacturing industry). Similarly, the company may decide to purchase a specific animal feed from a supplier and only that specific one (even if other types of animal feed are available from the supplier).

~~The 'supplier/product' or 'service provider / service' combination allows the company to link the~~ It is important to be able to establish this link by linking the supplier/service provider to one or more products or services.

For each product to be purchased, ~~the list with the 'supplier/product' combinations must include at least the following:~~ the following data should be gathered:

- the unique identification of the product (the most exact name possible of the animal feed).
This identification can be completed by:
 - i. The number from the European Catalogue of Feed Materials or from the Feed Materials Register, if it is feed material, or;
 - ii. The European number for additives, or;
 - iii. An internal reference (product code, etc.),
- the supplier identification number (supplier localization, qualification (e.g. certification). When the supplier is certified, the scope of the certificate and its validity (expiration date) should be specified.
- the link with the existence of hazards (HACCP, point of attention or CCP) and with the individual (see document 'AT-05: monitoring') or sector-based monitoring (see document 'BT 05: sector-based monitoring) should be made, applied to monitor these hazards (level 1, 2 or 3 or even specific monitoring related to the purchase);

This information must be recorded and, if necessary, updated regularly:

- when assessing the supplier and the ~~supplier / product combination~~ purchased products (at least 1 x/year);
- when purchasing any new product from an existing supplier (new ~~'supplier/product' combination~~ link to establish, to evaluate and record);
- for each new supplier to be evaluated (~~new 'supplier/product' combination~~ new link to evaluate and record between the product which will be purchased and the new supplier)

In case a new link should be made or evaluated, the company may also use existing data per product (group) (cf. specifications and danger analysis of the product (group)).

All data relating to ~~'suppliers and / products' combinations~~ must be available in a user-friendly manner during internal and external checks.

A similar ~~list~~ approach can be prepared for the ~~'service providers and the /services' combinations~~.



Application of document 'BT-02: Purchase: general provisions'

The conformity of suppliers and service providers with the qualifications indicated in document 'BT-02: Purchase: General provisions', is part of the evaluation of the suppliers. In certain specific cases the following documents will determine the qualifications:

- 'BT-03: Purchase: Specific provisions';
- 'BT-04: Purchase: Specific purchase protocols'.

The use of a supplier or service provider, not compliant to the requirements included in document 'BT-02: Purchase: General provisions', should, upon evaluation, not be assessed as compliant. Such a supplier or service provider should not be retained on the list of approved suppliers and service providers.

The decision tree in annex 1 of this documents summarizes the possible purchase options and the references to the monitoring which should be applied.

- b. A company will evaluate, at least once a year, its suppliers and service providers as regards the keeping of their commitments, required qualifications, and food safety of delivered products and/or services. This yearly evaluation should be documented (e.g. copies of certificates, statements and date of website consultations, contracts, etc.). The evaluation takes place individually:

- ~~for each supplier and/ product purchased from him/her~~
• ~~or for each service provider provider and /service purchased from him/her combination possible;~~

- c. In case of a negative evaluation, the company must take necessary measures. These actions should be proportional to the non-conformities identified with these suppliers.

Examples of such measures are:

- Modification of the purchase procedure, order and reception;
- Notifying the supplier, so that he himself can take the necessary measures;
- Stopping the purchases from this supplier, possibly ~~linked~~ limited to the purchases of ~~products to the supplier / product combination(s)~~ which were negatively evaluated.

When a supplier has received several negative evaluations for a same problem without a solution on his part, he should be removed from the list of suppliers.

These evaluations are registered.



Tool for the follow-up ~~of the 'supplier/product' combinations~~

The company is free to choose how the ~~list of combinations is drafted and updated~~ link between the suppliers and the products is being fixed and followed. However, to facilitate ~~this monitoring of these combinations~~, OVOCOM provides a ~~document tool~~ to:

- clearly resume all the information required ~~by combination~~;
- check the accepted qualifications by feed;
- individually track this information ~~e 'supplier/product combinations'~~;
- record the evaluations.

This ~~document tool contains a decision tree~~ allows for the user to define the qualifications accepted by feed (and thus to compare them with the supplier's) and to manage the information collected. It is available on the website www.ovocom.be.

The use of this document is optional. The company may also expand the proposed document by

adding one or more columns to add other data (eg information on registration or authorization).

7. General provisions regarding the purchase / sale of a product or service

- a. If a company certified for Feed Chain Alliance receives an order for a service or a product, first the feasibility and conformity of the order must be evaluated as to the objectives of FCA Standard (e.g. in terms of quality and safety of the animal feed or customer requirements). If this is not the case, the company certified for FCA cannot accept the order within the FCA circuit:
- b. All products originating from the pharmaceutical industry, not meeting the legal definition of an animal feed or not falling under the legal scope of medicated animal feed, are not allowed, even after transformation, to be purchased for use in an animal feed:
- c. Any organic or inorganic substance, used in one or other process as a "processing aid" and is called "substrate" after use. This substrate is not allowed to be commercialized as a feed material or incorporated into an animal feed or a 'by-product for reprocessing', unless the following provisions are observed:
 - The substrates concerned have been subjected to a HACCP analysis and monitored accordingly;
 - The incorporation of the substrate into an animal feed cannot be prohibited by the legislation in force;
 - The substrate originates from a step in the company's production process and is valorized as an internal flow;
 - If the substrate is valorized outside the company, it should not present a hazard to human or animal health, when used according to the terms of use as defined by the company;
 - By no means shall the substrate contain components actively absorbing the contaminants (e.g. activated carbon);
 - The substrate does not contain any substance that may harm animal production;
 - The incorporation of the substrate into an animal feed must not lead to the dilution of an undesirable substance present in the substrate and of which the legal maximum level was exceeded;
 - The animal feed containing the substrate must meet the standards mentioned in document BT-01;
 - The substrate or animal feed containing the substrate must meet the legal requirements on labeling;
 - The label of the substrate or the animal feed containing this substrate must also mention the following:
 - o Type and nature of the processing aid of which this substrate consists;
 - o Process from which this substrate originates.
 - The abovementioned requirements also apply if the substrate was incorporated into a "by-product for reprocessing".



Example

When *crushing* soy beans, a soybean meal as by-product is obtained. The type of clay used during the crushing process for bleaching the raw soy oil is added to the soybean meal after use.

Both the soybean meal and the used bleaching earth originate from the same production run. The label of the soybean meal must mention as a minimum the type and nature of the processing aid used (e.g. bleaching earth: bentonite, perlite, ...) and the process from which it originates (e.g. refining of soy oil).

- d. Depending on its activities, the company may sometimes need to implement an additional monitoring for certain animal feed. This is justified, e.g., for the control of an entire purchase of a determined feed from a specific origin. The monitoring is limited in time and is described in document 'BT-16: Temporary monitoring'. The company will integrate them in their control plan. If necessary, their documentary system will be adapted in order to ensure the correct application of these specific controls.

8. General provisions regarding control when receiving/sending

- a. Controls and inspections at reception should not only concern the incoming animal feed or 'by-products for reprocessing', but also the other products such as raw materials, auxiliary aids, detergents/disinfectants;
- b. Control of the transportation vehicles shall, if not systematically, be performed randomly according to an appropriate frequency, determined and controlled by the company. The controls must always be registered;
- c. If certain aspects of the control are in contradiction with the legislation in force (e.g. work security), the company must propose an alternative approach;
- d. When a company certified for Feed Chain Alliance contracts a third person or organization to intervene on its behalf in receiving or sending a product or service (e.g. inspection during unloading) the FCA certified participant must conclude a written agreement with the third party in order to guarantee that the quality of the products received or sent comply with the FCA requirements;



Performing Controls

The company draws up procedures for performing controls. The control may contain the following:

Before unloading:

- Before unloading, the controls consist of a product control (e.g. organoleptic inspection of the product), a visual inspection of the transport vehicle (e.g. in case a truck is muddy on the outside, it is not advisable to allow the vehicle run over a dumping pit) and verification of the accompanying documents (qualifications of the transport operator if relevant, a road document with previous transport loads and cleaning methods if relevant, a delivery receipt etc.)
- When unloading transport vehicles at the exploitation site, the parties certified for FCA must ensure an optimal emptying of the loading spaces regardless the type of load or transport means.

Before loading

- Before loading, the controls consist of a visual inspection of the transport vehicle (including the loading space), and verification of the accompanying documents (qualifications of the transport operator if relevant, a road document with previous transport loads and cleaning methods if relevant, a delivery receipt etc.)
- If the transport vehicle arranged by the buyer is found unsuitable to transport the product, the buyer should be informed before the product is loaded.

9. General provisions regarding the organization of the company

- a. Where appropriate, the existing waste in the company shall be correctly identified and stored separately from the animal feed, 'by-products for reprocessing', raw materials and/or auxiliary agents. The necessary precautions shall be taken to prevent this waste from causing any physical, chemical or biological hazards.
- b. Where applicable, the required or accepted entries ('by-products for reprocessing', logo etc.) in the context of the Feed Chain Alliance Standard must be clearly indicated on the packaging or accompanying documents.
- c. Raw materials, auxiliary materials, detergents, plant protection products and biocides should be stored separately, so that these products cannot contaminate the already stored feed.

10. General provisions for traceability

- a. All companies should comply with the sampling frequency listed in document 'BT-11 – Sampling and analysis'.

11. General provisions for calibration

- a. All weighing and dosing equipment should be calibrated on the basis of the following frequencies:

Activities inherent to the company	Concerned equipment	Frequencies
Production (AC-02)	Weighing or dosing equipment for additives and/or (medicated) pre-mixtures	Min. 2 x/year
	Other weighing and dosing equipment	Min. 1 x/year
Trade (AC-03)	All weighing and dosing equipment	Min. 1 x/year
Storage and/or Transshipment (AC-04)	All weighing and dosing equipment	Min. 1 x/year

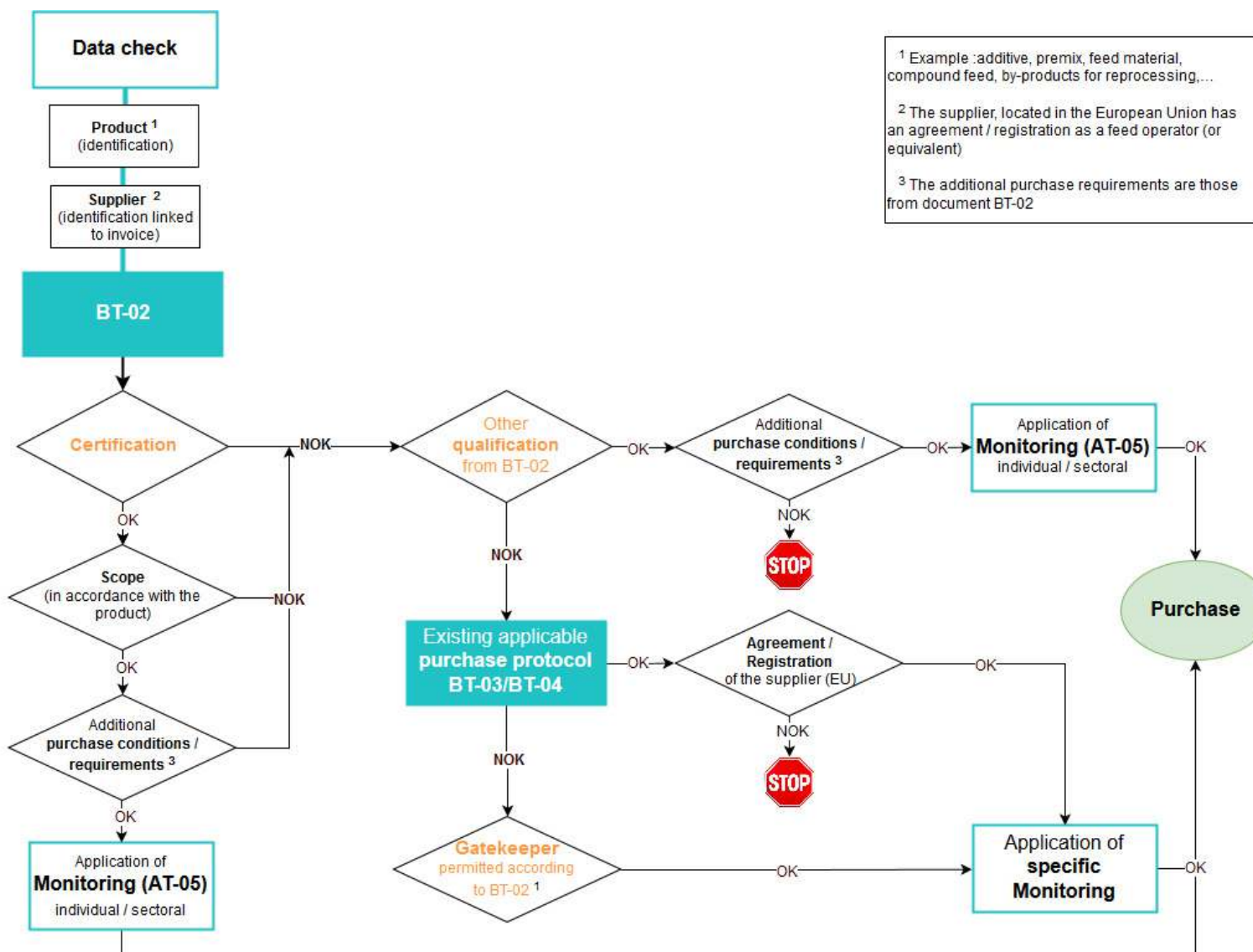
12. General provisions for conditioning (packaging)

- a. The company should define methods for the conditioning of feed, where it will be packaged. If necessary the company shall define a sequence order, possibly with the inclusion of prohibited sequences and flush charges.
- b. If necessary, the company will set up a system for the monitoring of packaged feed.
- c. The company must ensure good legibility regarding data indicated on packaging and label.
- d. Registrations of conditioning facilities should be integrated in the general traceability system in place (company).
- e. It is recommended to pay attention to the right storage conditions for the new packaging.

13. Recommendations for IT data processing systems

- a. The company will determine the rules for managing its IT system, including access rules, storage, the keeping and recovery of data.

Annex I: decision tree purchase – monitoring



¹ Example : additive, premix, feed material, compound feed, by-products for reprocessing,...

² The supplier, located in the European Union has an agreement / registration as a feed operator (or equivalent)

³ The additional purchase requirements are those from document BT-02