Certification Standard Animal Nutrition

Version 5 –For January 2020

Changes between version 4 and version 5, published in October 2019 are reported in red.

Corrections made in the version 5 (publication in December 2019) are reported in blue.

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GENERAL

1.1 Introduction

1.2 Scope (diagrams, potential hazards…)

This certification standard applies to manufacturing and/or placing on the market products which are used for nutritional purpose in feed for 'food-producing animals'. It applies to the following professionals:

- Manufacturers of compound feed (AC)
- Manufacturers of mineral feed (AM)
- Manufacturers of premixes (PM)
- Manufactures of milk replacers (AA)
- Manufacturers of liquid feed (AL)
- Distributors (D)

The certification scope are as follows

- Production and placing on the market of compound feed, mineral feed, liquid feed, milk replacers, premixes,
- Distribution of compound feed, mineral feed, liquid feed, milk replacers, premixes,
- Distribution of feed materials, additives,
- Trading of animal feed in the regulatory sense (feed materials, additives, premixes, compound feed).

NB: The distribution of feed materials, additives and trading of animal feed in the regulatory sense activities cannot be certified by itself. This scope of certification must be linked to an activity in the manufacture and / or distribution of premixes and / or compound feed including minerals, milk replacers and liquid feed.

Manufacturers of dietetic feed (feed with particular nutritional purposes) are also included in the scope of this standard and are concerned with its content depending on the type of products produced (mineral feeds, liquid feeds, compound feed ...) which apply to the general obligations and / or specific as indicated below.

The feed materials which have undergone treatment (lamination, flaking, extrusion, for example) on site are also within the scope of this standard, the general and / or specific obligations set out below apply to them.

Process steps		Manu-facturers of compound feed (AC)	Manu-facturers of mineral feed (AM)	Manufacturers of premixes (PM)	Manufacturers of milk replacers (AA)	Manufacturers of liquid feed (AL)	Distributors (D)
Reception of incoming goods		X	X	X	X	X	X
Storage and Transfer		X	X	X	X	X	X
Grinding		X					
Other process on incoming materials	Lamination	X					
	Flaking	X					
	Extrusion	X					
	Tanning	X					
Dosing		X	X	X	X	X	
Mixing		X	X	X	X	X	

Process steps		Manu-facturers of compound feed (AC)	Manu-facturers of mineral feed (AM)	Manufacturers of premixes (PM)	Manufacturers of milk replacers (AA)	Manufacturers of liquid feed (AL)	Distributors (D)
Heat treatment		X					
Granulation		X	X				
Cooling / Drying		X	X		X		
Crumbling		X					
Sieving		X	X	X	X		
Coating / spraying		X	X	X	X		
Other processes on semi-finished products	Extrusion	X					
	Agglomeration		X	X			
	Compacting	X	X				
	Expansion	X					
Packing		X	X	X	X	X	
Loading		X	X	X	X	X	X
Delivery of finished product		X	X	X	X	X	X
Recycling		X	X	X	X	X	

Some tools can also apply to manufacturing and/or distribution of medicated feed in accordance with current regulations (French Decision of 12 February 2007 relating to good manufacturing practices and distribution of medicated feed) in particular regarding specific control measures associated with:

- Receiving orders
- Storage
- inter-batch transfers
- Competence of staff members
- Formulation and Product Information
- Recycled Products / rework

This certification standard is recognized as equivalent by certification schemes in mutual recognition (AIC, GMP+ International, OVOCOM or QS), when the certified company follows the version of Appendix 1 without purchasing from suppliers certified under the certification standard for suppliers of feed materials (RCF) and the system of one unannounced audit per cycle. The companies which are certified according to these requirements will obtain a RCNA certificate with the mention “International”.

1.3 Terms and Definitions

Acceptance: Control operation of an incoming good to permit its entry on a production site.

Batch or lot: An identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together (Regulation 767/2009).

Batch delivered: Quantity of feed delivered at one occasion in one place.

Batch (medicated feed): All pharmaceutical units from the same initial bulk and having been subjected to the same series of manufacturing operations. In the case of a continuous production process, the batch is a set of units manufactured in a given period of time. (BPFDAM -Bonnes Pratiques de Fabrication et de Distribution en gros des Aliments Médicamenteux – Décision de l’ANSES du 12 février 2007).

Batch of incoming goods: Quantity of incoming goods considered as qualitatively homogeneous. This quantity of a batch cannot be less than the one defined by the supplier.

Batch manufactured: Group or set of identifiable feed considered as qualitatively homogenous consisting of a mixture or a set of successive mixtures of the same formula, or mixtures grouped in the same production cycle.

Batch cross contamination: Accidental presence in a batch of a residual fraction of another batch.

Capability: Capacity or ability to achieve a product conformed to the requirements for this product.

Calibration: operation that, under specified conditions, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, then uses this information to establish a relation for obtaining a measurement result from an indication.

CCP or critical control point: Step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (ISO 22000).

Complete feed: Feed which, by reason of its composition, is sufficient for a daily ration (Regulation 767/2009).

Compound feed: Mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed (Regulation 767/2009).
In this guide of good hygiene practice, compound feed include the complete or complementary feed other than mineral feed, milk replacers or liquid feeds.

Conformity: Fulfilment of a requirement. (ISO 9001)

Contamination: The undesired introduction of impurities of a chemical or microbiological nature of foreign matter into or onto an incoming or a finished feed during production, sampling, packing or repacking , storage or transport (EFMC guide).

Contamination level: Expression of cross-contamination in percentage.

Control measure: Action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (ISO 22000)

Corrective action: Action to eliminate the cause of a detected nonconformity to prevent recurrence. (ISO 9001)

Critical limit: Criterion which separates acceptability from unacceptability (ISO 22000).

Custom work: Process or set of processes entrusted (s) to a third party; this will mostly concern specific manufacturing processes and custom made packing services.

Curative / Corrective maintenance: Maintenance carried out on equipment for its rehabilitation after a breakdown.

Daily ration: Average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs (Regulation 1831/2003).

Default: Non-fulfilment of a requirement for a specified use or expectation.

Dietetic feed (feed intended for particular nutritional purposes): Feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC (Regulation 767/2009).
In this guide of good hygiene practice, the applicable requirements for dietetic feed are to be linked to the other categories of products manufactured and / or distributed by the company (see 1.2 Scope).

Disinfection: Reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability.

Distributor: physical holder of feed (excluding retail) performing the following process steps to the exclusion of any other: procurement, reception, storage - transfer, loading and delivery.
For the purpose of this standard, the terms "feed" will be used for all products falling within its scope (premixes and all types of food).

Feed or feedingstuff: Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals (Regulation178/2002).

Feed materials: Products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixes (Regulation 767/2009).

Feed additives: Substances, micro-organisms or preparations, other than feed material and premixes , which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5, section 3 of the Regulation (EC) No 1831/2003 (definition of the following regulation). Additives are organized into different functional groups belonging to one of the following five categories: technological additives, sensory, nutritional, zootechnical, coccidiostats and histomonostats.
Additives authorized in the European Union are listed in a Community register.

Feed for animals producing food: Any food intended by nature to animals producing continuously during their livestock products intended for human or animal consumption (e.g. laying poultry, dairy cow feed).

Feed potentially used for finishing diet: Any food whose labeling indications do not preclude a distribution until slaughter of the animal.

Feed business: Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding (Regulation 178/2002).

Feed business operator: natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control (Regulation 178/2002).

Feed hygiene: Measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use (Regulation 183/2005).

Feed Safety : Under article 15, §2 of regulation 178/2002, feed shall be deemed to be unsafe for its intended use if it is considered to:

- have an adverse effect on human or animal health;
- make the food derived from food-producing animals unsafe for human consumption.

Finishing diet feed: Feed with labeling indications which are specifically provided for distribution up to slaughter.

Group of companies : A consortium made of companies each having their own legal existence, but bound together by various relations by virtue of which one of them referred to the "parent company", holds others on its dependence, exercises control on the group and ensures unity of decision making.

Hazard: Biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect (Regulation178/2002).

Hazard Analysis and Critical Control Points (HACCP): A method to identify process steps where a loss or significant deviance from the required product quality and safety could occur if no targeted control is applied. (IFIF guide)

Heat treatment: Operation of a set time-temperature couple to reduce the number of microorganisms present in a product**.**

Incoming Material: In the text of this guide, any product entering in the composition of animal feed, for any purpose in business, manufacturing, distribution or trade, such as:

- Feed materials,
- Additives,
- Premixes,
- Processing aids,
- Medicated premixes

Incoming good matrix: All nutritional characteristics of incoming materials used in formulation.

Incompatibility: Inability to manufacture two sequences of products for regulatory, zootechnical or contractual reasons.

Liquid feed: Complementary feed in liquid form. This product category includes, among others, additional molasses-based liquid feed and complementary feed mixtures of liquid components or whose components are dissolved in water or another liquid product.

MASH feed: non pelleted compound feed, consisting of a mixture of feed materials visually distinguishable, with their different sizes, form, density, presentations (particles, coarse pieces, laminated, flaked, extruded, granulated,…) which may contains supplementary feed.

Maximum allowable differential: Differences between the value of the standard and the value indicated by the device beyond which the device is declared non-compliant during verification.

Medicated feed: Any veterinary medicinal product **consisting of a mixture of feed and medicated premixes, presented to be administered to animals without transformation in a therapeutic, preventive or curative**

purpose, according to sentence 1, article L.5111-1 of the same regulation (5° paragraph, Article L.5141-2 of the French Public Health).

Medicated premixes e(s): Any veterinary medicinal product prepared in advance and intended to be exclusively used for the manufacture of a subsequent medicated feed (Article 4 L. 5141-2 of French Public Health Code).

Merchant : an economic operator exclusively carrying out purchases and resale actions in the form of incoming materials or compound feed (without physical possession of feed).

Metrological confirmation: set of operations required to ensure that measuring equipment conforms to the requirements for its intended use. (ISO 9001)

Milk replacer: Compound feed administered in dry form or after dilution in a given quantity of liquid for feeding young animals as a complement to, or substitute for, post-colostral milk or for feeding young animals such as calves, lambs or kids intended for slaughter (Regulation 767/2009).

Mineral feed: Complementary feed containing at least 40 % crude ash (Regulation 767/2009).

Monitoring: Conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.
*Note: For CCP, monitoring should be **permanent,** that is conducted throughout the process, and related to one or more batches. It can be performed **continuously** (e.g. automatic registration of sterilization heat treatment) or **discontinuous** (e.g. control the gas composition of the products packed under modified atmosphere if the step is considered CCP).*
For oPRP, monitoring should be regular but is not necessarily permanent.
NOTE DE SERVICE DGAL/SDSSA/N2012-8156 du 24 juillet 2012

Nonconformity: Non-fulfilment of a requirement (ISO 9001).

Nutritional Matrix: All nutritional characteristics required for an animal at a given age or stage of production, and the incorporation ranges required to respect for this animal.

Operational prerequisite programme (PRPo) : **PRP** identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards (3.3) to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment (ISO 22000). In this guide, the term oPRP will be replaced by **Point of Attention** (PA)

Packaging article: Element for containing the feed to provide it an essentially physical protection and bear the information required for its usage. It participates in its preservation, identification and proper use.

Pests: Insects, birds, rodents and other animals including domestic which could directly or indirectly contaminate feed.

Pesticides: Pesticides should be understood broadly: insecticides, herbicides, fungicides, rodenticides, destruction of "Pest".

Placing on the market: Holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves (Regulation 178/2002).

Planning: Set of actions to implement, including definition of responsibility and deadlines**.**

Premixes: Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals (Regulation 1831/2003).

Prerequisite program (PRP) or Good Hygiene Practice (GHP): Basic conditions and activities which are necessary to maintain a hygienic environment throughout the food chain (3.2) suitable for the production, handling and provision of safe end products (3.5) and safe food for human consumption (ISO 22000).

Preventive action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation (ISO 9001).

Preventive maintenance: Preliminary maintenance of equipment intended to prevent breakdowns**.**

Process: Set of interrelated or interacting activities which transform inputs into outputs (ISO 9001).

Processing aids: Any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfill a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed (Regulation 1831/2003).

Product: The term "product" is used in this guide to designate incoming goods, semi-finished products, recycling and feed.

Recall: Any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor (Directive 2001/95).

Recommendation: Material or organizational suggestion that can be considered in a continuous improvement goal.

Record: Document stating results achieved or providing evidence of activities performed.

Recycling: Introduction, in one or more batches and at a defined process step, all or part of a previous batch having a similar level of quality.

Required ability: Measurement needed by the company to determine if the conformity of products is fulfilled.

Return: Recovery of food by the manufacturer or the distributor, although presenting or not a manufacturing defect.

Rinsing: Cleaning step aimed to eliminate or reduce to an acceptable level potential residual substance in the manufacturing process.

Sanitation: All operations to obtain and maintain adequate hygiene. This includes the operations of disinfection and pest control.

Supplementary feed: Compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed (Regulation 767/2009).

Traceability : Ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution (Regulation 178/2002).

Transporter: Authorized Economic Operator.

Undesirable substance: Any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production (Directive 2002/32).

Validation: Obtaining evidence that the control measures managed by the HACCP plan and by the operational PRPs are capable of being effective (ISO 22000).

Waste: "Waste is any residue of a production process, processing or use, any substance, material, product, or basically anything that is discarded or that the holder intends to discard. "(Environmental Code, legislative provisions, Article L 541-1).

Withdrawal: Any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer (Directive 2001/95).

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Zero point: Refers for a storage unit at the time where it was empty and recorded as such.

MANAGEMENT RESPONSIBILITY

2.1 Management commitment and feed safety policy

a) Top management of the company has defined an explicit policy on feed safety
b) Objectives are defined in line with this policy
c) Top management agrees to provide adequate resources to achieve these objectives, particularly with regard to responsibility and authority (cf. § 2.3)

2.2 Feed Safety management system planning

a) Top management of the company ensures that the organization and the resources in place enable to control the feed safety management system
b) The management system is designed to remain up to date as possible, at all levels.
c) Particular attention is given to ensure that changes occurring at different levels of the organization (new formula or amending formula, new equipment, new customers, new position, new supplier, ...) are taken into account in the system.

2.3 Responsibility and authority

a) Top management defines a clear organization including both line and functional responsibilities
b) Everyone in the company acknowledges the scope of their duties and responsibilities
c) The person in charge of managing the feed safety management system is directly attached to top management
d) Procedures of the system are explicit about responsibilities
e) Deputizing are planned and controlled in order to maintain skills of these deputies (see § 2.4)

2.4 Training and qualification

a) For each function the required level of qualification is defined, especially for functions that impact the safety of animal feed.
b) A clear process of recruitment, integration, continuous training is in place covering permanent staff and temporary staff (agency)
c) A continuous training plan is implemented and covers trainings required for the proper operation of the feed safety management system.
d) All staff members are trained on the Good Practices applicable to them.
e) The company has defined clearly the skills of each staff member holding positions that have a direct impact on the safety of animal feed, including positions with operating and / or monitoring of CCP / Point of Attention
f) Internal and external trainings that impact feed safety are recorded (attendance sheets, course content, evaluation) and their effectiveness is verified
g) For each training, reminders are carried out regularly, frequency of these session is consistent with the company's needs, including the versatility of staff members or results of verification activities (audits, inspections, individual interviews ...)

2.5 Internal and external communication

a) Internal and external interfaces in the business are identified; top management ensures that all stakeholders have a contact within the company (customers, suppliers, service providers, authorities, interprofessional unions ...).
b) Internal communication rules are established to ensure that everyone has a suitable delay for information that could impact the feed safety management system (new formula, new equipment, changing regulatory requirements ...).

c) External communication rules are established to ensure the awareness by the company of requirements and expectations of stakeholders, including customers and authorities that could impact the feed safety management system.

d) Any OQUALIM certified company must affix a positive declaration of the OQUALIM's brand on its manufactured and/or sold products:

- "from an OQUALIM certified site" for distribution and trading
- "manufactured by an OQUALIM certified site" for manufacturing

2.6 Emergency preparedness and response (alerts / crisis)

a) A procedure (or manual) defines the rules for reporting non-compliances, management of alerts and / or potential crisis, relating to the safety of animal feed; this procedure may not be specific to feed safety

b) This procedure establishes an explicit link with the conditions for withdrawal and product recall (see § 3.8)

2.7 Management review of the feed safety system

a) At an appropriate frequency, top management assesses the level of product conformity and the control of its feed safety management system and concludes on its effectiveness. Documents supporting this management review are maintained (see § 3.1)

FEED SAFETY MANAGEMENT

3.1 General principle

The deployment of the feed safety management system involves four phases:

1. Implementation of solid good practices, in line with industry recommended best practices (§ 4) and the sustainability of an effective traceability system
2. Analysis of the major feed safety hazards, determination and validation of relevant control measures (CCP / Point of Attention) when necessary
3. The operational implementation and monitoring of CCP / Point of Attention
4. Regular verification of the system to ensure its continuous improvement.

3.2 Documentation

a) The company shall establish a procedure regarding management of documents and control of records and data, which should enable to ensure the control and traceability of activities having an impact on the safety and compliance of the products it manufactures and distributes
b) The company shall document its HACCP
c) The company shall retain all necessary records and data for an appropriate time in order to provide proof of safety compliance of the products it manufactures and distributes

3.3 Regulatory watch

The company must have an organization in place in order to:

a) be informed of regulatory changes applicable to its business
b) assess the impact of regulatory changes on its business
c) to communicate internally on regulatory developments and their impact
d) to implement these applicable regulatory changes
e) ensure compliance with regulatory requirements applicable to its business

3.4 Identification and Traceability

a) In accordance with Regulation (EC) No 178/2002, companies must implement a traceability system and procedures to identify:
   - All incoming goods and packaging used for the manufacture of their products and contact information of their suppliers (upstream traceability)
   - The nature of the delivered products and contact information of the customers (downstream traceability).
b) The company must maintain an internal traceability system in order to enable of much as possible targeted withdrawals or recalls, helping to limit economic losses and to maintain customer confidence
c) The traceability system shall enable to at least retain:
   - The name and address of the suppliers and identification of incoming goods and packaging supplied, especially information related with traceability information, e.g. batch number or date of reception ...
   - The name and address of customers and identification of products delivered, especially batch numbers,
   - The date and, if necessary, the time of delivery,
   - The volume or quantity of products.

d) The traceability system should identify returns of feed products and the related cause and origin.

3.5 Risk analysis according to the HACCP methodology

a) Feed safety team leader sets up a multidisciplinary HACCP team. The skills of this team must ensure the analysis of relevant feed safety risks and implementation of appropriate control measures. These skills must cover the following areas:
   - Materials used (feed materials, ingredients, additives ...)
   - Hazards related to these materials and to their manufacturing processes
   - Formulation rules
   - Manufacturing processes, production methods and organization
   - Equipment and infrastructure
   - Methods of analysis for the detection of hazards considered ... "

b) The HACCP team ensures implementation of Good Practices in line with the requirements of §4.

c) The HACCP team identifies relevant hazards (microbiological, physical, chemical) within the scope of the system and identifies acceptable levels for these hazards according to regulatory requirements, customer requirements or other stakeholders.

d) The key feed safety characteristics are described for incoming goods, packaging and finished products. These specifications include in particular information on their composition, state (dried, fresh ...), their physicochemical characteristics (pH, aw ...) and their feed safety acceptance criteria.
   For finished products manufactured by the company the intended use of these products is also described.

e) Detailed flow diagrams are documented for categories of products or processes covered by the feed safety management system. The diagrams are sufficiently detailed to allow the hazard analysis. They must, if necessary, contain the following elements: entrance and exit points of feed materials, additives, processing aids, utilities (steam, compressed air,…) packaging materials; recycling or reworking points; technical information useful for conducting manufacturing processes ...
   These diagrams are formally validated by the HACCP team.

f) The HACCP team conducts a hazard analysis.

   The company conducts a hazard analysis of incoming goods (feed materials, additives, processing aids...). The hazards are assessed according to two criteria: their probability / likely of occurrence at the step or in the material and severity in terms of effect on the animal and / or consumers. The method of determining these risk levels must be a clearly described method, objective, repeatable and understood by all members of the team.

   The HACCP team conducts a hazard analysis of hazards which may occur at each step of the manufacturing processes, according to the flow diagrams (see e). The hazards are assessed according to two criteria: their probability / likely of occurrence at the step or in the material and severity in terms of effect on the animal and / or consumers.
   The method of determining these risk levels must be a clearly described method, objective, repeatable and understood by all members of the HACCP team.

g) Specific control measures are determined for the hazards assessed as having significant risk level; These measures are classified CCP or Point of Attention, CCPs are defined as process steps and Points of Attention are defined as "essential Good practices" - cf. Definitions § 1.3.
   A decision tree can be used to assist in this classification.

h) Each specific control measure (CCPs / Point of Attention) or combination of control measures is validated to be effective in maintaining the hazard to an acceptable level (see c). This validation involves determining the critical limits for CCPs and monitoring limits for Point of Attention (the

drift of a CCP systematically impacts the products while in the case of a Point of Attention impact, it is not systematic).
Evidences of these validations are documented.

i) For each CCP / Point of Attention monitoring instructions are formalized and communicated to staff members responsible for their application. These staff members are suitably qualified and trained (see § 2.4). Actions to be taken when monitoring results exceed critical or monitoring limits are formalized in these instructions. Instructions provide rules for the handling of potentially unsafe products and the recovery of operations (see §3.7)

j) Verification of the feed safety system is planned and supported by activities described in § 3.6 and 3.8. Updating of the system is ensured whenever internal or external changes justify it (see section 2.2 and 2.5) in order to ensure the continuous effectiveness of control measures.

3.6 Verification (internal audit, analytical plan)

a) In order to verify the effectiveness of the feed safety management system, internal audits must be performed

b) Internal auditors must be qualified to carry out this activity and should not audit their own activities to ensure the independence of the audit process.

c) Results of internal audits shall be recorded (e.g. in the form of an audit report) and actions must be taken as soon as possible to eliminate non conformities detected and their causes. Action plans implemented should be followed and their effectiveness verified.

d) The company must implement a plan of analysis of feed materials and finished products to ensure the effectiveness of its control measures

e) Test results must be recorded and corrective actions implemented in the event of non-compliant results above a maximum regulatory level or a maximum recommended value either by the legislator or by the profession.

f) The company participates to the pooled self-monitoring plan OQUALIM and applies OQUALIM's sampling protocols when available (protocol regarding sampling methodology which is applicable to samples taken as part of the OQUALIM "feed" sampling plan).

g) The company applies the notification requirements in the event of non-compliance.

3.7 Management of nonconforming products and customer complaints (withdrawals and recall)

a) The company must formalize the rules for managing and controlling of non-conforming products

b) Disposition of non-conforming products must be recorded and the traceability of these products maintained

c) The company must set up a system for managing and processing customer claims

d) In the event of a withdrawal, the company must implement all means to quickly identify the products concerned and must inform its customers of the non-compliance in accordance with the regulations.

e) In accordance with the note of the Scientific Committee for Animal Nutrition (CSNA), in the event of a recall the company should immediately inform the administration.

f) Any report made to the government on the advice of the CSNA "Reporting nonconformities-manual" will be simultaneously transmitted to OQUALIM.

3.8 Improvement (corrective and preventive actions)

a) The company must ensure that for each detected nonconformity a correction is consistently performed and if necessary corrective action to prevent reoccurrence of the issue is implemented and its effectiveness verified

b) In case of potential nonconformity or other undesirable potential situation detected, the company must implement preventive actions and evaluate their effectiveness

GOOD PRACTICES

4.1 Construction and layout of the building

Objective: To dispose of designed buildings for feed production.

a) The plant shall ensure that the activities carried out on the neighborhood of the site do not have a negative impact on the processed products quality.

b) Inside the plant perimeter, it shall :
- Maintain the wall and the roof of the buildings to avoid leakage or pest infestation.
- Use materials (for the walls, floors, as well as for the doors) relevant for feed production.
- Maintain the surrounding area of the production building to prevent standing water areas

4.2 Lay out of the buildings and the work space

Objective: To dispose of buildings and a work place that create a hygienic environment and prevent the feed from contamination.

a) The plant shall :
- Ensure that the buildings give an adequate space, and a logical flow of the materials, packaging, products and workers.
- Segregate the different products' storage area and facilities; entrants, veterinary drugs, materials, final products, non-conforming products …
- Allow access to veterinary drugs only to authorized personnel.
- Separate the production and storage of the feed products from the storage of hazardous non alimentary products (cleaning chemicals, maintenance chemicals, pest control, personal hygiene…).
- Organize the manual input workshops in the way to avoid mistake between products (means to tidy up and clean and product identification).

4.3 Cleaning and disinfection of the buildings and equipments

Objective: Ensure a constant level of cleanliness and hygiene in the work environment and on the equipments that are needed for the quality and feed safety.

a) The plant shall :
- Define and respect the procedures to clean the buildings, equipments and tools.
- When necessary, provide disinfection (swathing, fumigation…).
- Take care of the cleaning rules to apply between to non-compatible production for zoo technical reasons or due to the use of veterinary drugs, coccidiostatics, or linked to contracts or legal requirements (reinforced cleaning, filling out, rinsing…)

b) The plant shall record cleaning and sanitizing regular operations and keep the records to ensure their traceability.
NB: Routine cleaning tasks (sweeping floors...) are not considered as regular cleaning procedure and are not to be recorded.

c) Regarding chemicals used for cleaning and disinfection, the plant shall:
- Comply with the regulations in force on biocides,
- Adapt the product to its intended use;
- Use the product following carefully the producer instructions;
- Clearly identify and store separately these chemicals.

4.4 Skills and hygiene of the staff members

Objective: Supply the adequate human resources in number and skills to ensure the conformity of the « products » as well as the quality and the safety of the premixes.
Also ensure that the staff members does not carry out contamination to feed.

a) Staff member skills. The plant shall :
   - Describe the organization and manage the qualification and skills of the staff membersimpacting the quality and health safety of the product (diploma, professional experiences)
   - Train to the good hygiene practices and to run the process all the staff members categories in accordance with the detected needs, including temporary employees.
   - Train the staff members handling veterinary drugs on this task's hazards.
   - Keep the needed documents to prove the effective realization and contents of these trainings.
   - Verify that the rules are understood and applied by all the staff members of the company.

b) Hygiene rules. The plant shall :
   - Define and communicate the relevant hygiene rules to the staff members.
   - Forbid drinking, eating or smoking outside the designated areas.

c) Employees' facilities. The plant shall :
   - Implement the needed hygiene facilities to ensure a good level of personal hygiene in regards with the site requirements
   - Identify designated areas where the staff members are allowed to store, prepare and consume food.

d) Work wear. The plant shall:
   - Ensure that the staff members who work in or enter into, areas where exposed products and / or materials are handled, wear work clothing that fit for purpose, clean and in good condition.
   - Work wear shall be laundered at intervals suitable for the intended use of the garments.
   - Ensure that personal protective equipments are used when required, and are designed to prevent any feed product contamination.

e) Worker health status. The plant shall :
   - Define measures to prevent contamination of the product in case of employee illness or injury.

4.5 Pest control

Objective: Prevent any contamination of feed product by: rodents, insects, birds, and pets.

a) The plant shall :
   - Implement a pest management program to avoid pest activity (insects, birds, rodent).
   - Pest monitoring plan shall be documented and the records shall be maintained for traceability.

b) To prevent intrusion and infestation of pest in the buildings, the plant shall:
   - Check the incoming goods at their reception,
   - Buildings shall be maintained at the required level of cleanliness,
   - Protect carefully any potential access point for pest.

4.6 Utilities – air, water, energy

Objective: Prevent any contamination of the feed product coming from the utilities provision and distribution routes

a) The plant shall determine all the fluids used in the site: air, water (liquid, steam), fuel, lubricants and ensure these will not be a source of contamination of the manufactured products.
b) (Oil-free) Compressed air in contact with the product, the plant shall :
   - Define the quality specification of the air in regards with the hygiene requirements.
   - If needed, dry compressed air shall be used.
   - A dehumidifier system shall be implemented.
   - The purge systems shall be inspected.
   - Study the air inlet location to prevent pollution risks.
c) Regarding public water network, the plant shall :
   - Get a certificate notifying the connection of the plant to public water system or provide an invoice.
d) Water coming from a private source or mix of public and private sourced water, the plant shall:
   - For any new borehole, get the authorization to use the water from the local and sanitary authorities. In France: « arrêté préfectoral d'autorisation » (declaration) and approbation from « l'Agence Régionale de Santé » (Health regional agency)
   - Analyze the ground water at a suitable frequency to prove the required quality level against its use.
e) If non potable water is used on the site, the plant shall :
   - Demand a separate and labelled supply system.
   - Forbid the connection of the non-potable water routes to the potable water systems and any flush between the two systems.
f) When steam is used in contact with the product, the plant shall :
   - Require products for the treatment of a steam suitable for food grade contact.
   - Require the use of water that meets the chemical criteria (as defined by CSNA) for the production of steam.

4.7 Management of the purchased materials: packaging / incoming goods/ transports/ laboratory / cleaning …

Objectives: Ensure that materials and services purchased would not become a source of contamination of the feed.
Optimize the purchase of entrants conforming to the quality requirements

a) Purchase management, the plant shall:
   - Define, formalize and comply with procedures for selecting, monitoring and evaluation of its suppliers in compliance the requirements of Appendix 1 "Minimum requirements on selecting, monitoring and evaluating suppliers" and maintain up to date a list of approved suppliers.
   - The results of monitoring and evaluation shall be recorded and maintained, including decisions of corrective actions.
b) Purchase of incoming goods, packaging, transport, and bulk storage, the plant shall:
   - Take into account the physical, chemical and biological hazards to formalize the quality requirements in the specification for suppliers.
   - Single out the sources allowing a full traceability to fight against fraudulent acts.
   - Only purchase from suppliers that are referenced or the way to be referenced by the organization. Incoming goods transport and bulk storage suppliers shall provide the administrative required approval or record.

- Require the identification for each batch received to ensure traceability.
- Require from the suppliers that they notify before the delivery of incoming materials any significant change: new ingredients, new technological agents/ auxiliaries, or any significant modification of their processes. Record all these kinds of communication.
- Require the food contact suitability of the packaging items used for finished products
- Communicate to the staff members in charge of the supply, the suppliers, the incoming materials, the packaging, and the transport companies allowed for supplying the site.

c) Supplies must allow the delivery of incoming materials, taking into account the storage and usage capacities of the industrial site to:
- Ensure compliance to the procurement specifications and associated control measures (certificates of analysis ...).
- Ensure the availability of incoming materials (sufficient storage capacity, setting up regular inventory control at least once a year, management of out-of-stock …).

d) Delivery inspection – Refers to the step "Incoming material reception in HACCP », the plant shall:
- Define for each incoming material the relevant criteria to check in accordance with the specification. The delivery checking procedure should especially specify the following criteria:
  - The inspection frequency,
  - The method of verification – including sampling,
  - For bulk: verification of the traceability of the previous transported materials according to the ITDF rules.
  - The acceptance criteria,
  - The corrective actions foreseen according to possible exemptions.
  - If necessary , the procedure to record the inspection results.
- Preserve the sample in a dedicated room.

4.8 Qualification and maintenance of the equipment

Objectives: Ensure that the facility, production piece of equipment, as well as measurement and monitoring equipment are always suitable for working well.
Ensure either that the maintenance activities do not induce feed hazards.

a) New equipment qualification, the plant shall :
- Take into account principles of hygienic conception in the purchases.
- Qualify equipments that impacts feed safety according to these requirements :
  - Blending operation necessary to ensure homogeneity of the formulas (timing of the blending, level of filling, rotation speed),
  - The whole production process regarding the transfer between batches (see Chap. 4.9).
  - Equipment used for heat treatment / cooling process,
  - Sanitation activities.

b) Verification of the in place equipment effectiveness, the plant shall :
- Ensure the effectiveness of the equipments impacting the sanitary quality on an appropriate schedule, especially :
  - Blender (homogeneity tests to perform)
  - Inter-batch transfer process (cleaning, management of the beginning of the run....)
  - Heat treatment

- Record the protocols, results, analysis of the qualifications and verifications; keep all the relevant documents.

c) Preventive maintenance, the plant shall :
- Define and identify the facilities and equipment's necessary to the production.
- Define, formalize and follow the facilities and equipment preventive maintenance procedures.
- Record the preventive maintenance activities and keep the records

d) Product used for maintenance activities, the plant shall :
- use food grade lubricants where there is a risk of direct or indirect contact with the product, and keep the relevant technical data sheets.

e) Measurement and Monitoring equipment metrology, the plant shall :
- Define and identify the measurement and monitoring equipment needed to obtain or monitor the conformity or feed safety of the manufactured goods.
- Define, formalize and conform to instructions for each equipment (ability required and maximum tolerate deviation)
- Schedule and perform standardization and calibration of their equipment activities.
- Record the standardization and calibration results as well as their analysis and keep records.
- If necessary following the tests results repair the measuring equipment and then re-standardize it and record the conformity of the measures done previously on this equipment.

f) Corrective maintenance, the plant shall :
- Corrective maintenance activities shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.
- Maintenance staff shall be trained in the product hazards associated with their activities.
- Record the corrective maintenance activities and keep these records.

4.9 Measure to control transfers between batches

Objective: Manage the transfers between batches for zoo-technical reasons or due to veterinary drug use, coccidiostats, or contractual or regulatory requirements.

a) The plant shall :
- Define and formalize strict rules on « product » sequencing: temporizations, banning, de-obstruction of filters on the ongoing batch, management of the beginning of the batches… to avoid residues transfer from on batch to the following.
- Verify that the sequencing rules are well applied.
- Keep results of the verification activities.
- Meet the requirements set out in Annex 3 "Inter-Batch Tranfer (IBT)".

4.10 Product rework

Objective: Manage the rework procedure of « products » coming from several steps of the process or from a return, complying with the regulation and zoo-technical requirements.

a) The plant shall :
- Define and formalize rework procedure taking into account the product composition to determine the ratio and incorporation ways during the rework.
- take into account the incompatibilities: ban any rework containing coccidiostat agent other veterinary drugs not allowed in another product.
- Rule out any recycling of cleaning or vacuum waste (except thin particles from sieving).

- Record any rework operation and keep the records according to regulations in force to permits its traceability.
- Realize additional tests on products to rework / recycle : documentary, sensory, granulometry, and / or analytical.

4.11 Waste disposal

Objective: Ensure that waste (product, packaging, incoming materials …) are disposed of or recovered in a good manner, in compliance with the legal requirements, and which prevents feed contamination.

a) The plant shall :
   - Define procedures to classify, collect, recover or dispose of the waste following their types :
     - DND/ NHW: Non-hazardous waste.
     - DID/ IHW : Industrial Hazardous Waste.
   - Select sub-contractor specialized for collecting, recovering or disposal for each category of waste.
   - Record and keep the documents listing the products and packaging sent for recovering or disposal.

4.12 Storage activities

Objective: Prevent contamination or product adulteration during the warehousing activities in hard units (cells, silo, shelves…) or in temporary units (big-bags, tanker, containers …)

a) The plant shall :
   - Define the optimal storage conditions to preserve the product integrity (incoming materials, packaging, semi-finished products, final products…)
   - Prevent especially the non-appropriate warehousing conditions (wild open bags …)
   - Implement a visual physical inspection of the stocks and a schedule to reach the zero point in the cells (full emptying of the container)

b) When a company uses external storage spaces even temporary, it must ensure previous storage, check that no banned products were stored and a suitable cleaning was performed by referring to list it has previously drawn of prohibited products and the type of cleaning level based on previous storage.

4.13 Transport

Objective: Prevent contamination or product adulteration during the transport activities.

a) The plant shall :
   - Use the conditions and mean of transport designed to preserve the product integrity.
   - Ensure that vehicles, containers and conveyances are maintained in a state of repair, cleanliness and condition consistent with requirements given in the relevant specifications.
   - In the case of bulk transport, implement adequate provisions to determine, assess and record the previous loads, cleaning and disinfection carried out according to rules IDTF and the QUALIMAT Transport specifications and in compliance with safety regulations.
   - Record the information relating to loading and delivery.

4.14 Order taking

a) The company must establish a verification and validation system for orders placed by customers.
b) In the case of orders taken for medicated feed, the delivery process shall be respected.

4.15 Product formulation and information/ customer awareness

Objectives: Define the mix of the several incoming materials to get a final product meeting the legal, zoo-technical, contractual requirements and transmit this information to the production site.
Inform the clients and users on the product composition and intended use as feed.

a) Formulation, the plant shall :
   - Define the formula taking into account all the constraints and information necessary to get the product conformity against: regulations, contracts (clients' up dated specifications), industry and technology know-how (production equipment capabilities see chap 4.8), analysis (incoming materials and feed tests results), zoo-technics (incoming materials, nutritional intakes, incompatibilities).
   - Verify and validate the formula and labels before their implementation as well as the authorized substitutions done by an authorized and competent person.

b) Information for clients and users, the plant shall :
   - Communicate to the clients information on the recipe: presence of veterinary drugs, and intended use of the product in the feed (labelling).
   - define rules to ensure the labelling conformity in regards with the regulation.

4.16 Prevention against malicious acts

Objectives:To ensure the protection of animal feed against malicious actions by the implementation of appropriate protective measures to prevent damage to the health of the final consumer.

a) The plant shall :
   - assess animal food safety hazards reasonably expected to occur by potential acts of sabotage, vandalism or terrorism and shall put in place protective measures.
   - identify, map and submit to access control identified sensitive areas within the facility.

PRODUCT REALISATION

The table below indicates for each step of the process the best practices to be implemented:

	4.1	4.2	4.3	4.4	4.5	4. 6	4. 7	4.8	4.9	4.10	4. 11	4. 12	4.13	4.14	4.15
	Construction and layout of the buildings	***Lay out of the buildings and the work space***	***Cleaning and disinfection of the buildings and equipment***	***Skills and hygiene of the staff members***	***Pest control***	***Utilities – air, water, energy***	***Order taking***	***Management of the purchased materials: packaging / incoming materials / transports/ laboratory / cleaning ...***	***Qualification and maintenance of the equipment***	***Measures to prevent transfers between batches***	***Product rework / recycled***	***Waste disposal***	***Storage activities***	***Transport***	***Product formulation and information/ customer***
1. Reception of incoming materials	X	X	X	X	X		X	X	X	X		X	X	X	
2. Storage and Transfer	X	X	X	X	X				X	X		X	X		
3. Grinding			X	X		X			X	X	X				
4. Other processes on incoming materials: Lamination, Flaking, Encapsulation, Extrusion, Tanning			X	X					X	X					
5. Dosing		X	X	X					X	X	X				X
6. Mixing			X	X					X	X					
7. Heat treatment			X	X		X			X						X
8.Granulation			X	X		X			X	X		X			X
9. Cooling / Drying			X	X		X			X	X					
10. Crumbling			X	X					X	X					
11. Sieving			X	X					X	X		X			
12. Coating / spraying			X	X					X	X					X
13. Other processes on semi-finished products: extrusion, agglomeration, Compacting, expansion…			X	X					X	X		X			X
14. Packing		X	X	X			X	X	X	X	X	X	X		
15. Loading	X	X	X	X	X		X			X	X		X	X	
16. Delivery of finished product				X			X			X				X	
17. Recycling			X	X		X	X		X	X	X	X	X		X

5.1 Reception of incoming materials (AC, AA, AL, AM, PM, D)

The reception of incoming materials (bulk, liquid and bags) must be made in compliance with good practices defined by the company (4.7). The acceptance of these goods shall be performed by documentary, sensory and / or analytical checks before unloading.

The acceptance of these materials includes at least sampling and identification of each batch of incoming materials (in bulk or packed). This sample may have been made by the supplier. Storage and retention time for these samples must be defined in line with the company's activity.

Manual or automatic devices should prevent unloading and destination errors.

Receptions, monitoring results and their interpretation shall be recorded and kept.

5.2 Storage and Transfer (AC, AA, AL, AM, PM, D)

During all operations of storage (in storage cells, silos, hoppers, bushels, containers, bags, big bags ...) and transfer which could be passive (gravity fall) or active (material-handling equipment, elevators, conveyors, screws ...) preservation of the "product" must be ensured.

Inventory management shall take into account FIFO / FEFO principles. A physical inventory and planning zero points of the cells must be established.

5.3 Grinding (AC)

The control of the grinding step under good hygiene and quality conditions must ensure a reduction in particles of incoming materials as required for the manufacturing of the finished product and in particular by defining and meeting the cleaning and maintenance plans of mills to prevent abnormal wear-off ...

5.4 Other process on incoming materials: Lamination (AC), Flaking (AC), Encapsulation (PM), Extrusion (AC), Tanning (AC)

These steps should allow specific treatment of incoming materials to be performed under good hygienic conditions to ensure the quality of the products produced in particular by defining and respecting the cleaning and maintenance plan of the equipment...

The extrusion step must allow a sufficient reduction of antinutritional factors (e.g. trypsin inhibitors of soybeans). Specific records shall be in place to ensure this control.

5.5 Dosing (AC, AM, PM, AL, AA)

The quantities of incoming materials to be incorporated in the feed are controlled, such as:

- Weighing equipment is suitable (quantity, accuracy)
- Maintenance and cleanliness of dosing equipment and especially the cleanliness of the "bag pays" are insured
- Workstations of manual additions must be organized to avoid the mishandling of "products" (storage and identification) and be kept clean at all times.
- Dosing tolerances are defined for each incoming materials (ncluding liquids incorporation rate) and to be respected.
- Dosages outside tolerances control procedures are defined and applied.
- Prohibited succession and permitted substitutions must be defined and strictly followed.
- Nature and real quantities of measured incoming materials are recorded (manually or digitally) and allow the conservation of traceability. Records of dosing and succession during production are kept 5 years.

5.6 Mixing (AC, AM, PM, AL, AA)

This step should help spread evenly different incoming materials of a formula in good hygienic conditions and to ensure the quality of the products obtained through:

- Cleaning and maintenance of the equipment concerned,
- Performing homogeneity tests at regular frequency,

- Compliance with the requirements set out in Annex 2 homogenization.

5.7 Heat treatment (AC)

This step, whose purpose is to increase the temperature of a "product", modifying physical, chemical, nutritional or microbiological characteristics, must be controlled according to its final purpose, including:

- Qualification of the heat treatment process must be defined and validated to managed identified hazards (mold development at subsequent steps of the process and destruction of certain additives).
- Validation and monitoring of the heat treatment are controlled.
- The incorporation of fine particles which must be controlled.

5.8 Granulation (AC, AM)

This step, whose purpose is the transformation of a floury mixture of feed materials into agglomerated "products" (pellets ...) must be conducted under good hygienic conditions and help to ensure the quality of the products, including:

- Cleaning and maintenance of the balers,
- Control of the quality of the steam and / or liquid used to allow granulation,
- Establishing control measures to prevent the destruction of some type of enzymatic additives and microorganisms
- Achievement of durability tests
- Controlling the incorporation of fine particles

5.9 Cooling / Drying (AC, AM, AA)

This step, whose purpose is to lower the temperature and / or humidity of the "product" to ensure its preservation during storage, must be carried out in hygienic conditions and help to ensure the quality of the products including:

- Validation of the parameters such as the time of transit and time for discharge, in order to achieve the targeted temperature
- Cleaning and maintenance of coolers / dryers
- Establishing control measures to avoid mold growth in products (monitoring temperature or Aw of the product if relevant at this stage (for mineral feed, control is ensured in storage)

5.10 Crumbling (AC)

This step of transforming a granulated «product» into smaller fractions which size particle allows distribution to some animals (poultry, venison, piglets ...) shall be performed in hygienic conditions and ensuring the quality of the products is obtained, including:

- Cleaning and maintenance procedures for transmitters
- Parameters of the crumbling process such as the spacing of the rollers must be defined and controlled.
- Rules for monitoring of particle size of the "products" must be defined, formalized and respected.

5.11 Sieving (AC, AM, AA, PM)

This step, whose purpose is to remove particles which are too fine, or select the particles according to their size, shall be carried out in hygienic conditions and help to ensure the quality of products, including following cleaning and maintenance procedures for sievers.

5.12 Coating / spraying (AC, AM, PM)

This step of adding a liquid feed material by spraying the feed (the coating consists of both the dosing and mixing process) shall be carried out in hygienic conditions and ensuring the quality of the products is obtained, including:

- Cleaning and maintenance procedures for coaters / sprayers
- Dosing methods by species and product specifications (compliance with the established tolerances, regulations)
- Coating parameters must be defined and validated.

5.13 Other processes on semi-finished products: Extrusion (AC), Agglomeration (AM, PM), Compacting (AM, AC), expansion (AC)

These steps should allow specific treatment of products to be performed under good hygienic conditions and ensure the quality of the products is obtained, including:

- Cleaning and maintenance procedures for the equipment concerned
- Control measures to be implemented to avoid the destruction of certain additives during these processes.

5.14 Packing (AC, AA, AL, AM, PM)

This step of packing the "products" (in bags or big bags ...) shall be carried out under good conditions of hygiene to facilitate handling, preservation and storage of the finished products and ensure their quality, including:

- Cleaning and maintenance procedures of the packaging plant,
- Control measures involved during packaging activities,
- Procedures for product identification,
- Respect of weighing tolerances and unit weight,
- Sample collection and shelf life of these samples:
  - premixes: until the use-by date or best-by date (BBD) and at least one year after production
  - compound feed: up to the use-by date or best-by date (BBD) and a minimum of six months after production
- Define, formalize and respect the weighing tolerances, monitor and record the respect of unit weight and high readibility of the information given on each packaging unit.

5.15 Loading (AC, AA, AL, AM, PM, D)

This stage of loading is to transfer feed from their storage location into the delivery truck and shall be performed in good hygienic conditions to ensure that the quality of the products is maintained.
The company must define and ensure compliance to the following requirements:

- Cleaning and maintenance procedures for bulk and big bag loading
- Cleaning and maintenance procedures for trucks
- Control procedures for loading and sample collection during loading
- Sample collection and shelf life of these samples:
  - premixes: until the use-by date or best-by date (BBD) and at least one year after production
  - compound feed: up to the use-by date or best-by date (BBD) and a minimum of six months after production
- Respect of weighing tolerances
- Recording of traceability information on documents: batch number, weight, label ...

5.16 Delivery of finished product (AC, AA, AL, AM, PM, D)

Delivery and unloading of the feed at the customer (livestock, distributors ...) shall be performed in good hygienic conditions to ensure that the quality of the products is maintained, including:

- Compliance to procedures (amount of purges, wind tunnels ...) to control contamination from the traps / valves and drain circuits of the truck
- Consistency between the delivery document and the actual place of delivery (business / breeder site, silo / tank)
- Handling and transportation equipment must ensure the preservation of the quality and traceability of the products up to the customer.
- When delivery involves a distribution network, the manufacturer informs each actor of this network of the applicable requirements.

For delivery in breeder sites, in order to establish this «biosecurity» risk analysis, the company will refer to the data sheet on biosecurity measures for the delivery of livestock feed and to the CSNA 'epizootic.
The company must:
- define a hazard analysis linked to potential risks of contamination / spread of pathogens (bacteria, viruses) for livestock feeds (deliveries, takeovers).
- adapt biosecurity measures in place according to risk analysis and monitoring (eg new epizootics, changes in regulations, etc.).

The company must ensure:
- set up a plan for cleaning and disinfecting vehicles on the basis of this risk analysis.
- record the cleaning and disinfection of vehicles (traceability).

5.17 Recycling (AC, AA, AL, AM, PM)

Controlled incorporation (definition and compliance to recycling rules and identification of the products to recycle) of “product" or “fractions of product” at various stages of the process or product returns delivered, in compliance with the specification of the feed, including:

- Recycling operations must be recorded and retained in order to allow traceability.
- Cleaning wastes are excluded from recycling.

Appendix 1- Minimum requirements on selecting, monitoring and evaluating suppliers

I- OBJECTIVE

Set the base of common requirements to be met by suppliers of OQUALIM certified companies.

II- DEFINITION

Merchant : an economic operator exclusively carrying out purchases and resale actions in the form of incoming materials or compound feed (without physical possession of incoming materials or feed).

III- SCOPE

Purchases concerned by these minimum requirements for the suppliers are the following types:

- Incoming materials or finished products: additives, raw materials, processing aids, premixes of medicated additives, premixes, complete compounds or complementary foods (including mineral feed, milk replacers or liquid feed or medicated feed),
- Transport service,
- Delivery to external laboratories of analysis part of OQUALIM's pooled-self monitoring plan.

CASE OF PRIMARY AGRICULTURAL PRODUCTS:

Primary agricultural products (tubers, roots, grains, oilseeds, etc.), which are provided directly by the farmer are not required to obtain feed or food safety certification.

The producer of primary agricultural products must comply with Regulation (EC) No 183/2005. It must be registered as an animal nutrition operator by the competent authorities. Possible impacts of primary agricultural products on the safety of animal feed should be considered in the HACCP study of the company certified by OQUALIM (eg. concentration of undesirable substances in feed materials).

When the delivery of primary agricultural products is made by farmers, manufacturers of feed will define the requirements, for example regarding the cleanliness of the transport vehicle, and verify that these requirements are met.

CASE OF MEDICATED PREMIXES

Medicated premix manufacturers are not required to obtain a feed or food safety certification. The medicated premix manufacturer should refer to the French decision of 12th February 2007, relative to the good practices of manufacturing and bulk distribution for medicated feed.

IV- REFERENCING CRITERIA BY TYPE OF PRODUCT OR SERVICE

IV-1. COMPOUND FEED (included mineral, liquid feed, milk replacers & premixes)

For purchases of compound feed and premixes, the "RCNA" certified company must ensure that the supplier:

~~• complies with the referencing criteria defined in Table 1,~~

• is certified "RCNA" or a "feed" certification in mutual recognition. The supplier certification must cover the compound feed or premix concerned.

the list of acknowledged "feed" certifications is present "in Table 2 or online on the site: www.oqualim.fr".

Some ingredients of premixes and complementary feed may be categorized by regulation as premixes or complementary feed. These ingredients can be derived, as part of innovative products, from other sectors of activity than feed.

For these ingredients, in the exceptional case of a supplier whose main activity is not "feed" and so is not certified by a feed scheme, the company certified "RCNA" must:

• ensure that the supplier complies with the referencing criteria defined in Table 1,

• Conduct hazard analysis on the basis of RCNA requirements for the purchased product,

• put in place appropriate supplementary control measures;

• notify its Certification Body and OQUALIM of this exceptional case.

Table 2. List of compatible OQUALIM certifications for suppliers of compound feedingstuffs (including: mineral feed, liquid feed, milk replacer) and Premixes

Approved certifications and scope
OQUALIM – RCNA- Production and placing on the market, distribution, trade of compound feed, mineral feed, liquid feed, milk replacers, premixes
GMP+ B1 – '*production of compound feed'*- GMP+ B1 '*trade in compound feed'*-GMP+ B3 '*trade in compound feed'*. GMP+ B1 – '*production of premixtures'*- GMP+ B1 – '*trade in premixtures'* -GMP+ B3 – '*trade in premixtures'*. The supplier must always communicate in writing the status (certified or not) of the feed, either in the sales contract, order confirmation, invoice or label or any other accompanying document according to one of the formulas defined by GMP + International.
FCA -BC-02-MP Production of compound feed - FCA -BC-03-MH Trade in compound feed FCA -BC-02-VP Production of premixes - FCA -BC-03-vH Trade in premixes.
QS-certified producers of compound feed QS-certified traders of compound feed The compound feed must be within the scope covered by the certification. QS-certified producers of premixtures QS-certified traders of premixtures. The premix must be within the scope covered by the certification.
UFAS – 'Compound feed' UFAS – 'Merchant'
FAMI-QS – Certification under the 'European Code of Practice for Animal Feed Additive and Premixture Operators' for the scope of premixes.

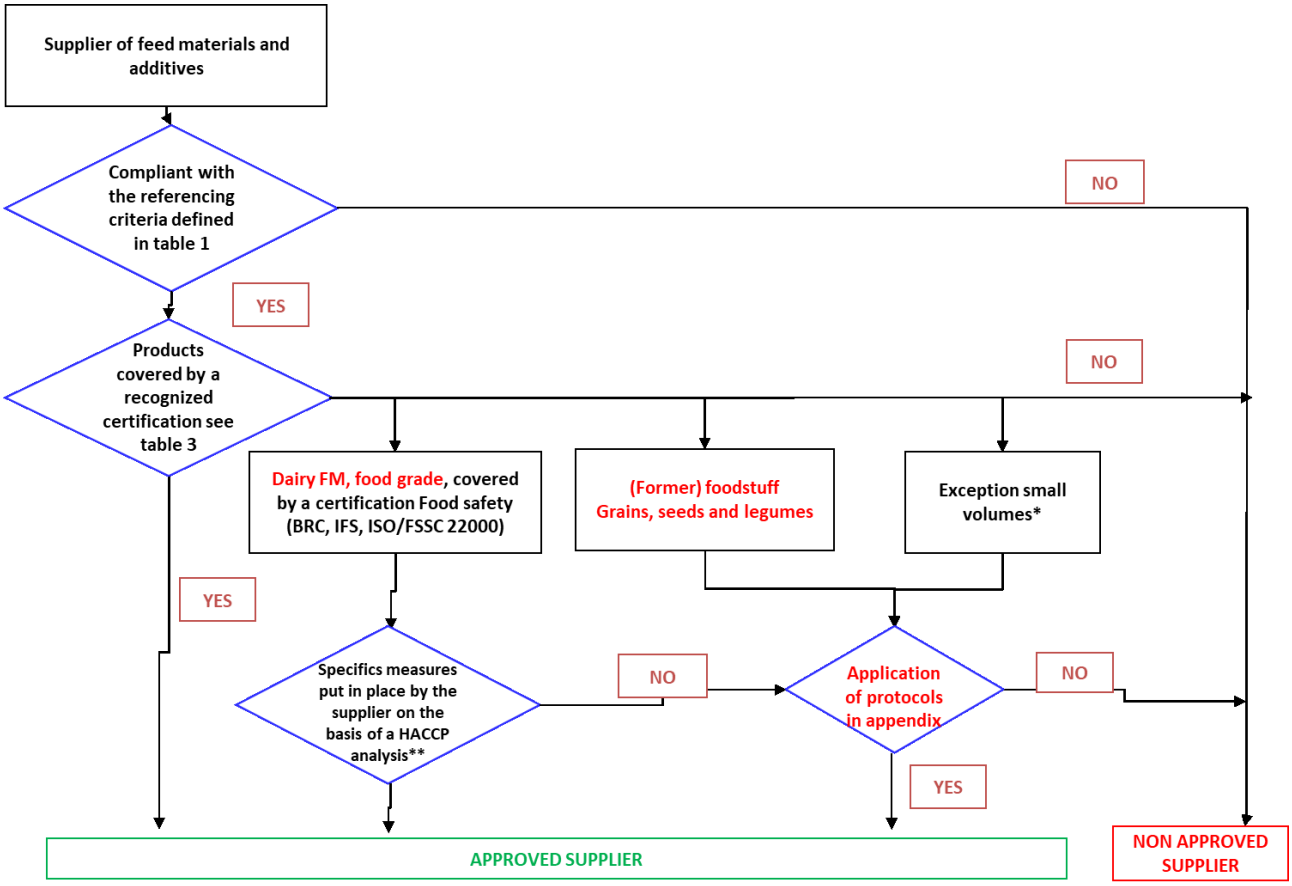
IV-2. ADDITIVES AND FEED MATERIALS

Feed manufacturers must implement a HACCP analysis of all their incoming materials based on Annex 1 of the GBPNA (Good Practice Guide).

The specific control measures implemented by the supplier or manufacturer must be consistent with the results of the HACCP incoming materials analysis.

The "RCNA" certified company must ensure that the supplier:
~~• complies with the referencing criteria defined in Table 1,~~
• is certified according to a recognized certification. The supplier certification must cover the additive or the feed material concerned. The list of recognized certifications is present "in Table 3 / online on the site: www.oqualim.fr".

The referencing of the supplier of additives or feed materials must respect the following flowchart:



** : Irregular or occasional suppliers of small quantities (2 tons / month or 30 tons / year maximum) or referencing of new suppliers whose main activity is not feed*
***: The RCNA-certified company carries out a hazard analysis of the 'feed material' or additive. This analysis is based on the HACCP method. The company must have documentation describing the supplier's manufacturing processes and the product it purchases (eg production diagrams, on-site evaluation reports, control limits, monitoring program and frequency of monitoring activities, technical sheets, certificates of analysis, etc.). The company puts in place a control plan for the feed material or additive based on the result of the hazard analysis it has carried out. The RCNA certified company informs its Certification Body and OQUALIM of the use of this type of supplier, of the hazard analysis carried out and of the control plan implemented. During the audit, the auditor will verify the respect of this analysis, the associated documents and the relevance of the whole in case of purchase of this type.*

Table 3. List of certifications compatible with OQUALIM for additives and feed materials suppliers for animal feed

Certification to ensure compliance with criteria The additives and or the feed materials must be within the scope covered by the certification.
CSA-GTP (collection, storage, placing on the market and transportation of cereals, oilseeds and protein crops). EFISC for feed materials from vegetable oils and protein meal, starch industries and collection, storage trading and transport of grains, oil seeds and coproducts. Fami-QS production and trading of feed additives FCA - 'BC-02-GP : Production of Feed Materials'', FCA BC-03-GH : Trade in Feed Materials'', FCA BC-02 –TP Production of additives, FCA BC-03-TH Trade in additives, FCA BC-02 VWH and GPVW "Production of 'by-products for reprocessing". FEMAS for " Production of Feed Materials" mentioned on the certificate. GMP+ FSA - B2 "Production of Feed Materials''- GMP+ B1 – "production of feed materials"- GMP+ B1 – "trade in feed materials" - GMP+ B3 – "trade in feed materials" - GMP+ B1 – "production of additives"- GMP+ B1 – "trade in additives" - GMP+ B2 "Production of additives" - GMP+ B3 – "trade in additives". The supplier must always communicate by writing the feed status (certified or not, either in the sales contract, or the confirmation order, the label, or any other accompanying document, according to one of the formulas defined by GMP+) QS-certified producers of feed materials, QS-certified producers of additives, QS-certified traders of additives, QS-certified traders of feed materials. When ordering, it will be clearly specified that the ordered animal feed must fall within the scope of the QS certificate. RCNA "Distribution or Trade in Feed Materials", "Distribution or Trade in additives", "Compound feed production" for laminated, extruded, flaked feed materials. *RCF: Standard for suppliers (OQUALIM). UFAS "Merchants"

***The RCF certification is to be excluded to the list of feed material suppliers for any certification RCNA "International" or the acceptance of RCNA "International by schemes in mutual recognition.**

REQUIREMENTS FOR SUPPLIERS OF PROCESSING AIDS

Purchasers of chemical products must expressly state that the products purchased will be used in the production of feed as processing aids when ordering.

Manufacturers using processing aids must carry out an assessment in HACCP of the risks of residues of these auxiliaries or their derivatives when their residual presence in the feed is technically unavoidable. They must offer guarantees that the use of processing aids does not pose a risk to the feed safety. For this purpose, the manufacturer will request the following information from its supplier to carry out a correct risk assessment:

- impurities present in the processing aids, and obligatorily potential contaminants and undesirable substances for animal feed,
- interactions between substances,
- substances which may form in relation to the manufacturing process,
- the chemical reactivity of the processing aid,
- the residue content after reaction.

The manufacturer must ensure from its supplier that:

- producers and distributors guarantee the traceability of processing aids,

- producers are aware of the provenance, processes and applications of their products,

- distributors are aware of the origin and applications of their products,

- producers shall only place on the market processing aids with specifications on the basis of a hazard analysis.

The list of CSA-GTP certified suppliers is available at: https://charte.incograin.com
The list of EFISC GTP certified suppliers and the certification scope is available on the website www.efisc-gtp.eu.
The list of Fami-QS certified suppliers of additives is available at: www.fami-qs.org
The list of FCA certified suppliers and the certification scope is available on the website: www.ovocom.be
The list of GMP+ certified suppliers and the certification scope is available on the website: www.gmpplus.org
The list of QS certified suppliers and the certification scope is available on the website: www.q-s.de
The list of UFAS or FEMAS certified suppliers and the certification scope is available on the website : www.aictradeassurance.org.uk

IV-3. Transport

Definitions:

Transport operator: transport professional who is entrusted with the transport of "products" intended for feed. This transport operator may be either a public carrier or a commission agent.

Own-account transport: manufacturer with its own fleet of vehicles.

All bulk transport operators must have a valid QUALIMAT TRANSPORT or equivalent certification. For any transport non covered by QUALIMAT transport, the manufacturer requirements, especially for risk management linked to previous transports, will be formalized in the order and the contract.

Any manufacturer that carries own-account bulk transportation meets the transportation requirements set out in the RCNA.

The list of certified QUALIMAT TRANSPORT operators as well as the list of certifications equivalent to QUALIMAT TRANSPORT are available on the website www.qualimat.org

The requirements of the manufacturers will be formalized in the order review and contract review.

IV-4. ANALYSIS LABORATORY : conducting analyzes as part of OQUALIM pooled - self monitoring plans

Criteria: External laboratories performing analyzes within the framework of OQUALIM's pooled-self monitoring plan will appear in the list of laboratories authorized for the relevant analysis.

The list of laboratories referenced by OQUALIM is available on the website www.oqualim.fr

Analyzes performed by manufacturers outside the plans of OQUALIM's pooled-self monitoring plan are not subject to this obligation.

V MINIMUM CRITERIA OF REFERENCING TO IMPLEMENT GATEKEEPER PROTOCOLS*

A gatekeeper company is a certified company undertaking purchases to a non-certified company.

RESPONSIBILITES AND REQUIREMENTS

The gatekeeping company is responsible for:

- Insuring that the feed material entering in the animal food chain is sure.
- Respecting the established and mandatory protocols. In case of nonconformity, the certification of the company is affected.

The company must:

- establish a clear and non-ambiguous contract with its supplier regarding to:
  - the respect of all the applicable conditions mentioned in the protocols
  - the responsibilities ("who does what")
  - forwarding of relevant information, including requested content in the protocols
- follow-up the implementation of a management system. The results of this monitoring shall be evaluated and if necessary, control measures must be taken,
- hold data and relevant elements, related to the application of the protocols.

Minimum criteria for referencing of all suppliers, in the case of the gatekeeper protocols, are detailed in the table 1

Table 1 - Referencing Criteria

Referencing criteria (excluding primary production)

The European supplier must be authorized or registered as an operator of animal nutrition by the competent authorities within the meaning of Regulation (EC) No 183/2005. French suppliers will comply to the amended "*arrêté du 28 février 2000*" if applicable. http://agriculture.gouv.fr/alimentation-animale-0)
The incoming materials are authorized and labelled in accordance with the regulations in force (catalog of feed materials UE 68/2013, Regulation (CE) n°1831/2003 on additives for use in animal nutrition, Regulation (CE) n°767/2009 on the placing on the market and use of feed.
For products of animal origin, the supplier is authorized under Regulation (EC) No 1069/2009. An accompanying commercial document is provided characterizing the product of animal origin.
The supplier has implemented an explicit HACCP risk analysis for incoming materials used for animal nutrition feed.
The supplier sets up, implement and maintain formalized procedures based on **the 7 HACCP principles based on the 12 steps of the Codex Alimentarius**. If a good hygiene practice guide exists for its activity, it isused as a support by the supplier.
The supplier has set up a traceability system compliant to Regulation (EC) No 178/2002
The supplier has defined the management of non-conform products and the procedures of withdrawal / recall falling under Regulation (EC) No 178/2002
The supplier undertakes to introduce appropriate control measures in accordance with its HACCP analysis in order to comply with the regulations on "undesirable substances" (Directive 2002/32/EC), microbiology (zoonosis directives), "pesticides" residues, etc...) linked to its activity and its outgoing feed.
When the manufacturer has specific requirements for the control of a hazard identified in his hazard analysis, he must oblige his supplier to respect them.

The regulatory requirements in force in the European Union and also applicable to suppliers in third countries wishing to supply the European market must be applied by them.

'In the case of substances imported into Europe from Third Countries and subject to the application of Article 24 of Regulation n° 183/2005 (EC), the supplier must obtain the import. "

Distributors, merchants must source from suppliers (except primary production) complying with the requirements set out in the table above.
Suppliers located in third countries and wishing to supply the European market must apply the regulatory requirements in force in the EU.

APPLICATION OF THE HACCP PRINCIPLES

The gatekeeper company must perform a hazard analysis, defined the measured to be implemented and controlled.

Data for hazard analysis
All information on the product, manufacturing processes and environment, influencing the health safety must be gathered

Necessary data

- product specification
- manufacturing process (existing production diagram?)
- the incoming materials and auxiliary aids used

- HACCP study: Hazard identification linked to feed materials and production, type of control measures implemented, which type of monitoring is done?
- Which guarantees are provided by the producer? Standard measures put in place, at least the HACCP?
- Legal registration requirement
- Feed safety data sheets,…

Based on this evaluation, the gatekeeping company must define and implement the necessary measures in order to ensure the feed health safety.

A supplier audit allows to obtain the additional information, confirm all provided elements, and verified the level and effectiveness of the health safety on-site.

Appendix 1.1 (Former) foodstuff gatekeeper

1.Introduction

This protocol is meant to purchase (former) foodstuffs via a gatekeeper system for use in feed, for purchases to non-certified company.
This protocol is not applicable to food grade dairy feed materials.
This protocol is not applicable when the (former) foodstuff demonstrably originates from a company already certified according to a recognized feed safety assurance scheme. This company must bring the production of the (former) foodstuff under the scope of his feed safety certificate in case he wants to sell the (former) foodstuff to other feed companies.

Intention should be to process the (former) foodstuffs into a feed product by the gatekeeper. Therefore, the scope 'Production' is necessary. Exception : the product may only be sold one step further down the chain, under the scope 'Trade', to a company with a production scope. Relevant information must be provided.

Excluded from the scope

- By-products originating from the food industry (e.g. beet pulp, brewers' grain, etc) and manufactured for animal feed
- Feed materials for foodstuff
- Feed additives
- Prohibited products

2. Definitions

Term	Description
Foodstuff (intended for use as feed)	Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Food includes drink, chewing gum, as well as any substance including water, intentionally added to food during production, preparation or treatment (Regulation (EC) No. 178/2002).
Former foodstuff (intended for use as feed)	'Former foodstuffs', means foodstuffs, other than catering reflux, which were manufactured for human consumption in full compliance with the EU food law but which are no longer intended for human consumption for practical or logical reasons or due to problems of manufacturing or packaging defects or other defects and which do not present any health risk when used as feed. (Commission Regulation (EU) No 68/2013)
Prohibited products	Products which are neither intended nor suitable for human consumption due to risk for human health and/or products of which the circulation and use in animal feed is prohibited.

3. Requirements for the gatekeeper

3.1 Supplier evaluation

To reference the supplier, the gatekeeper company conducts a desk study of the supplier to ensure specific measures for the (former) foodstuff on the basis of a HACCP study.

The risk assessment is carried out per (group of) (former) foodstuff per supplying food company, in consultation with the buying animal feed company.

The risk assessment must encompass all operations and activities, from original production of the (former) foodstuff 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), (as given in alinea 4 of this sheet).

The FSDS for the (former) foodstuff need to provide necessary information to evaluate potential risks and to define the appropriate use in feed. The FSDS provides a description and specifications in feed, data for identification and production, information from the HACCP analysis, ingredients used and chemical composition, storage and transport instructions, control,…).

The FSDS is updated when products or manufacturing processes are modified and at least once each 3 year.

3.2 Supplier audit

Each year, the gatekeeper performs an audit at the food company. When food supplier company is certified for BRC, IFS, ISO/FSSC 22000, 1 audit / 2 year is sufficient.

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

Internal auditors must be qualified to perform this task and must have an independent position in relation to the supplier and to commercial activities of the feed company.
The gatekeeper who wishes to conduct the supplier audit but does not have qualified supplier auditors, may delegate the conduction of these audits.

Monitoring in accordance with HACCP principles as laid down in the core standard of the scheme.

Witness audit (third party audit)

The gatekeeper 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 gatekeeper at the supplier.

Minimum number of witness audits per year depends on number of suppliers that are assured by the gatekeeper 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 gatekeeper, which suppliers are visited. Logistical reasons should be an important selection criterion. Preferably, the witness audit will be carried out during a certification audit.

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

3.3 Records

The gatekeeper creates a feed safety data sheet (FSDS), or an equivalent document, in cooperation with the supplier per batch of product and per supplier. See alinea 4 for an example of an FSDS. The commercial documents should refer to the FSDS or an equivalent document.

A written agreement with the food company about the rights and obligations for guaranteeing the requirements as specified in this protocol.

The gatekeeper 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.

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 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.

4. Model of Feed Safety Data Sheet (FSDS)

The Feed Safety Data Sheet, or equivalent document, which the participant and the supplier (non-certified) that wants to dispose of (former) foodstuff must fill out, includes at least the topics mentioned in the FSDS below. Participants can use this FSDS as an example to draw their own FSDS.

	FSDS Feed Safety Data Sheet	0.1 Product	
		0.2 Status	
		0.3 Version	
		0.4 Version date	
1. Responsibility for the Feed Safety Data Sheet			

1.1	Name of company producing (former) foodstuff(+)	Name	
	Contact	Address:	
		Town:	
		Telephone	
		Fax	
		E-mail	
		Website	
1.2	Approved by (Name and position of the competent official representative of the company)		
1.3	Name of commercializing company (trade – if applicable)	Name	
	Contact	Address:	
		Town:	
		Telephone	
		Fax	
		E-mail	
		Website	
1.4	Approved by (competent official company)		
1.5	Name of the processing company (manufacturing compound feed or premixes)	Name	
	Contact	Address:	
		Town:	
		Telephone	
		Fax	
		E-mail	
		Website	

1.6	Approved by (competent official company)	
2. Identification of the product		
2.1.	Product name	
2.2.	Trade name	
2.3.	Article code of the company	
2.4.	Permit number (if applicable)	
2.5.	Product description	
2.6.	Origin (produced by)	
2.7.	Supplied by (if different from 1.3)	
2.8.	Production process	
2.9.	Ingredients and auxiliary substances used (including feed additives and processing aids)	
2.10.	Logistical process (transport, (interim) storage, packaging)	
2.11.	Storage life	

2.12	Indicative analysis	Parameter	Unit	Average	Min.	Max.

3. Standards / requirements						
3.1	Relevant legislation and other requirements					
3.2	Relevant product standards (chemical, physical, microbiological)	Parameter	Unit	Statutory	Contractual	Internal
3.3	Intended use + reason for destination feed					
3.4	Processing of the product (indicate whether the (former) foodstuff needs further processing or has been processed into feed material)					
3.5	Processing steps and instructions for processing					
3.6	Storage and retention requirements					
3.7	Transport requirements					

4. Labelling

5. HACCP						
5.1 Hazard	5.2. Risk assessment				5.3. Control measures	5.4. Reason
	Category (C, M, P)	Likely ccurence	Severity	Risk		

6. Monitoring		
6.1 Parameter	6.2 Sampling moment / point	6.3. Frequency of analysis

7. Communication in case of non-conformities
In case the batch does not correspond with the FSDS or the suspicion exist that the health of animals or the food/feed safety is in danger, this must be actively reported to the gatekeeper.

8. Remarks	
9. Signatures	
…….. DD / MM / YY Company (Purchaser, gatekepeer)	…….. DD/ MM / YY Non-certified company (Supplier)

Appendix 1.2 Gatekeeper protocol for purchase of grains, seeds and legumes

1.Introduction

This protocol applies to

a) Purchase of grains, (oil-)seeds and legumes in unprocessed form from a company non certified by a scheme recognized by OQUALIM, from all countries with the exception of Germany, Austria, Belgium, Canada, Denmark, France, United Kingdom, Greece, Ireland, Italy, Luxembourg, the Netherlands where this gatekeeper protocol does not apply.
b) Purchase of intervention grain.

Each year, OQUALIM evaluates together with interested parties, countries concerned by this gatekeeper protocol.

RCNA certified companies, purchasing grains, seeds and legumes from one of the above indicated territories origins, must apply such protocol.

Primary products directly purchased from primary producers are not affected.

These feed materials can be transported by waterway (sea vessel, lighter or coaster), by rail or by road.

The company, applying this gatekeeper protocol must notify OQUALIM and the certification body beforehand. To this end, it is sufficient to send an email to contact@oqualim.fr and to the certification body, mentioning the feed material and its origin.

2.Monitoring and sampling

2.1 Sampling

Any delivery of the above-mentioned feed materials, must be sampled and analyzed. The frequency of analysis is different depending on the transport means.

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 20th sample

If one can demonstrate that multiple deliveries (or shipments) are part of the same batch, it is sufficient to analyze the batch upon the first delivery, provided it can be proven in writing that the sampling and the analysis are representative for this batch.

2.2 Monitoring

The RCNA 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 to be provided by the previous links in the chain, the RCNA certified company makes a selection of the supplier and draws up a monitoring program 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.

The analysis of the parameters indicated below must be performed, mandatorily, for each relevant feed material.

Parameter	Remarks/explanation
Crop protection agents and pesticides	See the minimum list of pesticide molecules defined for OQUALIM approved laboratories
Heavy metals (Arsenic, Lead, Mercury, Cadmium)	According to risk assesment
In the event of artificial direct drying using another fuel than gas: - Dioxins - Sum of dioxins and dioxin-like PCBs - Non-dioxin like PCBs - PAHs	In case the gatekeeper has a written statement from the drying company that proves - natural gas is used, or - indirect drying is applied, the 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.
Salmonella	According to risk assesment
HCN	Linseed
Free gossypol	Cotton seed
Rye ergot	Wheat, rye and triticale
Mycotoxins -Aflatoxin B1 -Deoxynivalenol (DON) -Zearalenon (ZEA) -Ochratoxin A (OTA)	 At least applicable for maize, At least applicable for all cereals, At least applicable for all cereals and soya beans At least applicable for all cereals,

2.3 Notification of analysis results

OQUALIM shall be notified of all deliveries falling under this protocol, along with the analysis results.

If a batch is supplied to multiple companies, it is sufficient for one company to communicate the analysis results. In this case, all companies having received their supplies on the basis of this protocol, must be indicated. There is no obligation to block the feed materials pending the analysis results.

Appendix 1.3 Gatekeeper protocol for small volumes

1.Introduction

This gatekeeper protocol defines the requirements for purchasing from non-certified companies in a way that allows small-volume suppliers to be controlled.

2.Definition

Small volumes suppliers: Irregular or occasional suppliers of small quantities for feed production (2 tons / month or 30 tons / year maximum) or referencing of new suppliers whose main activity is not feed.

3.Requirements

The RCNA-certified company carries out a hazard analysis of the 'feed material' or additive. This analysis is based on the HACCP method. The company must have documentation describing the supplier's manufacturing processes and the product it purchases (eg production diagrams, on-site evaluation reports, control limits, monitoring program and frequency of monitoring activities, technical sheets, certificates of analysis, etc.). The company puts in place a control plan for the feed materials or additives based on the result of the hazard analysis it has carried out.

The RCNA certified company informs its Certification Body and OQUALIM of the use of this type of supplier, of the hazard analysis carried out and of the control plan put in place.

During the audit, the auditor will verify the respect of this analysis, the associated documents and the relevance of the whole in case of purchase of this type.

Appendix 1.4 Gatekeeper protocol for processed feed materials

1. Scope

This protocol defines the requirements for purchasing processed feed materials from suppliers not certified by a scheme recognized by OQUALIM.

This protocol is not applicable for feed materials for which there is an existing protocol ((former)foodstuffs and small volumes).
For (former) foodstuff gatekeeper protocol see appendix 1.1,
For small volumes gatekeeper protocol see appendix 1.3.

The application of this protocol is submitted to restrictions depending on the origin of the supplying source. Each year, OQUALIM will evaluates together with interested parties, countries concerned by this protocol and the list of processed feed materials concerned. Spain, France, Italy and Poland will be the next countries to be evaluated in 2020.

This protocol is currently being harmonized with the other schemes involved in feed safety. It may be subject to changes during the year.

2. Definitions

Unprocessed feed material: any type of feed material in which the original state i.e physical, chemical or nutritional has not been altered. An exception is made for processes ensuring a stable storage for feed materials. When such a process is performed, the feed material is still considered as unprocessed (e.g Drying, chilling, cleaning/sieving, packaging).

Processed feed material: Any type of feed material in which the original state i.e physical, chemical or nutritional has been altered. (e.g: Crushing/pressing, milling, pelleting, cooking, fermentation, extrusion, expansion, toasting, chopping, grinding).

3. Requirements

The gatekeeper company must carry out a risk assessment of the supplier and the supply chain of the feed product in accordance with the HACCP principles.

This protocol applies except for the feed materials from the countries listed below :

Processsed feed materials	Countries
All processed feed materials	Germany, Netherlands, Belgium, Luxembourg, United Kingdom, Austria
Fishmeal	Peru
Oil seeds meals and citrus pulp	Brazil
Oil seeds meals	Argentina
Molasses	Pakistan
Palm kernel expellers	Malaysia
Palm kernel expellers	Indonesia

This protocol can be applied only by manufacturer.

Sampling is **mandatory** batch by batch.

Analyses have to be performed on each batch for the parameters reported in the next table.

Records and other documentation related to the application of this protocol must be documented. This must be available for the auditor and – if requested – for the scheme owner.

This includes the following :

- raw feed materials, production methods, process flow and environment from which the feed is derived, necessary for the risk assessment,
- Name and address data of the non-certified producer
- Name of the purchase feed materials,
- Record of each batch purchased,
- Results of risk and lab analysis
- Any other relevant data.

In application to the HACCP principles, the lack of one or more requested information listed above could conduct to define additional control and monitoring measures.

The gatekeeping company informs its CB and OQUALIM (by email: contact@oqualim.fr) of the use of this protocol for each new processed feed material including its type and origin.

Appendix 2 - HOMOGENIZATION

I- METHOD OF MEASUREMENT

TECALIMAN provides technical rules for the assessment of homogenization performance of a mixer load. These rules are presented in Annex 3B of the good manufacturing practice guideline for Animal Nutrition. They apply to compound feed including milk replacer, and can be adapted for manufacturers of mash feed, premixes, powdered minerals and dietary feed, liquid feed.

Initial validation of the mixture homogenization process shall take into account the extreme values for the mixing time, the degree of filling, the speed of rotation, the incorporation rate.
For periodic validation, the parameters will be validated to choose between the extremes, by the most representative example.
The values of the validation tests of homogenization as Coefficient of Variation (CV) are percentages.

II- INTERPRETATION OF RESULTS

The compliance of the coefficients of variation (CV) is evaluated according to:

- The obligations of the industrial site,
- The quality objective chosen by the manufacturer.

- For manufacturing **premixes,**
  - The homogenization capability test results with CV ≤ 5% are considered compliant.
  - The homogenization capability test results with a CV> 5% and ≤ 8% are considered compliant but to monitor in compliance with current legislation.
  - The homogenization capability test results with CV> 8% are considered non-compliant, root cause analysis and implementation of corrective actions must be taken.

- For manufacturing **mineral feed**,
  - The homogenization capability test results with a CV ≤ 8% are considered compliant.
  - The homogenization capability test results with CV> 8% and ≤ 12% are considered compliant but to monitor in compliance with current legislation.
  - The homogenization capability test results with CV> 12% are considered non-compliant, root cause analysis and implementation of corrective actions must be taken.

- For manufacturing of **compound feed**,
  - The homogenization capability test results with a CV ≤ 5% are considered compliant.
  - The homogeneity test results with a CV> 5% and ≤ 10% are considered compliant but to monitor in compliance with current legislation.
  - The homogenization capability test results with CV> 10% are considered non-compliant, root cause analysis and implementation of corrective actions must be taken.

- For manufacturing **a mix of compound feed (including mineral feed)**,
  - Measurement Methodology: counting or measuring one or more incoming material(s) representative (s) of the formula.
  - Thresholds of interpretation:
    - The homogenization capability test results with a CV ≤ 20% are considered compliant.

- The homogenization capability test results with CV> 20% and ≤ 30%, are considered compliant but to monitor in compliance with current legislation.
- The homogenization capability test results with CV> 30% are considered non-compliant, root cause analysis and implementation of corrective actions must be taken.

- For manufacturing **mash feed,**

For mixers exclusively used for mixtures of mash feed containing no additives, with content guaranteed by the labeling, or containing additives, incorporated only via a compound feed, with content guaranteed by the labeling and considering the size of the sample collected less than the size of the feed intake, the following adjustment is to be adopted:

↳ Measurement Methodology: counting or measuring one or more incoming material(s) representative (s) of the formula.

↳ Thresholds of interpretation:

- The homogenization capability test results with a CV ≤ 20% are considered compliant.
- The homogenization capability test results with CV> 20% and ≤ 30%, are considered compliant but to monitor in compliance with current legislation.
- The homogenization capability test results with CV> 30% are considered non-compliant, root cause analysis and implementation of corrective actions must be taken.

- For manufacturing of **liquid feed**,

The tests are performed on a chosen tracer (Total Nitrogen, ...) by a quantifiable method validated by laboratories.

Given the specificity of the liquid when a solid additive is incorporated directly or via a premix or supplement feed it is best to choose it as a tracer.

- The homogenization capability test results with a CV ≤ 5% are considered compliant.
- The homogenization capability test results with a CV> 5% and ≤ 10% are considered compliant but to monitor in compliance with current legislation.
- The homogenization capability test results with CV> 10% are considered non-compliant, root cause analysis and implementation of corrective actions must be taken.

In other cases, the thresholds of 5 to 10% for CV applies.

III- SUMMARY TABLE

	CF	LF	MF	PM	MASH Feed
Compliant	CV ≤ 5%	CV ≤ 5%	CV ≤ 8%	CV ≤ 5%	CV ≤ 20%
Compliant to monitor	CV > 5% and ≤10%	CV > 5% and ≤10%	CV > 8% and ≤12%	CV > 5% et ≤8%	CV > 20% and ≤30%
Non-Compliant	CV > 10%	CV > 10%	CV > 12%	CV > 8%	CV > 30%

IV- FREQUENCY OF TESTS

↳ Once a year if the company uses medicated premixtures or additives, coccidiostats and histomonostats or vitamins A, D or Copper, Selenium – as such or in the form of premixes.

↳ 1 every 2 years in other cases.

V- TECALIMAN TECHNICAL SHEET - TECHNICAL RULES FOR ASSESSING THE HOMOGENISATION PERFORMANCE OF A BATCH MIXER

Tecaliman
L'EXPERTISE AU SERVICE D'UNE INDUSTRIE DURABLE

DATASHEET N° 30
July 2012

Keywords: Mix, Measurement, Homogeneity

Technical rules for assessing the homogenisation performance of a batch mixer

Industrial obligations allied with French and European regulations are driving feedstuff manufacturers to assess the homogenisation performance of their mixers. These technical rules, which are recognised by several certification reference systems, can also be adapted for use by manufacturers of mashes, additive premixes, and powdered dietetic and mineral feeds (adjusting the choice of tracer, sample sizes, etc. as necessary).

Technical mastery over homogeneity is based on an assessment of how uniformly additives and premixes are distributed in feedstuffs. As such, technical rules for assessing a mixer's homogenisation performance have been defined, and established, based on:

- settings with a known impact on the results or their interpretation,
- the results of a bibliographical review on the homogenisation of compound feeds,
- the results and observations obtained from industrial assessment campaigns carried out since 1999 jointly with the DGAL (French Directorate General on Food Safety).

These rules provide businesses with a tool for technical mastery of the homogeneity of feedstuffs and take the form of recommendations; each user is free to use their preferred method provided that they can demonstrate that the result and its determination lie within a certain dependability range.

Compliance with these rules is a condition both for building a database on industrial performance in this area, and for enabling a comparison either between different sites or of a given site over a certain period of time.

Technical comments and rationales may be provided in the form of cross-references at the end of this document, identified by numbered superscripts. Important concepts are underlined.

1. Objective

- To test the homogenisation performance of a batch mixer under a given set of conditions. This is done by studying the distribution of a tracer in a mix of solids. The test conditions must be representative of the plant's chosen manufacturing practices.

2. Principle

The method consists in:

- stating the objective (to test a given practice, test a product, etc.),
- defining the test conditions (choice of tracer, mixing conditions, sampling conditions, etc.),
- preparing a mix containing the tracer,
- taking the samples,
- quantifying the amount of tracer in the samples,
- interpreting the results.

The assessment results provide a snapshot of the tracer's behaviour under the test conditions.

3. Apparatus

3.1. Choice of tracer

The following criteria are recommended for selecting the best tracer to use for testing the homogenisation capability of a mixer for powdered ingredients:

- It must be capable of being quantified using a method that is accurate[1] [2], repeatable[3], sensitive[4], simple and cost-effective[5].
- It should derive mainly, or even better, exclusively, from a single source[6].
- It is recommended that its main source comprises at least 1 000 000 part./g.[7].
- It must be stable with respect to the manufacturing process between the point of its incorporation and the point of sampling.
- It must be possible to incorporate it directly into a media or by scattering it over a media.

Other, less effective, tracers may be used; any deviation from the recommendations may provide grounds for interpreting a nonconform result.

If selecting a tracer with doubts over the analytical performance, the recommended procedure is to carry out duplicate analyses on each sample (see § 5.5). Other objectives may lead to the adoption of different tracer selection criteria (mash feeds, liquids incorporated into the batches, mineral or dietetic feeds, etc.).

3.2. Mix base

It is preferable to use a product that is representative of the plant's production output[8].

4. Production

4.1. Mix conditions

These must conform to the plant's standard practices (mixer's fill rate, mixing time, point at which the tracer is incorporated, etc.). Different sets of conditions can be tested for the purposes of experimentation.

4.2. Sampling method and location

It is recommended to take the samples at a point that is as close as possible to the mixer output. The sampling method and location should make it possible to:

- take samples safely,
- obtain samples that are representative of the product flow (Gy, 1996),
- obtain samples of the desired size (Gy, 1996),
- arrive at a result that is close to the result that would be obtained ex-plant[9],
- test a performance that covers the full range of the plant's product presentations.

To ensure the collection of a representative sample, it is strongly recommended[10]:

- to cut the flow in differing directions from one sample to the next,
- to choose sampling points with moderate flow rates[11].

It is recommended to take the following precautions:

- attach the sampling equipment to a fixed point outside the circuit,
- make sure there are no moving parts in the sampling zone (dual-direction boxes, pneumatic hatches, elevator buckets, etc.),
- wear a mask and goggles if dust is generated.

4.3. Number of samples

It is recommended to take at least 20 samples[12]. It is advised to provide extra sample containers to ensure that samples can be collected right up to the end of the batch.

4.4. Sample size

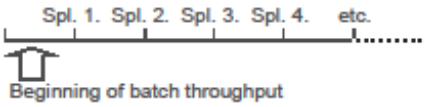
This can vary between 100 and 1000 g[13]. It is recommended to minimize variations in sample size for a given test.

4.5. Sampling frequency

This frequency is designed to distribute sampling points over the whole batch.
This is determined as follows:

- measure the throughput time for a batch that is similar to the batch produced during the test at the sampling point,
- calculate the time between two samples by dividing the throughput time by the number of samples to be taken plus 1, i.e. 21 for 20 samples.

At the beginning of the batch throughput, the stopwatch is activated in order to allow a suitable time to pass before taking the first sample[14]:



Batch start is considered effective when the sampling tool fills completely during a clean, direct penetration of the flow for a short period of time. Batch end is considered effective when the sampling tool no longer fills completely during the same period of time.
The samples are taken at each time period and packaged in chronological order. Samples have to be taken up to the end of the batch throughput, which is marked by a clear and significant reduction in flow rate.

5. Testing

5.1. Preliminary tasks and checks

The following has to be checked at the sampling point:

- Safety of the sampling conditions.
- Availability of the persons and equipments required to carry out the tests.
- Throughput time for a similar batch, in order to determine the sampling frequency.
- Absence of any factors that could disturb the test (strong or irregular flow, generation of dust, etc.).

5.2. Additional data collection

It is recommended to collect the following data in order to facilitate both subsequent interpretation of the test results, and the comparison of how the results change over time:

- physical characterizations of the tracer and the product,
- method used to incorporate the tracer: incorporation point, expected concentration in the feed, incorporation rate and the concentration of any possible premix, incorporation timeline, etc.
- quantities of dosed raw materials (including molasses, fats, and other liquids) upstream of the sampling point,
- mixer characteristics (brand, type, status, equipment size, etc.),
- all the information on all the operations performed during the test between the tracer incorporation station and the sampling point (molassing, pelleting, coating, etc.),
- any changes that have occurred since the previous test (equipment and apparatus, practices, etc.),
- formula(s) and weighings (Dosing log),
- any deviation from this method,
- list of and respective times for all mixing phases (pre-homogenisation, incorporation sequence for liquids and solids, homogenisation time, etc.),
- mixing conditions.

5.3. Sample processing and analysis

The packaging, shipping and laboratory processing of the samples must be carried out under conditions that preserve their representativeness of the manufactured mix.

One tracer dosing is made in each sample selected for analysis. These analyses must be performed according to validated procedures, particularly in terms of repeatability.

If an analysis is carried out on a test portion that is smaller than the samples, it is recommended to finely grind the whole mass of the sample (without destroying the tracer), then re-homogenise it and finally divide it to produce a sub-sample of a size that is as close as possible to that of the test portion. The bulk density and grain size of the feeds may also be analysed in order to characterise the test conditions.

5.4. Processing the results

The results undergo statistical processing. Firstly, a calculation of the mean (m) of all the analyses and the identification of the expected concentration (C) according to the weighings is used to determine the tracer's recovery rate (% TR):

$$TR = 100.\frac{m}{C}$$

For single analyses (one analysis per sample) on each sample, the calculations of the variance (V_{tot}) and mean (m) for all the analyses are used to calculate an overall coefficient of variation (as a %), based on the equation:

$$CV_{tot} = 100 \cdot \frac{\sqrt{V_{tot}}}{m}$$

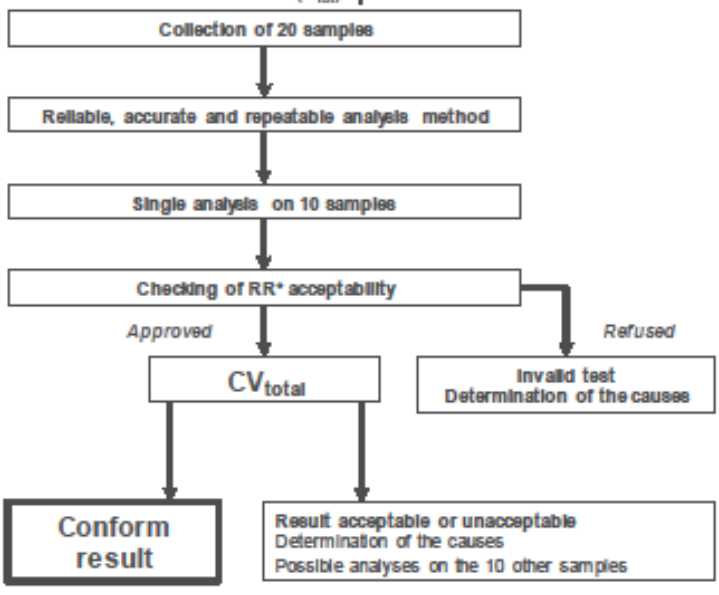
In cases where the overall variance could be explained largely by variability in the analysis method, it is recommended to duplicate the analyses on each sample. This will modify the statistical processing of the results and make it possible to derive from the overall variance, the residual variance including the analytical variance.

To do this, a variance analysis is performed based on the randomised model (see Technical Datasheet N°35). This makes it possible to compute the homogeneity variance (V_{hom}) by determining the "inter-samples" variance. This gives a CV_{hom} of:

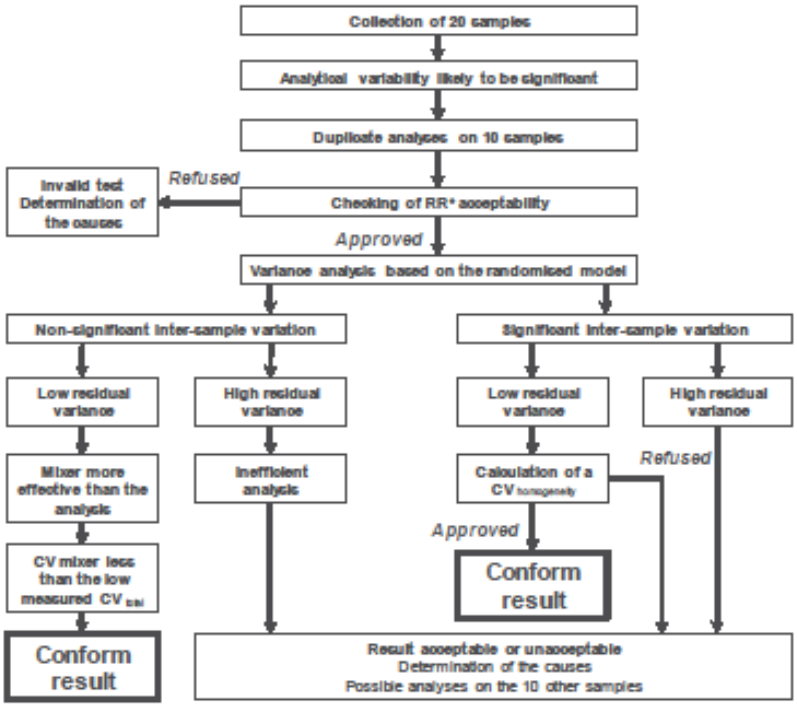
$$CV_{hom} = 100 \cdot \frac{\sqrt{V_{hom}}}{m}$$

5.5. Interpretation of the results

This interpretation is based primarily on the decision trees shown on the following page. The first tree corresponds to the conventional case, while the second is used if there are doubts over the analytical performance of the selected tracer.



* Permissible recovery rate (RR) ranging between 70% and 110%[15] (80% to 110% for the manufacture of medicated feeds).



CV conformity (homogeneity or overall) is evaluated based on:

- the obligations of the industrial site,
- the quality objective selected by the industrial in relation to the threshold values indicated in the corresponding guides.

Interpretation of the results is based on:

- the change in inter-sample concentrations,
- the change in CVs over time (from one test to another). It is strongly recommended to track this change given the comparable nature of the results (closeness of assessment conditions).
- the data collected over the industry as a whole and the variation recorded from one test to another concerning:
  - manufacturing practices,
  - test procedures (sampling point, selected tracer, batch size, etc.),
  - the tested manufacturing circuit.

6. Bibliography

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- Special report N° 41: Enquête auprès des fabricants d'aliments composés sur leurs essais d'évaluation de l'homogénéité des mélanges et des taux de contaminations croisées. (Survey of compound feed manufacturers concerning their mix homogeneity assessment testing and carry-over rates). Tecaliman - 2000.
- Report 2: Essais industriels de répétition de mélanges sur 3 sites industriels. (Factory testing on mix repeatability at 3 industrial sites) Tecaliman - 2000.
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- Le point sur l'homogénéité des aliments composés. (Review of the homogeneity of compound feeds) Tecaliman - 1998.
- Technical Datasheet N° 35

Cross-references

[1] Measurement accuracy: closeness of the agreement between a measurand and an actual value for the specific quantity being measured. (Standard NF X 07-001).

[2] Analysis quality depends primarily on the choice of sample processing protocol, and also on the method used to interpret the results.

[3] Repeatability of the results: closeness of the agreement between the results of successive measurements of the quantity being measured, where all the measurements are taken under the same measurement conditions. (Standard NF X 07-001).

[4] Sensitivity: ability to detect small variations in analyte (the analysed substance). (Standard V 03-110).

[5] Due to the large number of analyses required.

[6] This is to ensure that it is solely their behaviour in the mix that is represented. Due to the diversity of their sources, formula ingredients, such as proteins, fats or ash, cannot be used as a basis for testing the homogenisation performance of powdered ingredient mixers as they are usually already distributed fairly uniformly throughout the feed components.

[7] This figure ensures a presence of at least 10,000 particles in each sample when the product is introduced at a concentration of 100 ppm and the sample size equals 100g. It is possible to choose a tracer that contains a lower number of particles per gram, but it should be noted that any decrease in this particle number may result in a higher coefficient of variation.

[8] Technical mastery over the product's composition and physical characterization will provide scope for some test standardisation, thus facilitating the collection of historical data on comparisons.

[9] Various data support the existence of a small variation between the homogeneity achieved at the mixer output and that recorded in the loaded batch, i.e. the bibliography and, in particular, the study carried out by the IFF in 1982 (Einfluss der physikalischen stoffeigenschaften am beispiel spurenelemente auf die mischgüte und anforderungen an verarbeitungsanlagen beim einsatz von mikrokomponenten im mischftutter. Bull. Inf. N° 183, 10-26.), survey data, and one of the tests carried out on feeds for laying hens.

[10] It has been demonstrated that the tracer may follow preferential flows in the feed flow.

[11] If possible less than 70 t/h.

[12] This involves a compromise between the statistical validity of the results and the analytical cost of a given test. This number is important, as it is necessary to determine as accurately as possible a standard deviation rather than a mean. A study on how variation coefficients change as a function of sample number demonstrated that both this choice and that of the number of samples analysed were the most pragmatic solutions while still ensuring the statistical validity. This is a target objective, the achievement of which is facilitated by the method used to determine sampling frequency. However, this number can withstand variations of a few samples.

[13] This corresponds to a compromise between sampling constraints, representativeness, and the laboratory's sample processing options.

[14] The initial sample is collected after a certain time, so as to limit the potential impact of cross-contaminations on the homogeneity measurement and to obtain a balanced distribution of samples over the whole batch throughput.

[15] The aim here is to check the homogeneity of the feedstuff rather than its labelling compliance. Attention should therefore be focused on the distribution pattern. However, note than any reduction in the mean, at a constant standard deviation, will increase the coefficient of variation. This means that a loss of tracer may generate an apparent increase in heterogeneity.

Appendix 3 - INTER-BATCH TRANSFER (IBT)

I- DEFINITIONS

Additives presenting a risk: additive with a level high enough to affect the health of certain categories of animals (to be defined by each company according to its own context).

Compatible feed: feed that can succeed another in accordance with regulations (Annex Directive 2002/32 / EC for the transfer of coccidiostats) or without zootechnical or contractual impact.

Rinsing: activity aimed to eliminate or reduce to acceptable levels the presence of residual substances in the manufacturing circuit.

Inter-batch transfer: adventitious presence in a batch of a residual fraction of another batch.

II- PREAMBLE

Each manufacturing site shall establish its rules establishing production schedules, taking into account the HACCP study, inter-batch transfers tests, the characteristics of incoming materials and species for which they are authorized.
Depending on the incoming materials used in feed manufacturing plants, certain incompatibilities must be managed during manufacturing successions involving categories of animals sensitive to certain products.

When scheduling production, incompatibilities defined must be taken into account at least the steps of dosing and mixing.

When necessary (no compatible formula for production successions), the equipment will be flushed to avoid inter-batch transfers. The flush will be done using a specific amount of appropriate incoming material to adequately serve the system.

The efficiency of the rinsing or cleaning process must be validated.

When manufacturing medicated feed, the current regulation is applicable in particular to the rate of inter-batch transfers and on the limitation of rotations.

III- METHOD AND PLACE OF MEASUREMENT

TECALIMAN proposes technical rules for assessing the level of inter-batch transfers between feed. These rules are presented in Appendix 4-B of the good manufacturing practice guideline for Animal Nutrition. They apply to compound feed premixes and mineral feed.

In case of introduction through various channels (several verses bag, microdosing stations), control of inter-batch transfers should be made taking into account each of the points of introduction.

IV- OBJECTIVES CONTROL OF MINIMUM INTER-BATCH TRANSFERS

The hazards related to control inter-batch transfers:

- CASE 1:

The presence of coccidiostats and histomonostats additives beyond the maximum levels permitted by regulation.

- CASE 2:

The presence of an additive to a level high enough to affect the health of certain categories of animals.

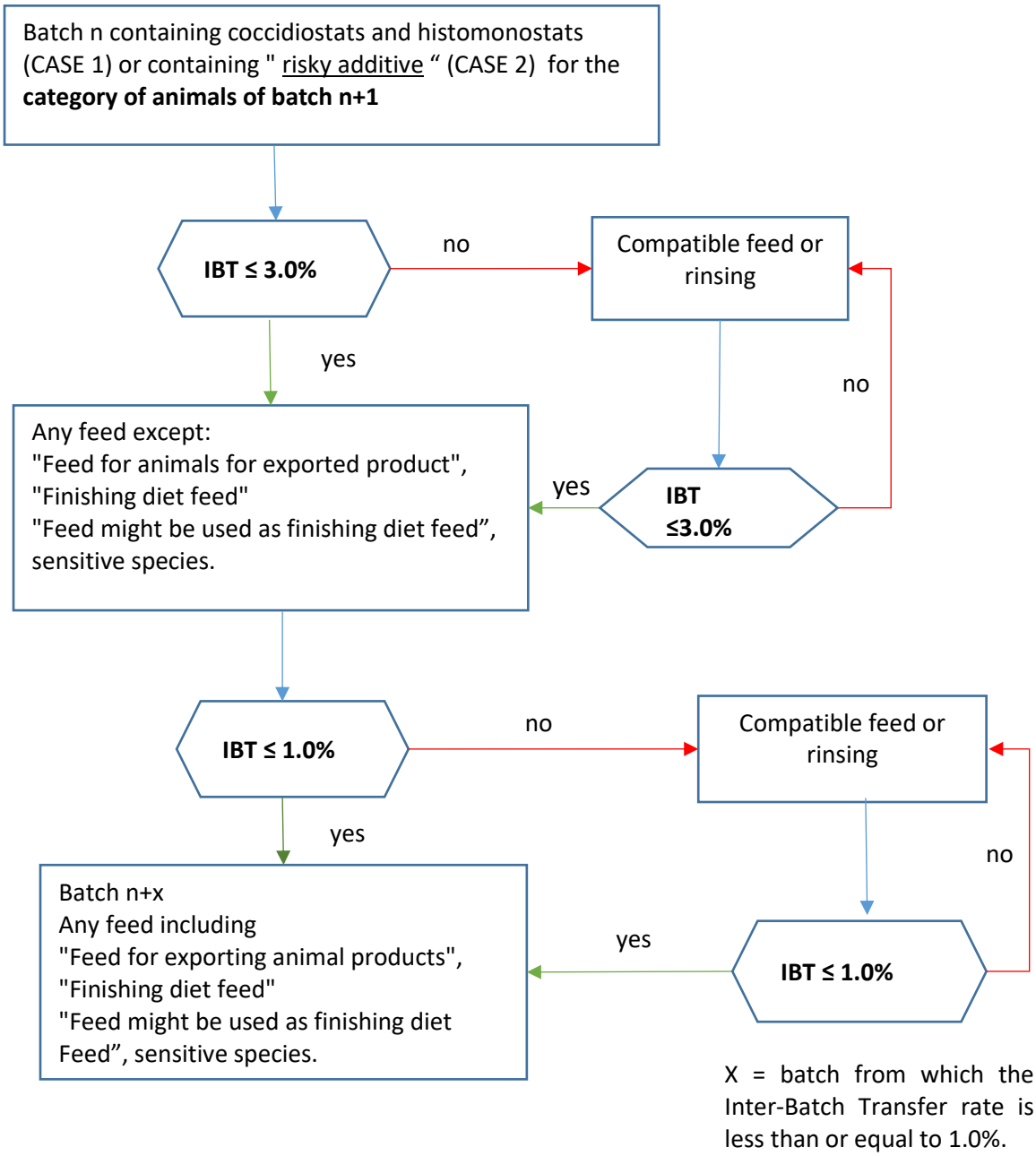
For example :

Copper has the distinction of being an authorized additive for sheep (*a fortiori* "compatible") up to a certain dose (15 mg / kg maximum permissible level, 10 mg / kg level triggering labeling), dose beyond which the sheep is a "sensitive species ". The "non-compatible" characteristic of copper additive of batch n must be evaluated with respect to its transfer into the next batch. Therefore, the manufacturer who wants to consider copper as "compatible additive" for sheep in its manufacturing sequences must demonstrate by calculating the rate of inter-batch transfers allows it to meet the regulatory thresholds previously mentioned, and with an adequate safety margin.

- CASE 3:

Other contractual incompatibilities may also require proper management by the plants according to specific specifications, especially for feed with official distinctive quality signs (labels, conformity certificates, export to third country...). It is not a question here of preventing a feed safety risk but to comply with contractual requirements resulting from official technical manuals or private specifications.

IV.1. COMPOUND FEED / MILK REPLACER / FEED MASH



X = batch from which the Inter-Batch Transfer rate is less than or equal to 1.0%.

IV.2. ADDITIVE PREMIXES

A specificity of the manufacture of additives premixes is the succession of non-homogeneous batch production: nature of coccidiostats and histomonostats, batch sizes, product concentration and incorporation rates are all factors that can affect the inter-batch transfer rate.

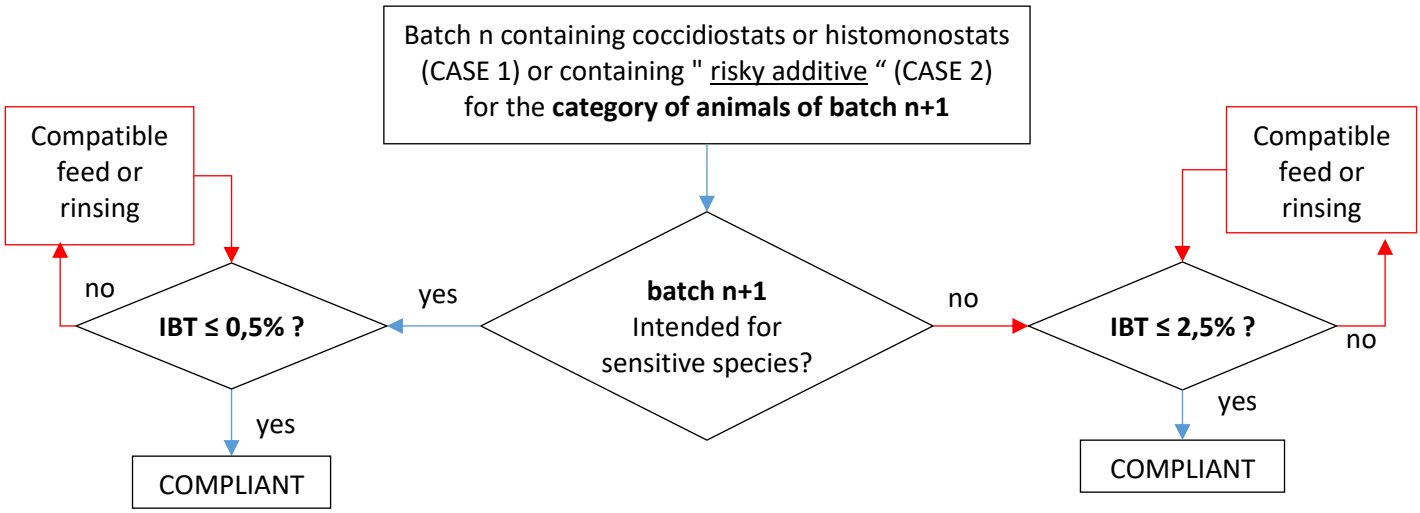
IBT risk control measures in a manufacturing plant of additives premixes:

They include all or part of the following:

- Design of equipment (without transfer, reduced transfer, dedicated lines ...);
- Definition of rules for manufacturing products sequencing (compatibility tables, manufacturing plans ...);
- Validation of the rinsing process (type and necessary and sufficient quantity);
- Validation of the cleaning process (if simple tools - see § III);

Verification

To verify the control of the IBT risk, application of the TECALIMAN protocol is an indicator for the initial release of the circuit and verification of its operation.



The validation of the IBT risk management, in the case of additive premixes manufacturing incorporating coccidiostats and histomonostats, is achieved by compliance with the maximum acceptable levels set by regulation (Dir. 2002/32/EC as amended).

IV.3. MINERAL FEED, LIQUID FEED, PREMIXES OF OTHER ADDITIVES AND OTHER COMPOUNDS FEED (CAS 3):

Depending on the incoming materials used, certain incompatibilities must be managed during production successions involving categories of animals sensitive to certain products.

The manufacturer must demonstrate that it meets contractual thresholds and *with an adequate safety margin.*

In the case of a banned incoming material regarding a specification, it is neither an authorization (sense of the term additive) or incompatibility (in terms of damage on the health), an inter-batch transfer rate less than or equal to 3% will be allowed without rinsing.

This level is a maximum threshold: it is up to each company to assess the risks of inter-batch transfer through its HACCP and lower down the level if necessary.

V- FREQUENCY OF MEASURING INTER-BATCH TRANSFERS

↳ Once a year

- if the company uses :
    - medicated premixes,
    - additives and coccidiostats, histomonostats
    - vitamins A, D or copper, selenium in the additive state.
- Or if there is incompatibility regarding a sensitive species or an incoming material prohibited in the specifications

↳1 time every 2 years in the particular case where only vitamins A or D, copper or selenium are present via an additive premixes.

When the manufacturer is using simple equipment, without transfer and systematically cleaned according to a validated protocol between production sequences, the control of IBT is not necessary.

VI- TECALIMAN TECHNICAL SHEET - TECHNICAL RULES FOR ASSESSING THE LEVEL OF CARRY-OVER BETWEEN FEEDSTUFF BATCHES

Tecaliman
L'EXPERTISE AU SERVICE D'UNE INDUSTRIE DURABLE

DATASHEET No. 29
July 2012

Keywords: Carry-over, Measurement

Technical rules for assessing the level of carry-over between feedstuff batches

Industrial obligations allied with French and European regulations are driving feedstuff manufacturers to assess the level of carry-over on their production lines. These technical rules, which are recognised by several certification reference systems, can also be applied to manufacturers of mineral and additive premixes.
These carry-overs consist of technically unavoidable traces of residual product in the production chain that may be transferred to follow-up batches during manufacture. They may also be referred to as "cross-contaminations" when this involves the transfer of contaminants. These technical rules are intended to provide a measurement tool that will facilitate technical mastery over such carry-overs and the presence of such traces.
These recommendations have been established on the basis of:

- settings known to impact on the results or their interpretation,
- the results of a bibliographical study on carry-overs between compound feeds,
- the results and observations obtained from industrial assessment campaigns carried out since 1999 jointly with the DGAL (French Directorate General on Food Safety).

Technical comments and rationales are provided in the form of cross-references at the end of this document, identified by numbered superscripts. Other comments and rationales are given in other technical datasheets (Nos 42, 45, 58, 78). Important concepts are underlined.
Compliance with these rules is a condition both for building a database on industrial performance in this area, and for enabling a comparison either between different sites or of a given site over a certain period of time.

1. Objective

These rules form a basic method for assessing carry-over levels (TIL). This assessment must be performed in tandem with a TIL-related hazard analysis. This analysis is used to specify the performance conditions according to the intended purpose. Note that this concerns the measurement of how carry-overs impact on follow-up batches; this type of measurement cannot be used to assess one-off, accidental or random carry-overs. This assessment forms part of an on-site carry-over monitoring system.

2. Principle

A batch corresponds to a mixer load.
The method consists in:

- Choosing a tracer and its related use conditions,
- Choosing a circuit that runs between the tracer's point of incorporation and the sampling point,
- Choosing and producing batches that contain the evenly distributed tracer (tracer batches),
- Choosing and then directly producing tracer-free batches in the same circuit[1] (collector batches),
- Taking samples from these batches,
- Processing the samples,
- Determining tracer concentration in the samples

3. Apparatus

3.1. Tracer characteristics

The tracer is selected based on the following criteria:

- Where possible, it should be a tracer used by the plant and selected with respect to the hazard analysis
- It should be derived from a single source. This means that it must not be present in the other ingredients found in tracer and collector batches.
- It should be incorporated at a rate sufficient to ensure that, given its detection limit, it provides for detecting a minimum carry-over of 0.5%[2].
- It should be analysed using a method that is accurate[3], repeatable[4], sensitive[5], has a low quantification threshold[6], and is simple and cost-effective[7].
- It should be stable in relation to the manufacturing process between its point of incorporation and the sampling point.

It must be possible to incorporate it directly into or scatter it over a media.

3.2. Batch characteristics

Two types of product can be used depending on the test focus:

- when assessing the production tool, a compound feed that is representative of the manufacture at the plant being tested may be used,
- when investigating the process in order to

develop corrective measures, a crushed raw material or a mix of crushed raw materials, with a defined set of physical characterizations, may be used.

It is recommended to use tracer and collector batches of a similar type in order to facilitate interpretation.

3.3. Circuit

The circuit runs between the tracer's point of incorporation and the sampling point. It is chosen according to the hazard analysis. The same circuit must be used for all the batches; there must be no modifications made between batches. Where necessary, the guarantee of the products having been incorporated at the tracer introduction station will have to be validated when producing the collector batches.

4. Methods

4.1. Batch size

Batch size must be representative of the plant's manufacturing practices. It is recommended that tracer and collector batches should be the same size[8].

4.2. Batch number

At least two "tracer" batches (T_1, T_2, ...T_n) have to be programmed to pass through the manufacturing circuit one after the other up to the sampling point[9].

At least two[10] "collector" batches (C_1, C_2, ...C_n) have to be programmed to pass through the same circuit one after the other and just after the tracer batches up to the sampling point.

A rinse can be programmed between the tracer and collector batches (this is not considered as a collector batch if it is common practice in the plant's operating procedures). Where appropriate, the rinse's presence and routing will have to be specified.

4.3. Sampling

4.3.1. Sampling point

This should enable operators to take samples reliably, rapidly and in complete safety. It is preferable to take the samples from a moderate product flow (< 70 t/h) without modifying the normal operating conditions. It is recommended to take the samples at the press gate inlet or at the loading station unit inlet[11].

4.3.2. Sampling procedure

The sampling procedure must provide for:

- taking samples safely,
- obtaining samples that are representative of the product flow (Gy, 1996),
- obtaining samples of the desired size,
- and be fit for use at the sampling point.

It is recommended to take the following precautions[12]:

- attach the sampling equipment to a fixed point outside the circuit.
- make sure there are no moving parts in the sampling zone (dual-direction boxes, pneumatic hatches, elevator buckets, etc.)
- wear a mask and goggles if dust is generated.

It is recommended to modify the flow penetration mode with each sample.

4.3.3. Sample number and size

The aim is to collect 30 samples from the final tracer batch (T_n) and from all the collector batches. Any reduction in the number of samples taken from collector batches and, therefore, any decrease in sampling frequency will have an adverse effect on the representativeness of the test and the measured TIL level[13].

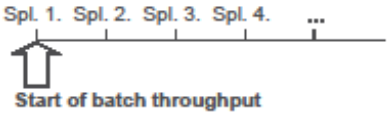
Sample size may vary between 100 and 1000 g, with a minimum variation between the samples for a given test[14].

4.3.4. Frequency

This is determined as follows:

- Measure the throughput time for the initial tracer batch at the sampling station.
- Calculate the time between two samples by dividing the throughput time by the number of samples to be taken plus 1, i.e. 31 for 30 samples.

To take a sample, at the start of batch throughput, the stopwatch is activated simultaneously with sample 1:



Start of batch throughput

Batch start is considered effective when the sampling tool fills completely during a clean, direct penetration of the flow for a short period of time. Batch end is considered effective when the sampling tool no longer fills completely during the same period of time.

The samples are taken at each time period and packaged in chronological order. Samples have to be taken up to the end of the batch throughput, which is marked by a clear and significant reduction in flow rate.

4.4. Testing

4.4.1. Batch follow through in the manufacturing circuit

Each batch has to be managed as a different feed[15]. During manufacture, each time that an intermediary storage phase is performed (hopper under the mixer, hopper on the molasser, silo bin upper the press, silo bin of dispatch, etc.), it is vital to wait until emptying is complete before sending in the next batch in compliance with common industrial practices. The initial tracer batch is used to run in all the transfer manoeuvres.

4.4.2. Additional data collection

This data is used to interpret the results:

- physical characterizations of the tracer and product,

- method used to incorporate the tracer: incorporation point, expected concentration in the feed, incorporation rate and the concentration of any possible premix, incorporation timeline, etc.
- quantities of dosed raw materials (including molasses, fats, and other liquids) upstream of the sampling point,
- line characteristics (brand, type, status, equipment size where appropriate, etc.),
- all the information on all the operations performed during the test between the tracer's point of incorporation and the sampling point (molassing, pelleting, coating, etc.),
- any changes that have occurred since the previous test (equipment and apparatus, method, etc.),
- formula(s) and weighings (Dosing log)
- any deviation from this method.

4.4.3. Sample processing and analysis

Each primary sample is homogenized and an aliquot portion representative of a constant, equivalent weight is sampled. The aliquot portions of the final tracer batch are pooled in order to make up a single, overall sample unless this batch has been set aside for an homogeneity test used to determine its mean concentration.

The aliquot portions from the primary samples of a given collector batch are pooled and mixed by group in order to make up three pooled samples:

- Group A: aliquot portions of the first 2 primary samples.
- Group B: aliquot portions of the intermediate primary samples (approx. 22 samples).
- Group C: aliquot portions of the last 6 primary samples.

If the number of collected samples is greater than 30, it may be decided to distribute them on a pro rata basis (6/74/20%).
The laboratory analyses each of the pooled samples in order to establish their tracer concentration.
The laboratory processes each sample to make it possible to take a representative test portion from each one. Therefore, if an analysis is carried out on a test portion that is smaller than the samples, it is recommended to finely grinding the whole mass of the sample (without destroying the tracer), then re-homogenise it and finally divide it to produce a sub-sample of a size that is as close as possible to that of the test portion.
It may be necessary to repeat the analysis for low concentrations.
The bulk density and grain size of the feeds may also be analysed in order to characterise the test conditions.

4.5. Expression and interpretation of the results

The mean concentration of a collector batch (CMC) is calculated using the following equation:

$$CMC = \frac{Ca \times 2 + Cb \times (n-8) + Cc \times 6}{n}$$

n: Total number of samples taken from the corresponding collector batch
Ca: Concentration of tracer in pooled sample A
Cb: Concentration of tracer in pooled sample B
Cc: Concentration of tracer in pooled sample C

The carry-over levels for each pooled sample from the collector batches are expressed as a carry-over rate: Percentage calculated according to the respective concentrations of tracer in the collector batches readjusted to the measured concentration of the final tracer batch.
The mean carry-over rate for a collector batch (TMTC) is calculated using the following equation:

$$TMTC = 100 \times \frac{CMC}{CMT}$$

CMT: Tracer concentration in the final tracer batch obtained by analysing the pooled sample from this batch or by averaging the analysis results of a homogeneity test performed on this batch.

In any case, the concentration of the final tracer batch must lie within 70% and 110% of the expected concentration (or 80% to 110% for manufacture of medicated feeds according to the BPFDAM [good manufacturing and wholesale distribution practices for medicated feedstuffs]). The distribution of tracer in the tracer batch is assumed to be homogeneous; this homogeneity will have been validated prior to testing.
The results obtained using this method must be assessed with respect to the:

- trend profile for the carry-over rate within each collector batch and throughout all the collector batches (degrowth curve),
- manufacturing practices,
- test procedures (sampling point, selected tracer, batch size, etc.),
- tested manufacturing circuit,
- obligations of the industrial site,
- analysis of the hazards involved.

The composition of the three pooled samples from each collector batch is useful in determining the carry-over profile.
Carry-over levels or concentrations should logically decrease in the order of the batches.

5. Bibliography

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d'homogénéisation d'un mélange et du niveau de contaminations croisées entre aliments en alimentation animale. (Summary of the findings aimed at establishing technical rules for assessing the level of homogenisation of a mix and the level of cross-contamination between animal feeds).

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- Report 4: Essais Industriels d'évaluation des niveaux de contaminations croisées. (Industrial tests designed to assess cross-contamination levels). Tecaliman - 2000.
- Technical Datasheet N° 42, 2002 Evaluation des contaminations croisées, de l'incorporation des additifs au chargement des produits finis (Assessment of cross-contaminations, from the incorporation of additives up to loading of the finished products).
- Technical Datasheet N° 45, 2003 Comparaison traceurs internes/traceurs externes (Comparison of internal/external tracers).
- Technical Datasheet N° 58, 2005 Evolution des contaminations croisées d'aliments au cours de leur fabrication dans une usine à l'aide de deux traceurs (Dual-tracer analysis of patterns of animal feed cross-contamination during factory manufacture).
- Technical Datasheet N° 78, 2011 Effet de la taille des lots sur les niveaux de transfert inter-lots (Impact of batch size on carry-over levels).

Cross-references

1 Without taking account of gravity fall
2 For instance, incorporation at 200 ppm and detection of 1 ppm
3 Measurement accuracy: closeness of the agreement between a measurand and an actual value for the specific quantity being measured. (Standard NF X 07-001).
4 Repeatability of the results: closeness of the agreement between the results of successive measurements of the quantity being measured, where all the measurements are taken under the same measurement conditions. (Standard NF X 07-001).
5 Sensitivity: ability to detect small variations in analyte (the analysed substance). (Standard V 03-110).
6 Quantification limit: the smallest quantity of analyte to be examined in a sample, that can be dosed under the experimental conditions described in the method with a defined variability. (Standard V 03-110).
7 Due to the number of analyses required.
8 In order to make it easier to determine the conditions for testing and sampling frequency. Tecaliman has demonstrated that size variations between collector and tracer batches only have a minor impact on TIL levels (Technical datasheet N°78).
9 In order to obtain a concentration of the second tracer batch that is as close as possible to the expected concentration.
10 In order to test the line for possible perpetuation of the carry-over created by the selected tracer.
11 Tecaliman's findings, and the results illustrated in technical datasheets N°42 and 58 in particular, demonstrate that there is only minor fluctuation of carry-over levels downstream of the silo bin upper the press inlet and that this sampling point is the easiest to use at a plant while minimizing disruptions to manufacturing practices.
12 Sampling issues may arise in the presence of high flow rates, powerful suction, the generation of dust clouds, or at the time of detecting batch ends.
13 Reducing the number of samples strengthens the impact of the samples with the highest concentration on the mean, thus maximizing the carry-over level.
14 This involves a compromise between sampling constraints, laboratory processing and shipping costs, and the average size of feed rations for factory-fed animals.
15 Take account of the management of batch follow-throughs and automations planned during follow-throughs between batches regarded as incompatible.

Appendix 4- Notification of non conformities

1.CSNA manual for non conformities reporting

ASSOCIATION DES FABRICANTS DE COMPLEMENTS POUR L'ALIMENTATION ANIMALE

SYNDICAT NATIONAL DE L'INDUSTRIE DE LA NUTRITION ANIMALE

NOTE OF CSNA

REPORTING NON-CONFORMITIES: MANUAL

TABLE OF CONTENTS

41 bis Bd. de la Tour-Maubourg – 75007 Paris
TEL : 01 47 53 64 00 ■ FAX :01 47 53 00 92
www.afca-cial.org

43 rue Sedaine - 75011 Paris
TEL : 01 44 17 57 12 ■ FAX : 01 40 26 64 64
www.nutritionanimale.coopdefrance.coop

41 bis Bd. de la Tour-Maubourg - 75007 Paris
TEL : 01 44 18 63 50 ■ FAX : 01 44 18 63 53
www.nutritionanimale.org

PREAMBLE

Regulation 178/2002 of 28 January 2002 on the general food law of the European Union establishes the obligation to report non-conformities to all operators in the food chain, including animal nutrition operators.

The aim of this information transmission is to limit the consequences of a problem encountered on an animal feed by rapidly disseminating information to all the links concerned. It is therefore an integral part of the food safety system.

Essentially, this text requires the leaders of establishments to report to the public authorities the non-conformities of the products they own, sell or market in case of:

- Non-conformities with undesirable substances regulation
- or serious risk to animal health, human health or the environment

Legal basis:

- **Regulation 178/2002** of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety – Article 20.
- **Directive 2002/32/EC amended** fixing the maximum levels for undesirable substances and products in animal feed.

Beyond the Community regulation, which has direct application in French law, these provisions have been incorporated on several occasions into French legislation without a perfect homogeneity between the different versions.

These texts raise many questions for their practical implementation by the operators.

Therefore, in order to facilitate this implementation by animal nutrition manufacturers, the Scientific Committee for Animal Nutrition (CSNA) has drawn up the present manual on the basis of the requirements of European Regulation No 178/2002.

This document consists of 4 parts:

- **What to report?**
  On the basis of examples, this part identifies, by major types, non-conformities to be reported.
- **When and who should report?**
  A decision tree will allow you to identify when and by whom to report.
- **To whom to report?**
  You will find here a link to the details of the contact persons to whom you must send the report form.
- **How to report?**
  The CSNA proposes a standard form containing all the necessary information for the report.

I. WHAT TO REPORT?

Identify the non-conformity to be reported – Examples of cases

General rule:

- Any non-conformity on an incoming good or packaging item must be reported by the supplier (marketer)
- Any non-conformity on the finish product must be reported by the manufacturer (marketer)

A. Origin of the non-conformity: Incoming good

1. **Substances and products prohibited in animal feed** (on incoming goods and / or finished products)

   Examples: Presence of chloramphenicol, furazolidone, raw materials (gelatin of ruminants ...), prohibited additives...

   ↳ Reporting to the public authorities and implementation of management measures

2. **Undesirable substances regulated by the directive 2002/32/EC amended** (on incoming goods and / or finished products)

   Examples: Heavy metals, dioxins-PCB, pesticides residues, gossypol...

   - Reporting to the public authorities and implementation of management measures:
     - ↳ Exceeding the maximum regulatory limit
     - ↳ Risk of non-conformity of the manufactured product with the admitted limits in the compound feed when the incoming good is not itself regulated
     - ↳ On an incoming good:
       - ↳ Information to the supplier for reporting by the supplier as soon as possible with duplication to the company and implementation of management measures
       - ↳ Reporting in the event of non-reporting by the supplier
     - ↳ On a finished product:
       - ↳ Reporting to the public authorities and implementation of management measures

3. **Contaminants or dangerous products not regulated in animal feed**

   Examples: Hydrocarbons, foreign bodies...

   - Analyzed level generating a serious risk to human health, animal health or the environment:
     - ↳ Reporting to the public authorities and implementation of management measures

4. **Abnormal content of substances whose use is regulated in certain species generating a serious risk for the health of some types of animals**

   Examples: Very high copper content in a raw material generating a risk in the use of this raw material for sheep

   - Analyzed level generating a serious risk to animal health
     - ↳ Reporting to the public authorities and implementation of management measures

B. Origin of the non-conformity: Manufacturing

(Any non-conformity resulting from a process error)

1. **Unwanted presence or incorrect dosing of an additive, a veterinary drug, a premix, a raw material…**
   - **Reporting to the public authorities** if it causes:
     - a serious risk to human health, animal health or the environment
     - a risk of exceeding the MRLs in the animal product
   - Implementation of management measures
2. **Feed labelling error or delivery error**

   Examples: incomplete or incorrect instructions, wrong target animal species
   - **Reporting to the public authorities** if it causes:
     - a serious risk to human health, animal health or the environment
     - a risk of exceeding the MRLs in the resulting animal product
   - Implementation of management measures

C. Special case of microbiological hazards

1. **Salmonella** (analysis on incoming goods and / or finished products)

		Presence *S.enteritidis* ou *S.typhimurium*	Presence *S.infantis*, *S.hadar*, *S.virchow*	Presence *S.kentucky**	Presence serotype not regulated
Raw material		**Information to the supplier** for reporting by the supplier with duplication to the company and implementation of management measures **Reporting in the event of non-reporting by the supplier**	**Information to the supplier** for reporting by the supplier with duplication to the company and implementation of management measures **Reporting in the event of non-reporting by the supplier**	**Information to the supplier** for reporting by the supplier with duplication to the company and implementation of management measures **Reporting in the event of non-reporting by the supplier**	**No reporting** Management measures
Finished product for	Layer poultry *Gallus gallus* and *Meleagri gallopavo*	**Reporting** Management measures	**Reporting** Management measures	**Reporting** Management measures	**No reporting** Management measures
	Poultry *Gallus gallus* and *Meleagri gallopavo* others than layer poultry	**Reporting** Management measures	**No reporting** Management measures	**Reporting** Management measures	**No reporting** Management measures
	Other poultry and « non-sensitive » species (pigs, cattle,…)	**No reporting** Management measures	**No reporting** Management measures	**No reporting** Management measures	**No reporting** Management measures

*** NB: At the date of publication of this "Reporting" notice, *S.kentucky* serotype is not regulated in animal feed.** However, this serotype is regulated in breeding since the beginning of 2015 with the publication of the decree of 17 February 2015 which classifies *S.kentucky* as a category 1 hazard for poultry species. A note from the DGAI issued in April 2015 (DGAI 2015-390) announces future management actions. For poultry feed, *S.kentucky* should be treated as *S.enteritidis* and *S.typhimurium*. An ANSES referral on the *Salmonella* file is expected soon and the *S.kentucky* case will be studied. Awaiting the results and regulation establishing clear rules, if the *S.kentucky* serotype is detected, the authorities should be notified according to the table above. The administration must then transmit to the manufacturers the management rules to be applied.

2. Enterobacteriaceae (30°C)

This paragraph applies **only** to *Gallus gallus* and *Melagris gallopavo* layer poultry feed as part of the "Salmonella" Approval defined by the decree of 23 April 2007.

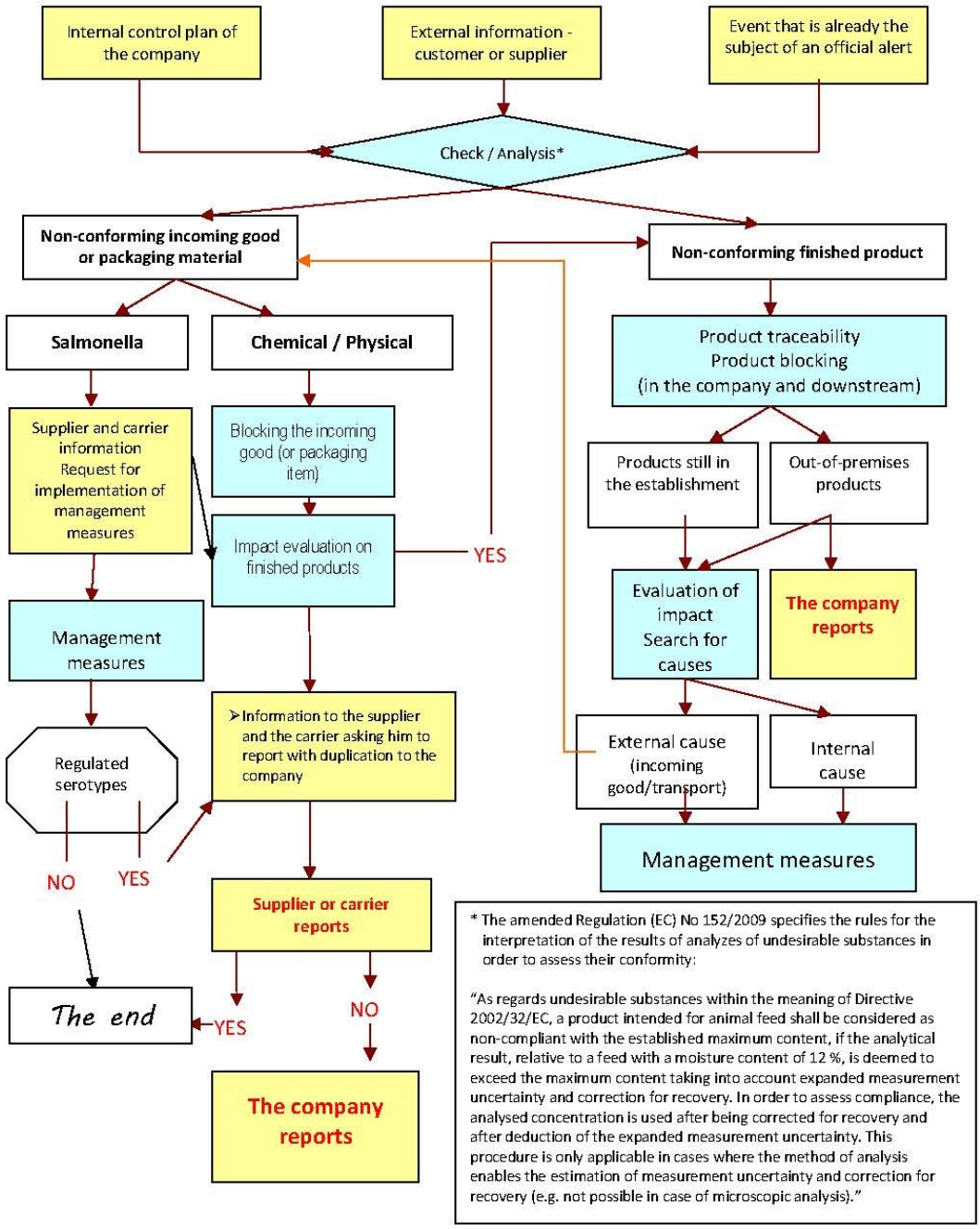
Indeed enterobacteriaceae are an indicator of the control of technological treatment as part of the "Salmonella" Approval.

- Enterobacteriaceae content ≥ 10^2 CFU/g et < 10^3 CFU/g of finished product on a 100 g sample (intervention limit giving rise to corrective measures)
  - The batch can be shipped
  - All manufacturing and packaging processes must be checked
  - The control of the raw materials according to the manufacturer's risk analysis or the elements in his possession can be reinforced

- Enterobacteriaceae content ≥ 10^3 CFU/g of finished product on a 100 g sample (non-conformity limit)
  - Implementation of intern management measures held at the disposal of the authorities
  - **No reporting** to the public authorities
  - Search for salmonella on a 100 g sample of the batch concerned and, if positive, refer to the previous paragraph on Salmonella.

II. WHEN AND WHO SHOULD REPORT?

DECISION TREE



NB: The reporting should take place as soon as possible after identifying the non-conformity in order to identify the problem as quickly as possible. In practice, reporting and first management measures will be in most cases concomitant.

III. TO WHOM TO REPORT?

General case: To the DDPP (Departmental Directorate for the Protection of Populations) or the DDCSPP (Departmental Directorate of Social Cohesion and Protection of Populations) of the department in which the professional establishment making the reporting is located.

The updated list of departmental directorates is available on the DGCCRF website:

http://www.economie.gouv.fr/dgccrf/coordonnees-des-DDPP-et-DDCSPP

IV. HOW TO REPORT?

Form Type of Reporting to Public Authorities

1 – Origin of reporting	
Company:	Contact :
- Establishment (if different):	- Last name First name: .....
- Address:	- Phone: .....
.....	- Fax: .....
.....	- E-mail: .....
☐ Manufacturer ☐ Distributor ☐ User } *Of the product at the origin of reporting*	- Position: .....

2 – Purpose of reporting	
Product: ☐ Premix ☐ Additive ☐ Compound feed ☐ Raw material - Trading name (s): ..... - Batch number (s): ..... - Quantities concerned: ..... - Date of manufacture or receipt: ..... - Date of start of marketing: ..... - Supplier of non-conforming product (if applicable) – Name and contact information:	Reason for reporting:

3 – Implemented measures			
Measures:	Taken	In progress	Comments:
Risk analysis	☐	☐	
Product removal	☐	☐	
Product recall	☐	☐	
Laboratory analyses	☐	☐	
Customer information	☐	☐	
Supplier information	☐	☐	
Other (specify):			

Addressed on: In:

Note of CSNA – September 2015 – Reporting – Manual 8/8

2.Notification to Oqualim
The requested information must always be communicated, in writing, to OQUALIM.

OQUALIM
Adress : 41bis boulevard La Tour-Maubourg, 75007 PARIS -FRANCE
Email: contact@oqualim.fr

3.Confidentiality of information
Unless otherwise stated in this document, OQUALIM shall not disclose any confidential information regarding a company (or certification body) to third parties, without written consent from the company in question.

Communication with respect to an incident will only take place between the parties concerned.

When companies, covered by a quality system other than the RCNA Standard, are involved in an incident, and as OQUALIM has a mutual recognition agreement with those feed safety systems, the information regarding the incident will be communicated to the systems concerned.

Under no circumstances, shall OQUALIM, instead of the company, perform a notification. The company remains responsible for its legal obligations in terms of notification and risk management.

Appendix 5- Requirements applicable to the « distribution of feed materials or additives » and « trade in animal feed »

I- Objective

This appendix aims to define the minimum applicable requirements and the verification modalities of the requirements of the Animal Nutrition Certification Reference (RCNA) for certifying the activities of:

- distribution of feed materials or additives for animal feed,
- trade in animal feed for manufacturers of feed products under the regulatory meaning (feed materials, additives, premixes, compound feed).

II- Scope of application

The RCNA Certification standard applies to the production, marketing and distribution of feed for “food producing animals”. It applies to the following professionals:

- Manufacturers of compound feed (AC)
- Manufacturers of mineral feed (AM)
- Manufacturers of premixes (PM)
- Manufacturers of milk replacer feed (AA)
- Manufacturers of liquid feed (AL)
- Distributors of compound feed and premix (D)

These professionals may request certification for their activities of

- manufacturing and placing on the market of compound, mineral, liquid, milk replacer feed and premixes ,
- distribution of compound, mineral, liquid, milk replacer feed and premixes,
- distribution of feed materials or additives for animal feed,
- trade in animal feed by manufacturers of feed products under the regulatory meaning (feed materials, premixes, compound feed).

Distribution activities for feed materials or additives for animal feed and trade in animal feed under the regulatory meaning are not RCNA certifiable alone.

They must be combined with a manufacturing or distributing activity for premixes or compound feed including mineral, milk replacer, liquids.

Professionals requesting certification in the regulatory sense for their trade activities of feed or additives for animal feed, must be either a compound feed (complete or supplement) manufacturing or premix company or be part of a group of companies of which at least one entity manufactures animal compound feed or premixes for animals and is RCNA certified.

III- Applicable requirements

Protocol, IV-3 a) Conducting audits: "In addition to best audit practices in which the auditor is trained and masters, the CB concerned will ensure compliance with the following conditions: Ensure that all RCNA items are audited at each audit, including during monitoring audits...".

1. Scope of application for certification

Certification of placing on the market without the manufacturing of animal feed is only possible if:

1. the concerned operator is a manufacturer or **distributor under the meaning of the RCNA**, i.e. physically holds animal feed (excluding retail sales). It must, therefore, **carry out on its own behalf** the following steps of the process:
   - Procurement,
   - Reception
   - Storage Transfer
   - Loading, delivery of compound feed or premixes.

2. For the mutual recognition with other certification schemes, the operator concerned must comply with **Appendix 1 Purchases in its entirety.**

2. Requirements in respect with the Management Responsibility

All requirements in this chapter apply to the distribution of feed materials or additives for animal feed and/or trade in animal feed by manufacturers of feed products under the regulatory meaning:
2.1 Commitment and Safety Policy for animal feed
2.2 Management system planning for animal feed safety
2.3 Responsibility and authority
2.4 Training and qualifications
2.5 Internal and external communication
2.6 Management of emergency situations (alerts / crises)
2.7 Review of health safety management

No requirements in this chapter may be assessed as Not Applicable.

3. Requirements in respect with the Management of Animal Feed Safety

All requirements in this chapter apply to the distribution of feed materials or additives for animal feed and/or trade in animal feed by manufacturers of feed products under the regulatory meaning:
3.1 General principle
3.2 Documentation
3.3 Regulatory monitoring
3.4 Identification and Traceability
3.5 Hazard analysis according to the HACCP method
3.6 Verification (internal audits, analysis plans)
3.7 Management of non-compliant products and customer claims (removal-recall)
3.8 Improvements (corrective and preventive actions)

Specific attention must be paid to:
- the management of regulatory monitoring for distributed or traded products,
- the identification and traceability of distributed or traded products,
- the production of an exhaustive, relevant hazard analysis for all distributed or traded products, in accordance with requirements 3.5.6 a and b in the audit grid.

Requirement 3.5.6 a "The company prepares a hazard risk associated with inputs (feed materials, additives, technological auxiliaries...). The hazards are assessed according to two criteria: their probability / frequency of occurrence in the material under consideration and their seriousness in terms of effect on the animal and/or on consumers.
The method used to determine these risk levels must be clearly described, objective, repeatable and understood by the entire team. "

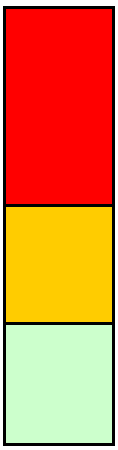
This hazard analysis for feed materials for animal feed, additives and additive premixes must allow the definition of specific measures to be implemented such as:

- Provision of traceability elements,
- Provision of a sample,
- Provision of a certificate of compliance.
- Provision of an analysis certificate by the supplier, to ensure the management of contaminants identified as sensitive in the concerned product,
- Production of specific analyses by the operator to ensure the management of contaminants identified as sensitive in the concerned product,

The **relevance of the hazard analysis** for inputs will be based on

1. The database in **Appendix 1 GBPNA Hazards** (see extract below)

Classification and risk table



Priority risk: Specific management measures at the supplier or feed manufacturer will be used to guarantee the management of the identified contaminants.

An inter-professional analysis and/or one under the manufacturers' responsibility on the concerned contaminants will enable the effectiveness of existing management measures to be verified.

Risk to be monitored: An inter-professional analysis and/or one under the manufacturers' responsibility on the concerned contaminants will enable the effectiveness of existing management measures to be verified.

Non-significant risk: Best practices enable the compliance of feed material to be managed, such as the selection and assessment of suppliers.

When digital coding is added, its signification is as follows:

(1) On imported products
(2) On Co-products

2. **The analysis and use of RASSF alerts** (Rapid Alert System for Food and Feed)
   Example: a RASSF alert on a specific contaminant identified on a product marketed by the operator must lead to the implementation of specific measures.

- the production of a **specific analysis plan** covering the products placed on the market.

No requirements in this chapter may be assessed as Not Applicable.

4. Requirements according to Best Practices

All requirements in this chapter apply to the activity of marketing without the manufacturing of animal feed:
4.1 Construction and layout of buildings
4.2 Layout of premises and working spaces
4.3 Cleaning and disinfecting of premises and equipment
4.4 Skills and hygiene of staff members
4.5 Pest management
4.6 General services — air, water, energy
4.7 Purchasing management: Packaging / inputs / transport / laboratory / cleaning
4.8 Qualification and maintenance of equipment
4.9 Measures to manage inter-batch transfers
4.10 Reprocessed/recycled products
4.11 Waste elimination
4.12 Storage activities
4.13 Transport
4.14 Order taking
4.15 Formulation and information on products
4.16 Prevention against malicious acts

5. Requirements in respect of product realization

At a minimum, the requirements listed below apply to the activity of marketing without the manufacturing of animal feed:
5.1 Reception of feed materials
5.2 Storage and transfer
5.15 Loading

For the certification of the distributing activities of feed materials and additives and trading activities of feed, specific attention must be paid for:
- purchasing management and **compliance with the totality** of appendix 1 – Minimum requirements on the modalities of selection, monitoring and assessment of suppliers, and specifically the requirement to only purchase products from "certified" suppliers

- Order taking to ensure compliance with current regulations and customer requirements

No requirements in this chapter may be assessed as Not Applicable.

Appendix 6 : Use of the trademark and logo

Instructions for use

Updated on September 2019,

I-Principles

Since 2008, the feed sectors have structured its approaches in favour of the quality and health safety through an association named “OQUALIM”.

OQUALIM is also a brand which include the use to ensure to promote the approach.

→ Firstly collectively, to provide a positive image of the feed sector. Using a single signature aims to increase the visibility of the approach and contribute to its recognition within the animal feed and food sectors and public authorities.

→ Secondly, within stakeholders of the sector, to allow to companies participating actively to OQUALIM to take advantage and benefit of the approach.

To this end, the professional organizations have created and filed a trademark with a logo

1. The use of this trademark is granted to companies with sites certified OQUALIM and participating to the pooled self-monitoring plan OQUALIM related to their activity.

2. When a company certified OQUALIM-RCNA places feed on the market within its scope of RCNA certification, this must be provided to the customers, through the label or any document accompanying the product for bulk products (proof of delivery, invoice), this characteristic associated to the product.
   The positive declaration must be clear and unambiguous linked to animal feed placed on the market.
   The positive declaration is optional for the trading activity
   Cf. section III for the list of terms to be used.

3. When a company certified OQUALIM-STNO places feed on the market on the sector “GM free<0.9%” Included in its scope STNO, this must be provided to the customers, through the label or any document accompanying the product for bulk products, this characteristic associated to the product.
   The positive declaration must be clear and unambiguous linked to feed placed on the market.
   The positive declaration is optional for the trading activity
   The OQUALIM-STNO declaration is optional for products to be exported
   Cf. section IV for the list of terms to be used.

4. The companies certified and participating to their corresponding monitoring plans can anticipated the application of the new rules when they are published.

5. The use of the logo for a general presentation of the company is permitted. When some of sites manufacturing feed or premixes have a certificate currently valid, only if the use of the LOGO is attached with the list of the certified sites.

6. The use of the trademark and the logo OQUALIM is free of charge to beneficiary companies

7. The company must respect the Graphic chart presented in paragraph II.

OQUALIM is a trademark and a logo registered. The use of one and or both outside the conditions described above will lead to prosecutions in competent authority.

II- Graphic chart

Logo OQUALIM

Colours

Gold = Cyan 32 / Magenta 47 / Yellow 100 / Black 9

R : 175 / V : 129 / B : 20

Grey = Black 50%

R : 156 / V : 157 / B : 159

The logo is downloadable on the website www.oqualim.com

The logo proportions must be maintained.

The logo is available in black and white or in colour, the defined colours must be maintained.

III. Positive declaration OQUALIM RCNA

Requirement to be in force in 1st January 2020 :
When a company certified OQUALIM-RCNA places feed on the market within its scope of RCNA certification, this must be provided to the customers, through the label or any document accompanying the product for bulk products, this characteristic associated to the product.

The positive declaration must be clear and unambiguous linked to animal feed placed on the market.

The positive declaration is optional for the trading activity

Valuable mentions

One of the mentions listed below must be clearly affixed on the labels or accompanying documents of products:

"Manufactured by an OQUALIM-RCNA certified site" for manufacturing
"From an OQUALIM-RCNA certified site" for distribution and trading

The mention must be clearly associated to the products under the scope of certification. In case of delivery, with certified and non-certified products, the distinction must be done without ambiguity. For example, one asterisk for products concerned by the certification could refer to the concerned mention. For example, in case of simultaneous delivery of animal feed for livestock, pets and sanitary products, only the animal feed for livestock will be associated to the positive labelling.

One of the mentions can be affix with the logo OQUALIM.

Particular cases
Case of a manufacturer certified RCNA, manufacturing and conditioning a distributing brand product, for a distributor which is not certified OQUALIM.
Details of the distributor are indicated on the label (address /logo), the approval number of the manufacturer is written. The mention **"manufactured by an OQUALIM-RCNA certified site"** must be stated on the label but the logo OQUALIM will not be included to avoid any confusion on the certification of the distributor cited.

When the customer is responsible of the labelling, he can choose to affix the positive mentions, or not. When the customer is not wishing to affix the positive mentions, the declaration must be formalized.

In practice, the Regulation 767/2009 defines the rules for labelling goods for animal feed, as the mentions to be attributed, indication, trademarks, pictures or other signs to an animal feed by including the information on any way referring or accompanying the feed as a packaging, a container, a panel, a label, a document, a ring, a collar or internet, including advertising purposes.

In case of products already registered for export outside EU, the labelling will be updated to include the mentions during the update of the registration dossiers of the products in the country. Before the update, the mentions must be affix on any other accompanying document.

IV. Positive declaration OQUALIM STNO

Requirement to be in force in 1st January 2020 :
When a company certified OQUALIM-STNO places feed on the market on the sector "GM free < 0.9%" included in its scope STNO, this must be provided to the customers, through the label or any document accompanying the product for bulk products, this characteristic associated to the product.
The positive declaration must be clear and unambiguous linked to feed placed on the market.

The positive declaration is an obligation only to customers ordering animal feed (feed materials and/or compound feed) which cannot be labelled GMO according Regulation 1829/2003 from 22nd September 2003.

The positive declaration is optional for the trading activity;

The notion of feed sectors from qualified sectors "without genetically modified organisms" correspond to de French decree 2012-128, 30th January 2012/ The positive declaration to other sectors is optional. Depending on the destination of the product the Regulation in force in the receiving country must be applied.

The following mentions listed must be clearly affixed on the labels or accompanying documents of products:

"Manufactured by an OQUALIM- STNO certified site " for manufacturing
"From an OQUALIM-STNO certified site" for distribution and trading
And for each of these mentions "suitable for animal production "fed without GMO <0.9%"

The mention can be affix with the logo OQUALIM.

Only the products covered by the certification scope STNO can be identified as such. The products manufactured and/or from an OQUALIM- STNO certified site but not complying with the specifications "fed without GMO* (<0.9%)" are excluded of this positive declaration.