



European Guide to Good Hygiene Practices

**for the collection, storage, trading and transport
of cereals, oilseeds, protein crops, other plant
products and products derived thereof**

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1. INTRODUCTION

Placing on the market safe food and feed products is first and foremost a question of good management practices at each stage of the feed and food chain from primary production to final processing. It is therefore the responsibility of each operator in the feed and food chain to implement good practices to ensure the safety of the goods that he or she handles. Regulation (EC) No 1831/2003 as amended on feed hygiene as well as Regulation (EC) No 853/2004 as amended, on the hygiene of foodstuffs acknowledge the positive contribution of good hygiene practices to achieve the objectives laid down in the EU food and feed safety legislation and encourages the development of national or Community guides to good practice by food and feed business sectors, in consultation with any interested party.

In correlation with the development of the European food and feed legislation which mainly focused on food safety objectives, Cocal, Cogeca and Unistock formed a special working group, who developed the European Good Hygiene practice guide for the collection, storage, trading and transport of cereals, oilseeds and protein crops as a reference document, to help ensure the compliance with the European hygiene standards, to control food and feed safety risks and to guarantee the safety of the food and feed placed on the market. The guide also helps the operators meeting the requirements of the buyers. In this framework, the three EU Associations did not forget the guidance document on the implementation of the General Food Law approved by the Standing Committee on the Food Chain and Animal Health at its meeting of 20 December 2004 which must be regarded as an essential document that operators should refer to for compliance with the General Food Law principles.

This joint guide has been developed in consultation with a large representation of sectors linked with production and consumption of food and feed materials and other stakeholders throughout the Community¹.

The Guide aims to prevent or reduce the risks of biological, chemical and or physical contamination that were identified in the hazard analysis, adapted by each operator according to the activities they control. The operators handle cereals, oilseeds and protein crops (hereafter referred to as “grains” or “food and feed materials”). They need to identify whether some of their outlets have specific requirements in respect of some identified hazards and, if necessary, increase their vigilance on the prevention of cross-contamination. In addition, the aim of this Guide is to help operators supporting the EU and national legislations for food and feed safety. Sometimes higher costs of implementation might occur, but they are justified as they bring additional warranty regarding food and feed safety.

The Guide, **to be applied voluntarily**, constitutes a progress tool supporting collection, storage, trading and transport operators in the day-to-day management of the food and feed safety; it was written **by** and is intended for use by collection, storage and trade professionals, in collaboration with the other concerned parties (partners of the industry, control administrations etc.) to help them to:

- Comply with good hygiene practices relating to operating sites, premises, equipment, transport, waste and staff.
- Identify risks which have a decisive influence on the consumer's safety and establish appropriate procedures for controlling them based on the principles of the H.A.C.C.P. system (hazard analysis, critical control points).

The Guide was built around complementary and autonomous modules allowing us to identify the covered activities carried out by one or more operators themselves or by a sub-contractor:

- Trading
- Collection
- Storage
- Handling
- Dispatch/Delivery including road, river, sea or rail transport

When the guide is applied, the operators must internally reassess and revalidate their own measures in the light of the guide recommendations and the regulatory requirements. This guide should form a basis for creating internal rules for each company but it should not be a substitute for the operator's own thinking regarding its own specific characteristics and should be adapted to them. Furthermore, the professionals can choose methods other than those proposed, although they are responsible for proving their effectiveness.

The public authorities acknowledge the existence of good hygiene practices relating to a given profession when performing their official controls. The operators can therefore refer to the good hygiene practices guide to explain the measures they take on the related level.

The Guide constitutes a help tool for staff training and for raising the awareness of suppliers (farmers, service providers etc.).

On Cocal, Cogeca and Unistock initiative, the Guide is periodically updated to take into account technological, scientific and regulatory developments. The next revision of the Guide should be 5 years after the publication of this version at the latest. Operators must, however, take into account any regulations subsequent to the date on which the guide is written, without waiting for its update. Cocal, Cogeca and Unistock perform routine regulatory monitoring in order to assist operators in the above mentioned task.

¹ The following Associations were consulted: AAF, APAG, CEFS, CEPS, COCERAL, COFALEC, COPA-COGECA, EABA, EAPA, EDA, EFPRA, EMFEMA, EUCOLAIT, EUROMALT, European Flour Millers, EUSALT, FEDIAF, FEDIOL, FEFAC, FERM, FoodDrinkEurope, IFFO, IMA-Europe and The Brewers of Europe

Revisions of the Guide may also be initiated by the co-owners of the Guide on request of the European Commission or Member States within the Standing Committee on Plants, Animals, Food and Feed (as per Article 9(4) of Regulation (EC) No 853/2004 as amended and Article 22(5) of Regulation (EC) No 1831/2003 as amended). The subsequent revisions will then be proposed to the Community authorities concerned with a view to their official validation.

The Guide may also be used as a starting point to develop national or regional guides which might be more detailed but should not be in contradiction with this Community guide. If Member States and or operators have already implemented higher standards and are applying them, the guide should never be used to lower the level of these standards.

Coceral is the EU Association representing the European cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agro-supply trade. The members of Coceral are the national trade organisations of most of the EU-28 Member States, who for their part represent collectors, distributors, exporters, importers and agribulk storekeepers of the above mentioned commodities. The members are composed of essentially private traders and in some countries also farmers' cooperatives. Furthermore, Coceral has associate members in Switzerland.

Cogeca, the EU agri-cooperatives Association, currently represents the general and specific interests of some 40,000 agri-cooperatives employing some 660,000 people and with a global annual turnover in excess of three hundred billion euros throughout the enlarged Europe. Since its creation, Cogeca has been recognised by the European Institutions as the main representative body and indeed the spokesman for the entire agricultural and fisheries cooperative sector.

Unistock is the European Association of professional portside storekeepers for agribulk commodities within the European Union. Unistock's prime objective is the representation of interests of the individual members towards the EU authorities. Since its creation, Unistock has developed a specific expertise with regard to health and environment-related problems affecting daily activities of European agri-bulk storekeepers.

2. SCOPE and DEFINITIONS

2.1. Scope

The present European Guide for the collection, storage, trading and transport of cereals, oilseeds and protein crops (hereafter referred to as the Guide) proposes good hygiene practices for operators that collect, store, trade and transport cereals, oilseeds, protein crops and other plant products as well as their co-products resulting from them (e.g. oils, meals and fats of vegetable origin), intended to be used as food and/or feed.

The Guide is applicable to all operations from receipt to dispatch of the above mentioned goods and it covers all food and feed operators in Europe carrying out the mentioned activities included within its scope, namely any first-stage trading operator on the domestic or intra-Community market as well as trading with third countries.

The Guide is not adapted for use by farmers with their own storage facilities. It is recommended to refer to specific guides for primary production.

The Guide does not cover the commercial characteristics of the products as they are an integral part of the contractual provisions.

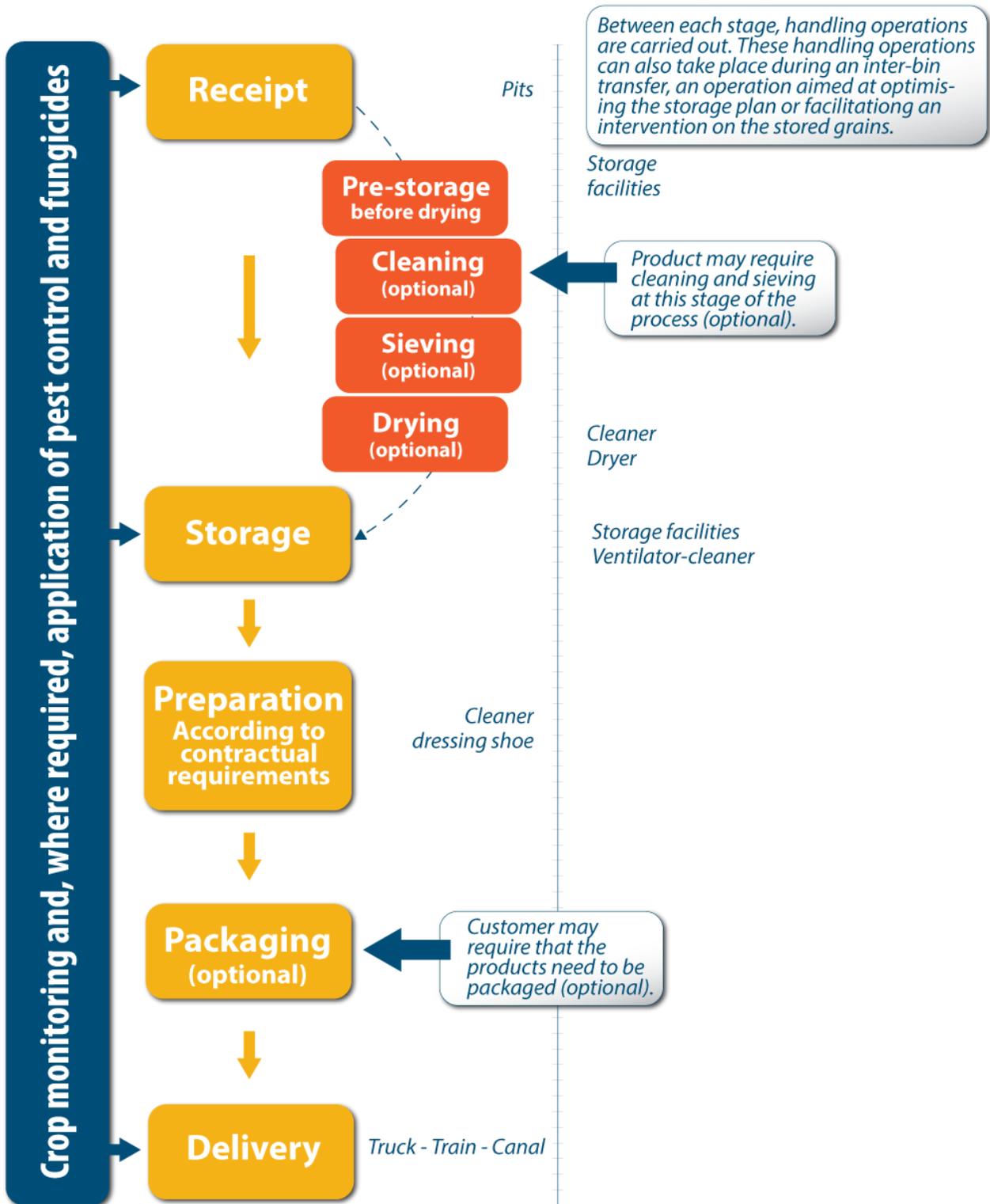
2.1.1. Trade operators in the food and feed processing industry



The operators' activities are carried out based on the following stages :

1. Receiving (identifying, sampling, inspecting, classifying, etc.)
2. Packaging (cleaning, sorting, drying, gathering, etc.)
3. Storing (cooling, ventilating, transferring between bins, treating with pesticides, inspecting, etc.)
4. Dispatching (loading, sampling, etc.), transporting, delivering.

All the technical processes are developed with a view to trading the goods.



2.2. Legal definitions²

Batch: an identifiable quantity of food and 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 (EC) No 1069/2009 as amended and Regulation (EC) No 767/2009 as amended).

Feed (or feedingstuffs): any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals (Regulation (EC) No 178/2002 as amended).

Food (or foodstuffs): any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (Regulation (EC) No 178/2002 as amended).

Feed Hygiene: the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use (Regulation (EC) No 183/2005 as amended).

Food Hygiene: the measures and conditions necessary to control hazards and to ensure fitness for human consumption of foodstuffs, taking into account its intended use (Regulation (EC) No 852/2004 as amended).

Feed material: 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 premixtures (Regulation No 767/2009 as amended).

Hazard: biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect (Regulation (EC) No 178/2002 as amended).

Operator (food/feed): natural or legal persons responsible for ensuring that the requirements of food and feed law are met within the food and feed business under their control (Regulation (EC) No 178/2002 as amended and Regulation (EC) No 183/2005 as amended).

Risk: a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard (Regulation (EC) No 178/2002 as amended).

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 (EC) No 178/2002 as amended).

Undesirable substances: 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/EC).

Waste: any substance or object which the holder discards or intends or is required to discard (Directive 2008/98/EC).

Ship-generated waste: all waste, including sewage, and residues other than cargo residues, which are generated during the service of a ship and fall under the scope of Annexes I, IV and V to Marpol 73/78 and cargo-associated waste as defined in the Guidelines for the implementation of Annex V to Marpol 73/78 (Directive 2000/59/EC).

Cargo residues: shall mean the remnants of any cargo material on board in cargo holds or tanks which remain after unloading procedures and cleaning operations are completed and shall include loading/unloading excesses and spillage (Directive 2000/59/EC).

2.2.1 Other definitions

Aflatoxins: mycotoxins produced by *Aspergillus* species of Fungi, mainly *A. Flavus*, *A. Parasiticus* and *A. Nomius*.

² When reference is made in this Guide to legislations, the operator is advised to check for updates/amendments

Aspergillus: very common type of mould, the control of which is of great sanitary and economic importance to the food-processing industries. Several species are toxigenic.

Individualized Bin: food and feed materials storage unit of varying capacity, in which cereals, oilseeds and products derived thereof are stored.

Bringing into line with contractual standards: preparation of the food and feed materials according to the contractual specifications (assembly, grading, cleaning).

Calibration operation used to check that a measuring device indicates a precise value via an appropriate procedure.

Collection (as used in this guide): receiving section of the raw material.

Control point: Point, stage or procedure which ensures the hygienic control of a process.

C.C.P. (critical control point): stage at which a control measure can be applied and where it is essential to prevent or eliminate a hazard jeopardizing the safety of foods or bring the safety to an acceptable level.

Cleaning: operation which aims to remove various impurities (husks, straw, soil etc.) which have a negative effect on the food and feed materials storage and shelf life. The cleaners work on the principles of suction and/or grading (gratings).

Corrective actions: actions to be carried out when the results of the monitoring applied to the C.C.P. indicate a loss of control.

Contaminant: any biological or chemical agent, any foreign matter or any other substance which is not intentionally added to a product which could compromise its safety or healthiness.

Contamination/Cross-contamination: the undesired introduction of impurities of a chemical or microbiological nature or foreign matter during production, sampling, packaging or repackaging, storage or transport.

Critical limit (or critical threshold): criteria which distinguishes acceptability from non-acceptability.

Control measures (or preventive measures): Actions or activities which can be implemented to prevent or eliminate a hazard which jeopardizes the safety of foods and feed or bring it to an acceptable level.

Documentation: any written information, media, and other document, whatever its form (hard copy, electronic, etc.) and format, which is kept by the operator.

Dust mark: mark (cross or disc for example) painted on the floor (contrasting with the colour of the floor) to assess the presence of dust.

FIFO (First In First Out): stock management method in which the first article entering the stock is the first to leave.

Flat bottom storage (or flat bottom box): store of food and feed materials, the floor dimensions of which are larger than the height.

Flow meter: device used to measure the flow of a product to be nebulized or sprayed.

Safety of food and feed: Assurance that the food and feed will not harm the consumer when they are prepared and/or consumed in accordance with their intended use.

Grading: mechanical operation which sorts a lot or batch to ensure compliance with the customer's specifications (example: grading of brewing barley).

H.A.C.C.P. (Hazard Analysis Critical Control Points): System which identifies evaluates and controls significant food and feed safety hazards.

Hazard analysis: action of gathering and assessing the data on hazards and the conditions that lead to their presence to decide which of them are significant in terms of food and feed safety and should therefore be taken into account in the H.A.C.C.P. plan.

H.A.C.C.P. plan: document prepared in compliance with the H.A.C.C.P. principles to control significant food and feed safety hazards in the food industry segment considered.

Handling equipment System used for mechanically or pneumatically moving food and feed materials in bulk.

Hopper: small capacity bin in which goods are stored for a short time.

Inter-bin transfer: operation which consists of transferring a mass of food and feed materials from one bin to another, for example to homogenize them or to prevent solidification.

Networks: public or private bodies/entities which provide food and feed business operators with the opportunity among others to share and get data / analysis results, to exchange views on technical matters related to the agro-business and to get assistance on how to build up efficient

food and feed safety monitoring plans for cereals and oilseeds (e.g. QUALIMAT Association or IRTAC in France, Galis.gmp in Spain, etc.)

Pesticide treatment: operation which consists of applying pesticides in solid, liquid or gas form on food and feed materials or onto the store walls.

Food and products derived thereof: as any product of vegetable origin derived from the primary agricultural production, whether processed, partially processed or unprocessed intended to be, or reasonably expected to be ingested by humans (adapted from article 2 of Regulation (EC) No 178/2002 as amended), The definitions of 'processing', 'unprocessed products' and 'processed products' is defined in points (m), (n) and (o) of Article 2(1) of Regulation (EC) No 852/2004 as amended of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

Ishikawa diagram [the five words below begin with M in French]: mnemonic method used in order to be thorough in research. For each stage in the silo diagram, the team asks itself the question: "Does a hazard stem from the **R**aw material entering the stage, the **E**quipment used for the stage, the **L**abour used in this stage, the **E**nvironment (working environment) or the **M**ethod (of working)?"

Maintenance: maintenance is keeping a tool in working order so that it can carry out the service for which it was designed. Two types of maintenance are practised: corrective, which consists in repairing as required, and preventive which is planned or scheduled.

Maize drying shed: maize stored outside in units covered with wire meshing and slowly dried by the ambient air.

Mycotoxins: toxic metabolites produced by certain species of mould which are dangerous to humans and to animals that consume the food and feed on which this mould has developed.

Monitoring: action which involves carrying out a scheduled series of observations or control parameter measurements to assess whether a C.C.P. is controlled.

Nebulization: process consisting of coating the moving food and feed materials with an extremely fine mist, it ensures the pesticide treatment is applied more consistently than with spraying of an environment.

Operating method: specified method for carrying out a task.

pH (hydrogen potential): unit between 1 and 14 characterizing the acidity (< 7) or alkalinity (> 7)

Pathogenic: something which causes diseases.

Pests: birds, rodents, insects and other animals able to directly or indirectly contaminate foodstuffs and feedstuffs.

Pit: receipt equipment in which the food and feed materials falls by gravity.

Prerequisites programs (PRPs): conditions and procedures that must be established throughout the food and feed chain as well as the activities and practices that must be performed in order to establish and maintain a hygienic environment. PRPs must be suitable and be capable of handling goods and providing to rest of the chain food/feed materials that are safe for human consumption. PRPs support HACCP plans.

Procedure: specified method of carrying out an activity or process.

Raw material: basic substance in its natural, modified, or semi-processed state, used as an input to a production process for subsequent modification or transformation into a finished good.

Record: document recording results obtained or providing evidence that an activity has been carried out.

Smell: abnormal odour (other than food and feed materials normal odour).

Specifications: Informative or contractual document between the supplier and the customer which determines the quality objectives of a product or service and criteria for assessing this quality (hygiene requirements etc.).

Silo thermometry: system used to measure the temperature in the mass of a bin using sensors.

Sorting: mechanical operation which sorts between two different species (example: sorting of a batch of wheat containing rape).

Terminal (or terminal operator): facility for transferring the commodity from one transport module to the other possibly with intermediate storage.

Thermodynamic activity of water (Aw): concept introduced in 1936 by Lewis who talked of the "Activity of Water" (hence the universally used abbreviation Aw). It concerns the water available in foodstuffs for microorganisms. The activity of pure water is equal to 1.

Verification: application of methods, procedures, analyses and other evaluations in addition to those used for monitoring, to determine whether the H.A.C.C.P. plan is complied with.

Ventilation: operation aimed at cooling the food and feed materials and maintaining it at a sufficiently low temperature to ensure it's good storage. Ventilation is carried out via the forced circulation of the ambient air towards a mass of cereals (the air is forced or extracted using a ventilator, sent to food and feed materials via pipes, then distributed in the mass by a distribution shaft system).

2.3. The regulatory requirements

The European Union has revised all of its food and feed legislation to implement a consistent, transparent hygiene policy applicable to foodstuffs as well as feedstuffs and all food and feed business operators.

The good practices set out in this guide originate from the application of the HACCP method and meet the requirements of the "food and feed hygiene regulations". The main regulations taken into account in the drafting of this guide are listed in Appendix 8.

SECTION I

GOOD HYGIENE PRACTICE RECOMMENDATIONS FOR COLLECTION, STORAGE, TRADING AND/OR TRANSPORT OPERATORS

Chapter I

General good hygiene practices

1. Management responsibility

1.1. Management commitment, responsibility and policy

Management shall be committed to the implementation and adherence of the guide in order to help ensure food and feed safety of the agribulk commodities.

Management shall ensure that responsibility and authority are defined, in written form, and communicated within the organisation.

Staff appointed by management shall have defined responsibility and authority to:

- Identify and record any problems with regard to product safety and the operator's HACCP system.
- Initiate remedial measures and control of any such problems.
- Initiate action to prevent the occurrence of nonconformities relating to product safety.

Management shall:

- Establish a safety policy and ensure that objectives are established.
- Define the scope of the HACCP system, by identifying the products/product categories which are covered by the system and ensuring that safety objectives are established as part of the system; and
- Ensure that these objectives and policies are in compliance with business goals of the operator, statutory and regulatory requirements.
- Review the management commitment, responsibilities and policy on a regular basis.

1.2. Management structure and allocation of resources

Top management shall appoint a HACCP team leader who, irrespective of other responsibilities, shall organize the work of a team and have the responsibility and authority to:

- Ensure that the management system is established, implemented, maintained and updated in accordance with this guide.
- Report directly to the organization's top management on the effectiveness and suitability of the management system for review as a basis for improvement of the system, and
- Arrange relevant training and education of the team members.

The HACCP team leader must be a management representative or have direct access to management.

The operator shall provide adequate resources for the establishment, implementation, maintenance, updating and control of the HACCP systems.

Adequate communication must be in place to inform the HACCP team (leader) of significant changes in products or processes.

In order to establish a risk assessment system, the operator must appoint a HACCP Team to produce an effective HACCP Plan.

The HACCP Team must include:

- Staff from all of the relevant operations and functions within the Operator.
- At least one member with demonstrably effective HACCP training.
- Where operators delegate key activities to third parties, it is desirable for representatives of the third party organisation to be included in the HACCP Team.

The composition of the HACCP Team and competence of the members must be documented. It is acceptable for individual personnel to fulfil multiple roles in the HACCP Team or to use resources from outside of the operator, provided that the role of the Team remains effective.

1.3. Staff

All provisions are developed in compliance with the safety rules defined by the operator. An organisation chart as well as a summary of responsibilities may be prepared. The employees, including temporary recently hired staff and maintenance or transport staff, are informed and trained about their duties and areas of responsibilities and are aware of hygiene requirements. A corresponding record of the instruction is kept.

The staff dealing with the operations are trained and kept regularly informed of the internal management and recording procedures, developments in rules as well as the commercial uses. In order to ensure that the employees' training levels are up-to-date, it is recommended that training sessions take place prior to the introduction of significant changes to relevant procedures.

Furthermore, if appropriate, the staff dealing with operation are regularly trained on the legislation concerning the contaminant thresholds of any pesticide treatment, the cleaning procedures and, more generally, on the Good Hygiene Practices (GHP), Good Managing Practices (GMP), traceability sampling and analysis rules.

Specific training and specific administrative management and technical intervention procedures are developed when the company deals with goods with specific regulations.

1.3.1. Hygiene awareness raising

Ensure that all staff is made aware of hygiene issues, including temporary, recently recruited staff, maintenance and transport staff. Provide regular refresher courses on the subject.

Make staff, including seasonal staff, aware of human-induced contaminations to help them understand hygiene rules and facilitate their compliance: particularly in terms of cleaning the pits, dosing pesticide products and washing hands.

Train the staff responsible for developing and maintaining the HACCP system or implementing this guide with the operator. All staff should be made aware of the principles and requirements of HACCP and this should be recorded.

1.3.2. Behaviour at work

In the work place, make instructions relating to compliance with the present guide available to staff by the most appropriate means, for example signs, internal notes, notices etc.

Put in place maintenance instructions for internal and external services, stating the need for systematic cleaning after maintenance work.

Ban smoking in product handling and storage areas and remind staff of this obligation with signs or instructions. Designate a smoking area and ensure this is adhered to.

Make staff aware of the problems that could be caused by internal maintenance work such as foreign bodies or debris from building work. Make staff also aware of the cross contamination that could occur with chemical products or seeds, such as a leak of pesticide products or the non-detection of treated seeds on receipt.

Make staff aware of the need to comply with any necessary waiting times (harvest interval) after goods or containers (bin, transport receptacle) have been treated with pesticides.

1.3.3. External companies and visitors

Inform them of the fundamental hygiene rules in place within the operator's company and ensure they are adhered to at the operating site. Where the assistance of external experts is required for the development, implementation, or operation of the management system, records of agreement shall be made defining the responsibility and authority of such experts.

Staff: examples of controls and records

- Records of training, certificates.
- Seasonal workers welcome guide.
- Specifications with external operators.
- Cleanliness/hygiene audit.

2. Prerequisite programmes

2.1. Premises

2.1.1. Sanitary facilities and staff rooms

Make sanitary facilities available to staff, equipped with a sink and toilets supplied with running water and keep them well cleaned.

Make changing rooms or private closets available to staff so they can change their clothes.

2.1.2. Lighting

Light the premises appropriately.

Avoid any contamination by pieces of broken glass by using safety lamps or sealed diffusers.

2.1.3. Water

Non-drinking water, used for example for fire fighting must be distributed in a separate pipeline system.

2.2. Equipment and maintenance

Equipment shall be fit for the purpose of the operator's activities and shall be designed to facilitate cleaning and maintenance. The equipment must also be designed and operated in such a way that the goods are not altered by sludge, water, rain, snow and other potential contaminants. Equipment must be maintained in a sufficiently clean and hygienically acceptable condition in order to avoid pest damages and microbiological contamination.

Technical maintenance/service is to be done by qualified staff. Maintenance inspections at predefined intervals shall be performed and recorded on all equipment where corrosion or failure to operate correctly will result in product degradation or cross contamination.

Records are to be kept about the service and maintenance of the equipment used in the operations.

These records are a part of the internal management system.

2.3. Traceability

The traceability of food and feed materials must be established at all stages from farm to fork.

Food and feed business operators must be able to identify from whom they have been supplied and to whom they have supplied with food and feed materials. Storage and transport operators should be able to demonstrate their traceability of the goods. To this end, such operators must have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

Food and/or feed which is placed on the market or is likely to be placed on the market in the Community must be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

2.4. Testing and measuring instruments

The testing instruments used during operations (scales, measuring devices) must be suitable for the purpose they are used for. Devices have to be calibrated and maintained according to EU and/or national legal requirements.

Testing equipment is to be inspected regularly. The kind of inspection, the inspection intervals and the next inspection date must be registered in an inspection summary.

Devices to measure the temperature of the goods during storage shall be available at all times.

The inventory of testing instruments is a part of the internal quality assurance system.

2.5. Cleaning

Cleaning programmes shall be established to ensure that the equipment and environment are maintained in a good hygienic condition. The effectiveness and suitability of those programmes shall be monitored on a regular basis.

The equipment and facilities are to be cleaned on a regular basis, and prior to a change in products by means of sweeping and collecting dust or equivalent procedures, when those products are not compatible.

Records of the cleaning measures must be kept. The record is a part of the internal quality management system. If vehicles (such as pay loaders etc.) are used, they are to be cleaned on a regular basis.

The premises and installations shall be kept clean and well maintained at all times. A housekeeping plan shall be in place.

2.6. Pest and microbiological control

The operator must establish and document a pest control program and take preventive measures. This pest control program needs to be based on recognised pest control methods and means. This service can be externalised.

Pest control as well as the risk of microbiological contamination to the products and facilities shall be part of HACCP system and should be documented. Special attention should be taken for processed feed material such as oilseeds meals, fish meal, maize products, meat and bone meal, etc. as regards the possible occurrence of salmonella.

2.7. Waste management

The operator must control waste and materials containing hazardous levels of contaminants or other hazards. These must be disposed of in an appropriate way to prevent contamination of the product.

Where necessary, to prevent such hazards:

- Dispose in a manner which avoids contamination.
- Store waste in closed or covered containers at defined and separate waste accumulating areas.
- Waste containers should be clearly marked.
- Waste must be disposed of according to local Regulations and in a manner which ensures that equipment and the safety of food and feed materials are not affected.

3. Monitoring plan

The operator should implement a plan for monitoring the main hazards that affect its activity. This plan aims to:

- Confirm the relevance of the hazard analysis.
- Verify the effectiveness of the control measures put in place.
- Ensure that the goods being marketed are compliant with the regulations.
- Initiate improvement actions appropriate to the detected or potential anomalies.

The plan should be adapted to the products handled, the outlets and the operator's hazard analysis. This plan first of all aims to monitor the main hazards in the main marketed productions concerned (chemical, physical, biological harmful substances, pathogenic flora, mycotoxins, etc.).

The sampling frequency should be determined on a case-by-case basis according to the risk analysis, the storage duration and any other relevant criteria.

To create its individual monitoring plan, the operator must draw up a documentation system which aims to ensure proper traceability of food and feed materials. The operator may include the following elements depending on the activities he carries out:

- The number of sites and bins.
- The volume collected.
- The contaminant/product pair.
- The origin of the product (barn storage, field, silo etc.).
- The effect of the time of year (climatic conditions).
- The storage duration.
- The geographical area.

- The historical data.
- The destination – customer requirements etc.
- The sampling and analysis method used.
- If relevant and upon the case, a reference to local, national, and community legislation.

In addition, operators should carefully follow the technical information made available by professional networks and constantly adapt their monitoring plan based on that information.

3.1. Sampling

The operator may define its own appropriate sampling method and rules as per existing legislation (Regulation (EC) No 152/2009 as amended and Regulation (EC) 401/2006 as amended), standards in force (e.g. CEN, ISO) or contractual provisions (e.g. GAFTA, FOSFA). The sampling procedures and methods should be tailor-made to the type of analysis to be performed, based on the risk analysis and on the distribution (homogenous or not) of the contaminant.

A sampling plan needs to be adapted to the characteristic of the contaminant: mycotoxins, for example, are known to be distributed heterogeneously. This is largely due to the uneven distribution of contaminated particles within a lot.

A procedure generally consists of three steps: sampling, sample preparation, and analysis (quantification). Even when using accepted sample selection, sample preparation and analytical procedures there is always some level of uncertainty associating with a mycotoxin sampling plan.

Three critical steps need to be considered to come to a decision on acceptance or rejection of a consignment, lot or subplot. The sampling step specifies how the sample will be selected or taken from the bulk lot, the number of incremental samples, and the size of the aggregate sample(s). For granular products, sample preparation includes the processing of the laboratory sample (i.e. grinding in a mill to reduce particle size) and the selection of a test portion, which is removed for subsequent analysis. Finally, in the analytical step, the analyte is solvent-extracted from the test portion and quantified using validated analytical procedures.

The measured analyte concentration in the test portion is used to estimate the true mycotoxin concentration in the bulk lot or compared to a defined acceptance/rejection limit that is usually equal to a maximum limit or regulatory limit. It is, therefore, important that the sampling procedure defines a laboratory sample that is as representative as possible of the bulk lot.

Special attention on sampling should be taken for contaminants which are not homogeneously distributed in order to have a representative sample, such as mycotoxins.

3.1.1. Sampling for aflatoxins in cereals and derived products

The known heterogeneous distribution of the aflatoxin contamination and the representativeness of the samples taken from the lot (especially of large lots) can result in a variability of aflatoxin results between several samples taken from the same lot and between samples taken from the same lot but at different stages of the distribution chain. For these reasons, the following management measures are recommended in situations and feed materials where an increased risk for aflatoxins contamination is observed and extra vigilance in the chain is needed. This extra vigilance is required particularly when risk is high.

All sampling recommendations should be applied. Additionally, the following points are of particular attention:

- A description of the applied sampling procedure should be available and can be provided upon request.

- In years and/or regions with high prevalence of aflatoxins and in case of large lots, it is prudent to apply the sampling procedure on smaller sublots in order to have a better view on the variability of the presence of aflatoxins throughout the lot.
- The analytical result(s) should be communicated upon request along the chain.

3.2. Analysis

The monitoring plan can be individual that is performed by the operator who is the only person who will make use of the results. In order to gather a larger number of samples and have a more exhaustive view, operators are encouraged, however not obliged, to become part of public or private networks which propose food and feed safety monitoring plans for food and feed materials (for more details, see definition of “network”).

Testing and analysis must be performed by laboratories applying appropriate official normalised methods covered by the scope of their accreditation, whenever available.

For internal monitoring purposes, other competent laboratories may be used. It is recommended that all methods are traceable to officially normalised methods, whenever available. Both, accredited as well as non-accredited laboratories, are encouraged to participate in inter-laboratory proficiency tests (ring tests).

3.3. Interpretation of results: how is measurement uncertainty taken into account?

In the context of official testing of animal feed, Regulation (EC) No 152/2009 as amended states: *“As regards undesirable substances within the meaning of Directive 2002/32/EC, including dioxins and dioxin-like PCBs, a product intended for animal feed shall be considered as non-compliant with the established maximum content, if the analytical result is deemed to exceed the maximum content taking into account expanded measurement uncertainty and correction for recovery. In order to assess compliance, the analysed concentration is used after being corrected for recovery and after deduction of the expanded measurement uncertainty”.*

In the context of official control of foodstuffs for mycotoxins, Regulation (EC) No 401/2006 as amended states:

“The analytical result must be reported as $x \pm U$ whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.”

“That a lot or sub-lot is accepted if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty”.

“That a lot or sub-lot is rejected if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty”.

3.4. Records and documentation

The records deriving from the implementation of the monitoring plan should be kept for an appropriate period of time as per relevant EU and/or national legislation.

4. Communication along the supply chain

Communication between suppliers and customers on the quality of the delivered goods can improve the risk assessment and the design of control plans. The communication is therefore encouraged, especially in years or in areas where the conditions of risks development (e.g. mycotoxins) are important.

Parties may agree on detailed data transmission based on contractual agreements and on the declared and intended final use of the products.

4.1. Communication of information on aflatoxins in cereals and derived products

When an increased risk for aflatoxins contamination is observed, an extra vigilance in the chain is warranted.

In case of only one single analytical result for a large lot, it should be realised that aflatoxins are heterogeneously distributed and that an analytical result of 10 µg/kg aflatoxin B1 on a large lot might hide higher levels in certain parts of the lot (and lower levels in other parts) and this should be taken into account when considering the use of parts of such lots for the production of compound feed.

In case of several analytical results for a large lot, the variability of the analytical results provides an estimate on the variability of the presence of aflatoxin in the large lot.

In both cases and when appropriate, these results should be communicated upon request along the chain in order to allow downstream operators to consider the most appropriate management measures for risk mitigation.

When appropriate, the operator is encouraged to communicate information upon request downstream to the supply chain in case:

- Different analytical results on a lot suggest a variable content of aflatoxin B1 in the lot, notwithstanding that all results are in compliance with EU regulatory maximum levels.
- One analytical result for aflatoxin B1 in a lot exceeds 5 µg/kg, notwithstanding that the result is in compliance with EU regulatory maximum levels.

It is the responsibility of downstream operators to use this information in order to mitigate the risk of producing non-compliant feed.

5. Monitoring plan on dioxin in fats, oils of vegetable origin and products derived thereof for use in feed

The following minimum monitoring requirements on “dioxins” are applicable to all operators dealing with vegetable oils and their derived products³, pure or in blends and intended for use in feed. These requirements are not applicable to goods destined to the food or industrial sectors.

Feed Business Operators must in any event comply with the maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in feed and foodstuffs as per relevant legislation referred to in appendix 8 of the present Guide.

Sampling and analysis taken from homogeneous and clearly identified lots must be performed by relevant laboratories according to the good practices. It is the responsibility of the FBO to instruct the laboratory to communicate the results of analysis to the authorities. This does not exempt the Feed Business Operator from his obligation to inform the competent authority. When the laboratory having performed such analysis is located in a third country, the operator will inform the competent authority of the Member state where he is located and provide evidence that the laboratory performs the analysis in accordance with Regulation (EC) No 152/2009 as amended. The

³ Products derived from vegetable oils” means any product derived from crude or recovered vegetable oils by oleochemical or biodiesel processing or distillation, chemical or physical refining, other than the refined oil. This includes also meal feed and expeller feed. Glycerol, lecithin and gums are excluded though.

minimum monitoring frequency varies according to the type of products at stake as per Regulation (EU) No 225/2012 as amended.

If the operator can demonstrate that a homogenous consignment is bigger than the maximum batch size according to Annex II to Regulation (EU) No 183/2005 as amended and that it has been sampled in a representative way, then the results of the analysis of the appropriately drawn and sealed sample will be considered as acceptable.

In cases where the Feed Business Operator proves that a batch of a product or all components of a batch has/have already been analysed at an earlier stage of production processing or distribution, or is/are in compliance with minimum requirements, he is exempted from his obligation to analyse the batch and analyse it according to the general HACCP principles (see appendix I on HACCP method).

6. Non-conforming products

The management must establish a documented procedure for dealing with products which do not comply with intended uses. Notification to national authorities should be done by the operator in accordance with articles 19 and 20 of Regulation (EC) No 178/2002 as amended.

The procedure should include:

- Identification.
- Segregation of affected batches.
- Detoxification where appropriate and if authorised.
- Provision for disposal of products where appropriate.
- Evaluation of the root cause of the non-conformance.
- Documentation of non-conformance, root cause analysis, corrective actions and verification.
- Recording of internal information of relevant parties.

Responsibility for review and disposal of the non-conforming product must be defined.

A non-conforming product should be reviewed in accordance with competent authorities, with documented procedures and actioned in one of the following ways:

- Rework.
- Reclassification (e.g. as a product intended for industrial use).
- Dispensation (not in case of a food or feed safety issue).
- Rejection and subsequent destruction or disposal according to waste disposal procedures.

7. Withdrawal and recall procedure for safety reasons

The management must implement a documented withdrawal and recall procedure that ensures customers and regulatory authorities can be informed promptly in the event of any irregularity that may adversely affect food and feed materials safety.

If the management considers or has reason to believe that a food or feed material which it has collected, stored, traded or transported does not satisfy the food or feed safety requirements, it must immediately initiate procedures to withdraw and if necessary, recall from users the goods at risk and inform the competent authorities thereof:

- The withdrawal and the recall procedure must be documented.
- Responsibility must be defined for notifying customers and regulatory authorities.
- Responsibility within the operation for product withdrawal and recall(s) must be defined.
- All relevant contacts (including relevant authorities) must be listed and kept up-to-date.

Food and feed materials which are considered unsafe will be handled as non-conforming product. The recall procedure must be tested on a regular basis by a simulation to ensure its validity.

8. Internal audits

The management is encouraged to perform internal audits to verify that the food and feed safety management system is:

- Effectively implemented and maintained.
- In compliance with regulatory and other defined requirements.

Internal audits may also be used to identify potential opportunities for improvements.

It is recommended that all relevant activities are audited internally once a year.

9. Complaints

Each complaint related to food and feed safety shall be examined following a documented complaint procedure. This procedure must establish the person responsible for managing those complaints and include system for:

- Prompt recording and investigation of complaints.
- Prompt feedback to the complainant with findings.

In case this complaint is affecting food and feed safety, official authorities should be informed as per national legislation and in accordance with article 19 of Regulation (EC) No 178/2002 as amended.

10. Verification

All procedures should be regularly checked by the management in order to ensure that they are well implemented and respond to the initial purpose.

Chapter II

Good hygiene practice recommendations for trading operations

1. The domain

The commercial activity mainly concerns the purchase of cereals, oilseeds, protein crops and products derived thereof with the intention of using them all as food and/or feed.

The activity is carried out by farmers, first-processing industries from the food and feed materials industry and trade intermediaries, being exporters or not, for human food, animal feed and other industrial uses, within the European Union and also to third countries.

2. Registration of the operators

The operator must be duly registered with the relevant national authorities for each of its sites, for its activities in the food sector (Regulation (EC) No 852/2004 as amended) and the feed sector (Regulation (EC) No 183/2005 as amended).

3. Traceability

Traceability in itself does not ensure food and feed safety; it must be perceived as a tool or risk management instrument to be used to contain a food and feed safety problem more easily. Consequently, traceability must allow the food and feed business operators as well as the competent authorities to proceed with precise and targeted withdrawals and recalls, in accordance with Regulation (EC) No 178/2002.

When the operator purchases crop raw materials or from the market, even when there is no physical transit through its facilities, it must ensure that its EU suppliers' dispatch sites are registered for food activities (Regulation (EC) No 852/2004 as amended) or feed activities (Regulation (EC) No 183/2005 as amended). An assessment of the supplier should be conducted. For instance an assessment may take the form of monitoring performance through in-house checks, certificates of analysis or supplier inspections, as appropriate.

For both purchases and sales, the transactions are carried out at the operator stage in compliance with the commercial uses, good hygiene practices and food and feed safety regulations, as well as current European and national traceability rules.

When a paper-trader is using different kinds of service suppliers, he should choose service suppliers applying good practices as described in Chapter III, Chapter IV and Chapter IV bis.

3.1. Physical traceability⁴

The physical traceability records must indicate:

- They must be able to identify their suppliers and customers of the goods; (For stores this may just be supplier/customer and next transit phase).
- They must have systems and procedures allowing this information to be made available to competent authorities on request.
- They must label or identify appropriately the food or feed placed on the market, to facilitate its traceability.

⁴ Physical traceability is being done mostly by the operators who store the good

3.2. *Administrative traceability*⁵

The administrative traceability records must indicate:

- The name and address of the seller and the buyer.
- The point of loading and unloading of the products.
- The marketing name of the feed and/or the name of the food, the batch or lot number as well as its quantity.
- Identification of the transport company and the means of transport used, such as boats (in hold or tank), vehicles (with reference to trailer), etc.
- Identification of the storage company and the means of storage used, such as warehouses, silos or tanks and the number or distinguishing mark of the store or silo.

The duration for which the transport documents have to be kept is for a minimum of 3 years depending on national legislation.

4. Recording of movements

The appointed staff apply a stock movement recording procedure (receipts and dispatches, including inter-silo transfers) adapted to each site, for which they have been trained. This serves as a basis for managing the stocks and enables the computer transfer or gathering of the information required for invoicing and, more generally, account and declaration management.

Inter-silo transfers refer to the storekeeper internal management principles. Storekeepers keep their own traceability system and follow their internal requirements and rules. However, when an inter-silo transfer leads to the combining of two (or more) batches coming from different physical origin (e.g. from different vessels), the storekeeper must obtain the consent of the owner(s) of the batches concerned, prior to the inter-silo transfer if this is agreed in the contract between the trader and the storekeeper. A new batch number has to be allocated by the owner(s) of the batch, if possible and if required.

5. Labelling and accompanying documents

Each goods movement recorded by the operator is materialized by the creation of supporting documents (receipt, transfer, delivery or collection notes and weighbridge tickets) issued in as many copies as there are counterparties when required. These documents are drawn up in accordance with the regulations regarding the labelling of foodstuffs (Regulation (EU) No 1169/2011 as amended), feedstuffs (Regulation (EC) No 767/2009 as amended) and transport. Where a commodity is identified as not fit for food or feed use, a procedure must be in place to ensure that it ends up in a technical or waste destination with records being kept.

Each operator has to define batch according to the characteristics of the product and his traceability requirements.⁶

The notes indicate:

- The marketing name of the feed and/or the name of the food, the batch or lot number if available as well as the weight loaded. The lot number is a requirement for labelling of feed materials, unless there is a written proof that the buyer has renounced this information, for each transaction (Article 15 d and 21.1 of Regulation (EC) No 767/2009 as amended).
- The names and addresses of the delivery people and the customers or consignees, the date and full address of the dispatch and delivery location (otherwise customer name), the type of goods and the weight loaded.
- Potentially additional commercial information.

⁵ Administrative traceability is mainly made by paper-traders

⁶ It is not possible to give one single definition for batch as it depends on several characteristics – for example product specifications, contractual agreements etc.

- If required, other labelling regulatory information.

For further information on the labelling demands for feed materials, please consult Regulation (EC) No 767/2009 as amended (Article 15 and 16) and the derogations in Article 21.

The notes are kept as evidence of receipt or dispatch, for as long as is requested in commercial contracts if applicable, or as per local, national or EU legislation or standards applicable to such documentation or for a period appropriate for the use to which the products are placed on the market. Rules concerning accompanying documents for feed are mentioned in Regulation (EC) No 767/2009, article 11, paragraph 2. If necessary, the dispatch documents will refer to the relevant commercial contracts. They are added to by other transport documents relating to the same movements: waybills, applications, bills of lading etc. and any documents relating to the batches concerned stipulated in the contract such as quality, origin or acceptance certificates.

Containers and other means of transport shall be accompanied by the documents like labeling.

6. Quality monitoring

Prevention is mainly carried out by means of actions, information, instructions and specifications supplied to the delivery people and delivery intermediaries.

Food and feed safety quality monitoring throughout the process, from receipt through to dispatch, is mainly carried out via a control plan and warning systems which should help choose the appropriate corrective measures to be applied.

Product specifications must be determined between the operators and confirmed in a contract and/or agreement. These specifications must be clear and unambiguous.

The operator must ensure that all delivered products meet the specifications laid down in the contract and/or agreement.

A plan of the facilities referencing each storage bin is available at each site.

Labelled and referenced samples, for commercial use and traceability are taken according to the usual standards and wherever possible in the presence of both parties, during commercial receipts and dispatches. If an appointed approver is present, then this person will be responsible for these operations.

The samples are stored by the manufacturer or food/feed processors, if applicable, for a period appropriate for the use to which the products are placed on the market or as per existing local, national or EU rules and/or per contractual requirements. These samples allow for quality controls to be carried out with regard to the conditions of receipt, contractual criteria or regulatory standards.

7. Goods with specific regulations

During the entire process from receipt of the crop to its commercial delivery, appropriate measures are implemented to guarantee the strict physical separation between ordinary goods and those with specific trading regulations: such as products originating from organic agriculture, GMO products, goods intended for certified seed production or other specificities.

To limit the risks of these products being accidentally mixed together, specific measures must be put in place. If the circuits are not dedicated to specific goods, then all mixed use circuits (pits, lifts, conveyors, equipment or bins) must be cleaned appropriately and the cleaning effectiveness verified before goods with different regulations are allowed to pass through. It is important to remember that dedicated circuits are a regulatory requirement for the production of certified seeds. The administrative management must be adapted to the various goods regulations that coexist within the same operator or site:

- Stock records keeping specific to goods with particular regulations.
- Organisation of any certification needed and recording of certificates.
- Specific communication to upstream operations (instructions, specifications, contracts).
- Specific rules are provided for labelling and transport supporting documents.

Chapter III

Good hygiene practices recommendations for collection/receipt operations for unprocessed products

1. The external environment

Pests living in unmaintained pits or unused equipment or attracted by waste or stagnant water are known sources of contamination.

It is therefore important to ensure that:

- Areas immediately surrounding stores are well maintained. In particular, lawns, areas not covered with concrete and intake pits.
- Sites to be free-draining.
- Rodent traps are positioned in the areas surrounding food and feed materials and waste storage locations. As regards the rodent traps, they should be checked regularly and used according to conditions of use.

2. Receipt of goods

Crops deliveries by farmers are transported by agricultural trailer or by truck. Collectors are recommended to:

- Remind contractors and farmers of their obligations (by post, training courses printed material and signs etc.) in terms of the internal and external cleanliness of the means of transport.
- Ask for the truck to be cleaned if a product other than cereals or oilseeds has been transported.
- Farmers and contractors should adhere to the recommendations contained in the good hygiene practices guide for field crops, particularly regarding rules on cleaning and succession of transport.

The nature of the previous cargoes should be checked and registered.

3. Control at receipt

When products are received, for each unit delivery ensure to:

- Identify and register the delivery (contributor, name of the product, quantity, etc.).
- Ask whether storage pesticide treatments have been applied to the food and feed materials prior to delivery to the operator's premises and if available, details on the active substance used, doses applied and date of application.
- Drawing samples using adequate procedures and methods.
- Carry out olfactory and visual inspections of the delivered batch to detect the potential presence of a bad smell, insects, foreign bodies or treated seeds.
- Analyse the moisture and impurity contents for crops coming directly from farmers, and dry if appropriate.
- Take temperature and moisture for agribulk commodities received and stored by terminal operators.
- Any control applied must be validated to ensure they are effective. For example, this means demonstrating by analytical or other means that a statement made about a control is true and the control works as intended. Records of this must be kept for future reference.

The operator must also set criteria for classifying and allocating the products received. They will in particular determine the type of technological analyses to be performed on receipt to characterise the product.

As concerns mycotoxins, the internal checks at receipt should include:

- Taking a representative sample from each trailer received (or when taken out of the dryer in the case of drying).
- Obtaining a representative sample from each bin and analyse these samples using the risk analysis of the collector.

Chapter IV

Good hygiene practice recommendations for storage operations for unprocessed/processed products

1. The premises

a. *The construction or modification of storage and handling premises and galleries*

Foreign bodies such as pieces of metal from ceilings, storage bins or equipment above the food and feed materials are sources of contamination. The design of the premises must allow for the implementation of good hygiene practices, particularly regarding risks of contamination from insects and animals and to prevent any contact with toxic and non-food substances. The recommendations contained in this guide must be integrated during the construction or modification of the facility.

It is important to ensure that:

- The lay-out and construction of the store protects the goods from damage and contamination. Windows must be kept closed or fitted with nets or grids or any other appropriate means to exclude pests and birds. Premises should be built up in order to avoid cross contamination with animal production premises.
- The premises are kept in good state of repair. The roofing in particular should be kept watertight to prevent the stored products from being effected by water ingress, which can cause mould and attract insects.
- Foreign bodies are prevented from dropping down, thus contaminating the food and feed materials; it is especially important to take this into consideration when designing new equipment or affecting repairs to existing structures.
- Consideration is given to the design and layout of new buildings to minimise areas that will create roosting and nesting places for birds and other areas that will harbour and attract pests.
- Facilities should undertake Salmonella testing on a risk based approach. All facilities can have different levels of Salmonella depending on the different commodities and practices of handling. This will reflect the nature and design the individual premises. The EFSA Scientific Opinion from 2008 should be consulted for updated information about salmonella.

Construction materials and more specifically joints and coatings must be carefully selected in order to prevent contamination of the stored products. In particular, it is recommended not to use bitumen or equivalent substances in warehouses for the storage of cereals, oilseeds, protein crops and their derived products. The operator should prevent non-dedicated vehicles from parking (fork lift trucks, Lorries) or circulating in storage areas, where possible.

As regards the transport of liquid oils and fats by sea, reference should be made to Commission Regulation (EU) No 579/2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council.

b. *The layout of the storage and handling premises and galleries*

i. Prevention of cross contamination

Chemicals and pesticides must be stored in bunded facilities well away from the main storage areas.

Store pesticides, fertilizers, seeds or substances considered dangerous or inedible and waste in premises that are clearly separate from those used for storing food and feed materials to prevent any accidental mixing.

Label the substances considered dangerous or inedible in order to prevent any confusion.

Take measures to prevent food and feed materials from being contaminated by rodent poison, for example by using bait in boxes. These should not be located inside storage areas.

Access to the storage areas is to be restricted with a special care in order to avoid the intrusion and the nesting of birds and rodents which are an important source of contamination, especially of salmonella when goods such as oilseeds meals are stored.

Prevent non-dedicated vehicles from parking (fork lift trucks, Lorries) or circulating in storage areas, were possible.

Animal protein meal and fish meal must be, based on risk assessment, stored separately in specific sheds separated from each other as laid down by Regulation (EC) No 999/2001 as amended. Upon specific conditions, this requirement can be derogated according to Annex IV of Regulation (EC) No 999/2001 as amended. The derogation has to be granted by the competent authority.

Other feeding stuffs including minerals may be stored in the same shed but they must be kept physically separated.

ii. Maintenance and cleaning

Food and feed materials infested or attacked by mould, residues from the bottom of bins that have not been cleaned, insects or mould proliferating in premises where dust has accumulated due to poor cleaning or the inability to clean due to the design of the premises, are all sources of contamination. This is also the case with foreign bodies such as pieces of metal or glass fragments or building materials from ceilings, storage bins or equipment above food and feed materials.

It is important to ensure that:

- Routine preventative maintenance is applied in the premises (roofing, storage bins) to prevent the presence of foreign bodies (pieces of metal, glass, concrete).
- At least once a year or every time the bin or warehouse becomes empty, the handling premises and galleries are cleaned to limit the accumulation of dust which favours the development of mould and attracts insects, rodents and birds. Particularly in areas where dust hides marks present on the floor, clean the premises so that the marks always remain visible.
- The storage facilities (bins, compartments, etc.) are cleaned and, if needed, disinfected, particularly if the previous goods stored were contaminated (insects, mould, bacteriological contamination such as salmonellas, etc.).
- A cleaning plan is defined (who, what, when, how, recording) and the cleaning and disinfecting effectiveness verified.
- Cleaning and disinfecting agents shall be food and feed grade and used only in compliance with existing legislation and/or manufacturers' instructions for use.

iii. Ventilation and inter-bin transfer

The absence of or poor inter-bin transfer or ventilation conditions can lead to the proliferation of insects or development of mould, which are sources of contamination.

✓ Ventilation

Ventilation consists of sending a mass of air at least equivalent to the mass of food and feed materials in a volume.

This operation removes heat and helps obtain a mass of food and feed materials that are in balance with the air temperature. Ventilation optimization largely depends on the operator's know-how. Ventilation is important also for removing humidity in order to prevent condensation, thus preventing microbial growth such as moulds or salmonella. Inter-bin transfer is a way of ventilating the commodity.

It is important to ensure that:

- Food and feed materials are quickly cooled to avoid sweating and heating and thus not attracting insects.

- Food and feed materials are ventilated with air that is cooler than food and feed materials. A minimum temperature difference of 5°C (to be adjusted according to the external temperature and the ventilation equipment) is recommended. These conditions can be ensured by using a thermostat.
- The removal of hot air is facilitated to prevent dew points from forming. This could be achieved by means of ventilation shafts, skylights or extractors for example.

✓ Drying

Two types of drying can be distinguished: direct and indirect drying. Direct drying refers to all drying processes during which the flue gas of an air heater has contact with the product that must be dried during the drying process. Indirect drying refers to all drying processes during which no flue gas has contact with the product that must be dried during the drying process. It is advisable to avoid piling or heaping high-moisture, freshly harvested commodities for more than a few hours prior to drying or threshing to lessen the risk of fungal growth. If it is not possible to dry the commodities immediately, aerate them by a forced air circulation. When necessary, pre-cleaning before drying can be carried out.

Risk of microbiological development (such as for example salmonella) can occur during the storage of materials that have an inadequate moisture level, therefore special attention should be given.

Sorting and washing methods can be utilized to clean the grain. However, it is important that the grain is not damaged during the procedure and that it is dried thoroughly if washing is used. Freshly harvested cereals should be dried immediately in such manner that damage to the grain is minimized and moisture levels are lower than those needed for fungal growth during storage.

Drying could be considered as a CCP or as a prerequisite program depending on the risk analysis of the company. Drying aims to reduce the food and feed materials' water content and prepare them for subsequent good storage. The drying activity is therefore an important stage in maintaining the food and feed materials' hygiene quality at the storers. However, during the storage stage, storage mould and mycotoxins can develop from sound food and feed materials due to a practice fault, poor insulation or a condensation phenomenon. According to the decision diagram, the drying stage is therefore the last stage at which the risk of mould and storage mycotoxins development can be controlled.

Direct drying can lead to the presence of dioxins, PCB or PAH if not-well controlled (no control of heating, inappropriate fuels). This risk should be taken into account when deciding whether drying has to be a CCP or not.

✓ Inter-bin transfer

Inter-bin transfer aerates food and feed materials by allowing the pile of food and feed materials to come into contact with the air (thermal evacuation is therefore very local and limited). It also aerates food and feed materials in which air can no longer flow and favours the dissipation of heat.

If there is no means of ventilation, it is important to ensure that the food and feed materials are transferred between bins to ensure the products preservation, until their temperature has achieved the appropriate level.

✓ Food and feed materials aeration

In the case of food and feed materials of vegetable origin and products derived thereof, which are stored in horizontal warehouses, to open corridors in the heap of cargo with a bulldozer increases the surface of contact of the goods with the air which in turn results in lowering the temperature of the goods.

iv. Pest control

The accumulation of dust or infested food and feed materials favours the proliferation of insects and attracts rodents in the galleries, contaminating the food and feed materials stored in the bins nearby.

It is important to ensure that:

- Domestic animals as well as birds are excluded from the premises.
- A rodent control plan is implemented. The bait must be checked and replaced regularly. For further information please refer to the biocide Regulation (EU) No 528/2012 as amended. 35 days is considered an appropriate time period to clear up rodent infestation. Primarily baits should not be used continuously. The use of services of an external company for pest control is highly recommended.
- The storage and handling premises and galleries are cleaned and treated with pesticide, especially controlling all points where dust and food and feed materials can stagnate, where required.
- Residue levels and compliance with legislation are primarily demonstrated by records of correct usage of pesticides. This should be verified by random sampling according to a schedule. Records of this must be kept for future reference.
- The food and feed materials are protected against insects by using all measures available at the site (cleaning, storage control, ventilation, fumigation, rational use of storage pesticides etc.).

c. Storing samples

It is important to ensure that:

- The samples are stored in a place appropriate to the storage duration.
- These places are kept clean and protected from pests by cleaning them, treating them with pesticide and organizing a pest control plan.

Premises: examples of controls and records

- Control the cleanliness (visibility of dust crosses) and tidiness of the premises.
- Control the presence of insects and pests (visual controls during transfers, odour, control of birdlime boards or dead animal count etc.).
- Monitor the consumption of pesticide products, rat poison etc.
- Keep a record of the maintenance, cleaning, pesticide treatment and rodent control operations carried out in the premises.
- Keep a record of any noted anomalies (leaks etc.) and ensure a plan is made for their repair.

2. The pits, handling and sorting equipment

The foreign bodies generated by a lack of maintenance and the presence of pests due to a lack of cleaning and/or pesticide treatment are sources of contamination.

It is important to ensure that:

- When new equipment is being purchased or designed, it should be made accessible to make cleaning and maintenance easier and prevent the creation of conditions favourable to the appearance or development of hazards (insects, mould).
- The equipment is periodically cleaned, particularly before the storage of cereals and other food and feed materials (pits, dryers). Treatments are made according to Plant Protection Products manufacturers instructions so that residues do not exceed authorised levels. Where applicable and based on Risk analysis and/or monitoring plans, the residue level may be validated after the cleaning.

- Preventive maintenance is carried out on the equipment by lubrication with agents of appropriate grade to prevent breakages which could cause foreign bodies.
- The pits are protected against bad weather and run-off, rodents and birds, for example by covering the pits situated outside the buildings after use or closing the pits' shutters.
- In the case of an initially contaminated circuit, it is treated and/or cleaned if necessary before sound food and feed materials are transited to prevent it from becoming contaminated.
- The sensitive points (pits, elevator bases) are treated with pesticide if necessary. The pesticide treatment appliances are regularly monitored and preventive maintenance is carried out. An appropriate pesticide treatment appliance is used to prevent siphoning (unintentional product drainage).
- The presence of foreign bodies from equipment is combated by fixing grids onto the receipt pits, tidying away the equipment after it has been used and cleaning the food and feed materials if there is any doubt as to the presence of foreign bodies.

Examples of equipment which aims to improve food and feed safety

Equipment	Hazards controlled
Grids on pits	Foreign bodies and pests of a size larger than the grid holes
Cleaner	Foreign bodies, microbial load, mycotoxins
Pesticide treatment appliance	Insects

Equipment: examples of controls and records

- Preventive – curative maintenance book.
- Preventive maintenance plan for sensitive equipment.
- Record of equipment maintenance and cleaning.
- Record of the product used for the pesticide treatment.

3. Traceability

The storekeepers must be able to identify from whom they have received the goods and to whom they have delivered them. For this purpose, storekeepers are to establish a system of documentation recording any intake, outtake and internal movement of goods.

It therefore has to be assured that the goods can be traced back from delivery to reception (one step back, one step forward). This information must be made available to the competent authority upon their request.

4. Waste

Waste, as per its definition in Directive 2008/98/EC and in Directive 2000/59/EC, can be a source of contamination or attraction and proliferation of insects and rodents, which carry diseases. Whenever applicable, existing national transposition rules and definitions shall be complied with.

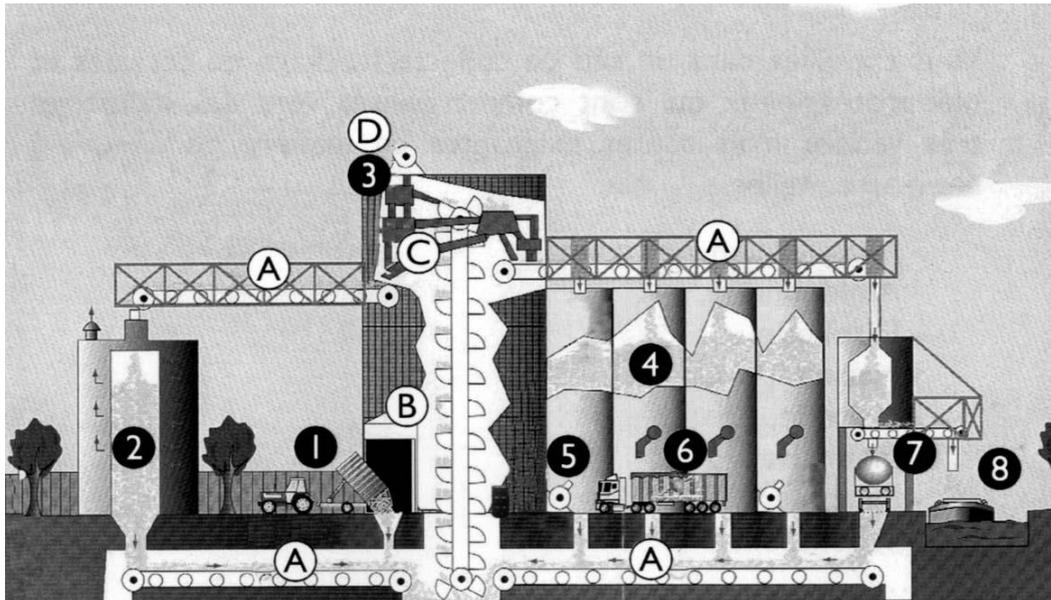
It is also important to ensure that:

- The waste (boxes, packaging, scrap iron) storage area is located in a place that is separate from the storage facilities.
- Closed and covered waste containers are provided.
- Waste collection is scheduled with appropriate frequency.

Residues from maintenance work, such as pieces of metal, due to the bin being insufficiently protected during the maintenance team's intervention are contaminants. These should be regularly cleared and the site should be cleaned once the maintenance operation is complete.

Example plan of a grain silo

"West Indies Illustration"



Stages of the grain's progress:

1. Receipt
2. Drying
3. Cleaning and separation
4. Storage bin before dispatch
5. Ventilation of food and feed materials
6. Dispatch by lorry
7. Dispatch by train
8. Dispatch by barge

Mechanics of the silo:

- A. Belt or chain conveyors
- B. Bucket elevators
- C. Dust suction system
- D. Vacuum equipment with air outlet

Chapter IV bis

Good hygiene practices recommendations for terminal handling operations for unprocessed/processed products

This chapter covers good hygiene practices specific to terminal operators and portside storekeepers that receive, store and deliver agri-bulk commodities on behalf of their owner. General good hygiene practices laid down in chapter I are applicable to all type of operators covered by this Guide, including terminal operators. As terminal operators are not the owner of the goods, they are neither involved in the buying/selling contracts, nor in the placing on the market of the goods.

1. The premises

The good practices laid down in chapter IV § 1 also applies to terminal operators carrying out storage operations.

2. Receipt of goods

Crop deliveries may be performed either by road (trucks), rail (trains) and/or waterway (barges, ships, vessels).

Irrespective of the type of deliveries, the terminal operator must ensure that adequate cleaning (see definition in introduction of the Guide) is carried out prior to loading to prevent the presence of foreign bodies or impurities in the transport means (where this is under his remit or control).

All goods from different suppliers but of same type, origin and safety status may be commingled in appropriate cells and/or batches upon receipt at the silos premises, unless otherwise contracted with the cargo owners.

a. Deliveries at import and inland terminals

At import and inland terminals, batches have been previously defined at loading port, so the case is that homogeneous batches are received and distributed among many different receivers most of the time.

b. Deliveries at export terminals

While constituting homogenous batches by co-mingling incoming deliveries, it is the terminal operators' responsibility to consider not only contractual quality criteria but legal food and feed safety requirements as well.

Sampling points have to be at a point where the incremental samples drawn are representative of the goods delivered/unloaded. Incremental samples shall be drawn uniformly and systematically, concurrently with unloading, from various parts of the truck, wagon or vessels hold.

If for any reason they cannot be drawn from trucks, wagons or vessels hold, incremental samples shall be drawn during delivery/unloading, at the nearest practicable safe point to the hold, preferably from a moving stream throughout unloading.

Analysis of these samples will be performed either at stage if professional analysis equipment is available or through professional laboratories. The analysis results will be recorded and held at the disposal of official authorities upon request.

3. Control at receipt

Before arrival of the goods at the terminal, the terminal is to be informed by the cargo owner about the description and characteristics which are necessary for the terminal, particularly when the

goods are to be taken into storage for a longer period and when the goods do not comply with the principle of sound and non-dangerous.

Aspects which influence a safe working area for the operatives in and around the compartments should also be part of the information flow to the terminal, for instance in case of fumigation of the goods, during transport of before, is to be informed, including the fumigant used.

Upon arrival of the goods at the terminal a visual condition check is carried out by the terminal before the goods physically enter the terminal.

The visual condition check enhances the following aspects:

- Conformity of the goods with the pre-advised description (to be seen in the light of – when soya meal is agreed; is it meal and not pellets, nor corn meal).
- Colour.
- Physical form.
- Odour.
- Possible contamination by insects, dirt or other items which do not belong to the product.
- Temperature.
- Moisture resulting in damp/mould.

Should the terminal operator have doubts on the condition of the goods, he shall be entitled to take the appropriate necessary measures.

4. Traceability, product monitoring and notification

The terminal operators must be able to identify from whom they have received the goods and to whom they have delivered them. For this purpose, storekeepers are to establish a system of documentation recording any intake, outtake and internal movement of goods.

It therefore has to be assured that the goods can be traced back from delivery to reception (one step back, one step forward). This information must be made available to the competent authority upon their request.

In general, the transport means do not fall under the responsibility of the storekeeper. Nevertheless, this latter has the right to refuse the loading/dispatching of the goods into/from a compartment in apparent bad condition.

The terminal operator has the duty to provide storage facilities in such a way that the integrity of the goods is maintained. Regular organoleptic checks are performed with due diligence by the storekeeper to ensure that the characteristics of the goods are not altered. The owner shall be informed about any change in characteristics of the goods affecting their food and feed safety. If the goods are damaged in the course of handling/storage, the owner of the goods will also be informed without delay.

The owner of the goods must inform authorities in the event of any urgency related to the food and feed safety of the goods, who will be responsible for initiating the withdrawal or recall procedure. The storekeeper may provide its assistance and cooperation, if relevant and appropriate.

5. Waste

In addition to good practices laid down in chapter IV § 4, terminals have port reception facilities for the reception of ship-generated waste and cargo residues are in place at distance of storage areas. Waste reception and handling plans are developed at port terminals.

Chapter V

Good hygiene practice recommendations for dispatch / delivery and transport operations

Food and/or feed materials are transported by road, river, rail or sea. Goods must be transported in compliance with the regulations specific to transport, particularly the provisions relating to food and feed safety. Whatever means of transport is used; the transport contractor and the transporter are responsible for ensuring the equipment conforms to food and feed safety requirements.

The presence of foreign bodies, impurities or residues in the containers (due to insufficient cleaning or other bad practices) is a source of contamination.

1. General rules (applying to all kinds of transport)

Food and Feed business operators shall notify the appropriate competent authority of any establishments under their control, active in transport as laid down by Regulation (EC) No 183/2005 as amended and Regulation (EC) No 852/2004 as amended.

As a reminder, Regulation (EC) No 852/2004 as amended indicates in its annex II - Chapter IV transport:

- Point 4 states: “Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked “for foodstuffs only”. Point 5 states: “Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.” As regards the transport of liquid oils and fats by sea, reference should be made to Commission Regulation (EU) No 579/2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council.
- Point 6 states: Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimize the risk of contamination.
- The entry into force on this Regulation is part of the scope of application of the Regulation (EC) No 178/2002 as amended which defines the responsibility in regards of safety of all the operators of the Food and Feed supply chain.

In addition, Regulation (EC) No 183/2005 as amended (FEED hygiene) indicates in its Annex II – Chapter “Facilities & Equipment” and “Storage & transport”):

- Chapter “facilities and Equipment” in Art 1 of Annex II states that “Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented”
- Chapter “Storage and Transport” of Annex II states that “:
 - Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any cross-contamination of the processed feed; proper packaging materials shall be used.
 - Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operators have access.
 - Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or cross-contamination and to prevent deterioration.
 - Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.
 - Any spoilage shall be minimised and kept under control to reduce pest invasion.

- Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.”

Food and feed safety must be maintained at all times during transport. It is necessary to prevent any contamination caused by undesirable substances and products. Mixing with other products must also be avoided.

It must be ensured that the operation is not performed outside during inclement weather conditions and that rain and spray cannot enter the container during transport.

The sender of the goods keeps the references of the means of transport used for each batch that is dispatched (e.g. registration numbers of the trailers, wagon numbers, names of the canal boats, barges, ships etc.).

Before the loading compartments are loaded they must be inspected by staff authorised by the operator, the owner or the receiver of the goods (e.g. the truck driver in case of self-service truck stations). An inspection of the loading compartment will be carried out to establish that the loading compartment(s):

- Are clean, dry, odourless and correctly maintained.
- Are compatible with the loading and transport of the specific products.
- Are suited to the transport required and form a closed whole.
- Do not contain pests and rodents in the widest sense of the term.
- Do not contain residues or remains from previous loads and/or from cleaning products.

The transport compartment must sufficiently protect the products being transported from the influence of other products transported at the same time when or where this occurs. Appropriate means must be taken to prevent any harmful influence from other products that could arise during loading and transport. This must include consideration of other operations when transporting within a port complex.

Compartments that have been used to transport products regarded as “high-risk” during the previous load must undergo a risk analysis and may be refused. Depending on the previous load, cleaning / disinfection / requalification rules for the containers are defined in Appendix 9.

Bulk products must be transported in accordance with the requirements detailed in Appendix 9 “Transport” of this Guide or equivalent guidelines.

For transports chartered by the operator from external transporters, the transport contracts will refer to the specifications the operator must enforce with its transport service providers. These specifications set out the obligations of the external transporter, particularly with regard to:

- The rules for successions of loads (see Appendix 9).
- The availability, for each piece of equipment, of chronological records or documents allowing the previous transport type to be traced.
- Compliance with hygiene rules and the use of appropriate means to keep the equipment thoroughly clean and free from any risk of contamination.
- The need to inform and train the drivers and maintenance staff of the transport equipment on how to comply with these rules.
- The need to include compliance with these obligations in the service provider’s own contracts if any work is sub-contracted.

The operator informs his silo staff of the food and feed safety risks linked to the transport operations.

Any control applied must be validated to ensure they are effective. For example, this means demonstrating, randomly, by analytical or other means that a statement made about a control is true and the control works as intended. Records of this must be kept for future reference.

If a company uses a sub-contractor for its transport activities, the sub-contractor has to be registered as a food or feed business operator and has to respect the Regulation (EC) No 852/2004 as amended for food and Regulation (EC) No 1831/2003 as amended for feed.

Regulation (EC) No 852/2004 as amended implies that transport of liquid food, such as vegetable oils & fats, should be done using dedicated tank cars, rail tanks and barges.

Regulation (EC) No 225/2012 as amended also implies some specific requirements for the storage and transport of oils, fats and products derived thereof to be used as feed.

Containers which are to serve for storage or transport of blended fats, oils of vegetable origin or products derived thereof intended for use in feed shall not be used for the transport or storage of products other than these unless the products comply with the requirements of:

- This Regulation (EC) No 225/2012 as amended or of Article 4(2) of Regulation (EC) No 852/2004 as amended, and
- Annex I to Directive 2002/32/EC.

They shall be kept separate from any other cargo where there is a risk of contamination.

Where this separate use is not possible, the containers shall be efficiently cleaned so as to remove any trace of product if those containers were previously used for products not meeting the requirements of:

- This Regulation (EC) No 225/2012 as amended or of Article 4(2) of Regulation (EC) No 852/2004 as amended, and
- Annex I to Directive 2002/32/EC.

The operator should take special care, when transporting by sea or coaster, edible oils, in bulk to verify and ensure that the immediate previous cargoes fully complies with the requirements in Commission Regulation (EU) No 579/2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea; the lists as established by the Commission Directive 96/3/EC, as amended by Directive No 2004/4/EC on the hygiene of foodstuffs as regards the transport of bulk liquids oils and fats by sea and its list of accepted immediate previous cargoes.

When storing and transporting food and feed liquids materials in bulk, the operators should take particular attention to the following, non-exhaustive, list of potential hazards:

- Toxins from pest control materials.
- Contamination by the previous cargo residues or remains during storage, handling, and transport (special care to be taken on cleaning of pumps, pipes and hoses) or by cross contamination with other products transported/stored/handled.
- Contamination by residues of cleaning agents (need to use feed or food grade approved cleaning agents).
- Contamination by leakage of THF (Thermal Heating or cooling Fluids) from equipment's (stainless steel tanks are preferable) or by hydraulic oils from portable pumps.
- Contamination by tank's coating or solvents.
- Foreign bodies.
- Adulteration with mineral oils.

2. Road transport

Road transport can be done by the operator on its own behalf or by external transport companies which have a food and feed safety system in force.

For all road transports, the driver must be able to present the logbook stating the last previous loads and, if relevant, any cleaning operations that have been carried out.

Road transport must be done in accordance with the following requirements:

- Before loading the products, all visible residues from the previous loads must be cleared from inside and outside of the vehicle, including the chassis.
- In order to facilitate traceability, loads must be accompanied by supporting paperwork.
- The documents used to check the transport's compliance with the specified requirements (previous loads, cleaning etc.) are recorded and stored by the operator. The operator defines the storage duration for these documents in line with its outlets.
- If tarpaulin covers are used they must be clean and watertight.
- When undertaking store to vessel transfers inspection of this equipment may be done at the start of the operation or when changing commodities.

a) Transport carried out by the operator

- Before use, check the trucks for cleanliness and clean them if necessary.
- Visually check that there are no hydraulic fluid or fuel leaks.
- Check the nature of the last load and clean the truck if necessary, in accordance with Appendix 9 of this guide.
- For each truck/trailer, record and store the history of the loads and cleaning operations.
- Drivers should be trained in the safe handling of the food and feed. Training should include the necessary cleaning operations for their vehicle according to the products transported.

b) Transport carried out by external companies

- If the operator charters the transport, draw up specifications with the transport service providers. These specifications include requirements relating to the cleanliness of the receptacle, recording of the previous transport and management of transport incompatibilities, in accordance with Appendix 9 of this guide or equivalent guidelines.
- In all cases, before any loading takes place, check the condition of the truck in accordance with paragraph 1 of this section. Visually check that there are no hydraulic fluid or fuel leaks. Ask the transporter to clean the vehicle if necessary. Record any requests for corrective actions.
- The history of the loads and cleaning operations must, for each container, be recorded and stored by the transporter who must keep them available to the contractor.

According to feed hygiene regulation companies transporting feed for other feed business operators need to be registered as well.

3. Transport by sea and waterways

Boat men must be able to present a logbook listing their successive journeys, where possible (type of goods, type of cleaning carried out and on what date).

The cargo hold, hatch covers and loading hatches of the vessels used to transport food and feed materials must be clean, watertight, dry, odourless, and in maintenance well maintained condition. They must also be suitable for the cargo for which they have been chartered.

For trains, the equipment provided is specialised, that is, exclusively intended for transporting raw agricultural products (cereals, oilseeds pulses, other plant products and their derived products thereof). The hoppers inside the wagons used to transport food and feed materials must be clean, watertight, dry, odourless, and in a well maintained condition. This equipment is suited to the required transport and able to protect the goods effectively.

Before loading the products, operators using a ship or wagon approved for transporting their products must be told what the previous load was by the transporter.

When products are transported by sea, waterway or rail under the operator's responsibility, the loading compartment must be inspected or a certificate of cleanliness must be issued for the compartment, along with a description of the previous load, before loading can begin. Food and feed safety must be preserved at all times during the loading operation.

The compartment is inspected or the cleanliness certificate is issued by:

- A recognised inspection company operating in accordance with recognised international standards, who may be working for the owner or end receiver of the goods, or
- A qualified person (freight forwarder) who is recognised as a qualified loading inspector, or
- The operator's qualified staff in the event of loading entrusted directly to the operator alone or in the absence of an appointed inspector during loading.

This conformity inspection operation is recorded. If the inspection is carried out by an inspection company or a qualified inspector, the results of the Loading Compartment Inspection and the previous load must be recorded in writing in the inspection report (LCI = Load Compartment Inspection) and any cleaning /washing/disinfection operations carried out according to the type of products transported should if possible be communicated to the shipper or to the inspectors in the charter contract, in the LCI or on any contractual document approved by the parties.

The ship chartering operators must ensure that details of the last load and any cleaning / washing / disinfection operations carried out are provided in the chartering contract or any other contractual document approved by the parties.

Any anomalies noted must be recorded. Appropriate corrective actions must be requested (disinfection, pesticide treatment, replacement etc.) and recorded.

4. Transport by rail

Railway companies use a lot of different railcars. Normally, the railway companies use wagons for agri-commodities only. In this case, they must build up a system which allows them to verify the last loads of each wagon.

If the railway company has not such system in place, the train driver must be able to present a logbook for each wagon listing their successive journey (type of goods, type of cleaning carried out and on what date).

The wagon/railcar must be fit for use to transport food and feed materials. It must be clean, watertight, dry and odourless and maintained in good condition. Before loading, a load compartment inspection has to be carried out in order to verify that it is clean.

The compartment must be inspected by:

- A recognised inspection company operating in accordance with recognised international standards, who may be working for the owner or end receiver of the goods, or
- A qualified person (freight forwarder) who is recognised as a qualified loading inspector, or
- The operator's qualified staff.

The conformity inspection carried out must be recorded.

SECTION II

APPLICATION OF THE H.A.C.C.P. SYSTEM (HAZARD ANALYSIS, CRITICAL CONTROL POINTS)

Chapter I *Presentation of the study*

The second section of this guide deals with establishing a control and monitoring system for the food and feed risks specific to the collection, storage, trade and transport of cereals, oilseeds and protein crops by applying the principles of the H.A.C.C.P. method. (Refer to Appendix 1 on the H.A.C.C.P. method).

The study presented in the remainder of the guide constitutes an adaptable basis for implementing the H.A.C.C.P. method as a given operator. It constitutes reflection material, a reference for collection/storage organizations. Each operator must adapt it to its own organization and markets. For optimum effectiveness, a working group should be created and a hazard analysis carried out by the operators.

The scope of the study concerns the collection, storage, trading and transport of cereals, oilseeds and protein crops, from receipt through to dispatch. The chemical, biological and physical hazards dealt with are specific to the collection/storage task. Only hazards that could affect the consumer's safety are addressed in this study.

In relation to each of the stages as described in Appendix 3 (receipt, pre-storage, storage, pesticide treatment, preparation relevant to the contractual requirements, dispatch delivery) specific types of control are foreseen based on adequate risk analysis and sampling/monitoring plans.

Chapter II *Content of the study*

1. Creating the H.A.C.C.P. team

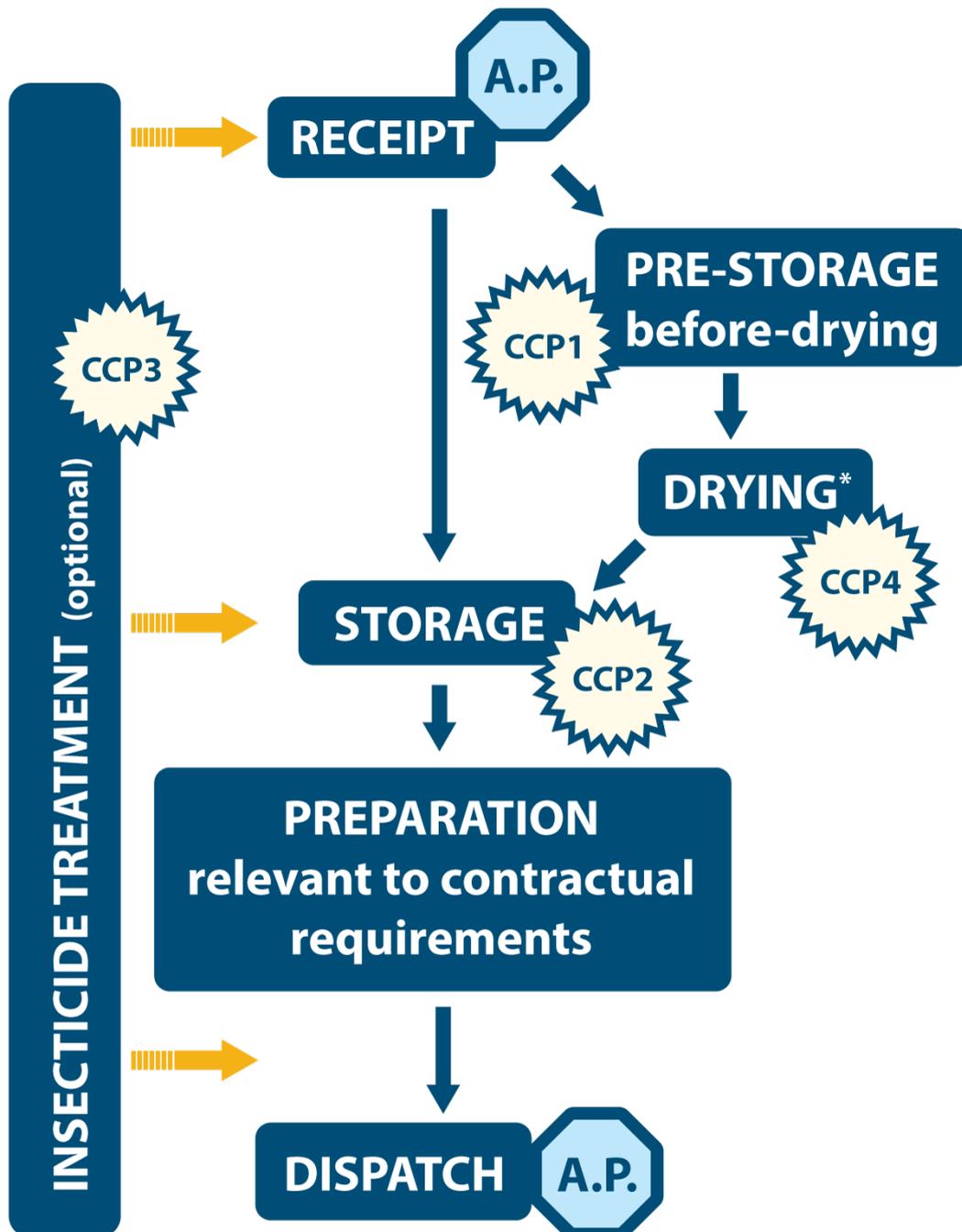
The H.A.C.C.P. analysis is the result of work carried out by a team with multi-disciplinary skills with the support of experts in the scientific, technical and regulatory domains. Refer to the Acknowledgements page in the introduction to this guide.

2. and 3. Describing the product and identifying the intended use of the product

The working group has described different product categories. Refer to the product fact sheets in Appendix 2.

4. Drawing up a diagram of the stages (an example for unprocessed “grains”)

There are seven stages in the collection/storage of cereals, oilseeds and protein crops, which follow on from one another as shown below. For products derived from the first processing of cereals, oilseeds, protein crops or other plants products, the methodology remains identical except that traders will receive processed products in bulk, or liquid (such as vegetable oils or ethanol for example) and in such case some steps are not concerned.



*Drying is optional depending on the drying equipment and energy use.
A.P. = Attention Point

- Cleaning is carried out, where necessary, during the drying, storage and preparation stages according to contractual requirements.
- Between each stage, handling operations are carried out. These handling operations can also take place during an inter-bin transfer.
- Inter-bin transfers are carried out if necessary to optimize the storage plan or facilitate an intervention on the stored food and feed materials (aeration).

Refer to the description of the stages in **Appendix 3**.

5. Checking the operations diagram on site

The diagram above is an example of "standard diagram" created for conducting the hazard analysis and determining the ensuing critical points. The order and number of stages may vary from one site to the next and also depending on whether the products are "grains" or derived from the primary processing of the "grains".

6. Carrying out the hazard analysis

6.1 List of the hazards

The potential main foreseeable hazards which could arise during the collection and storage of cereals, protein crops and oilseeds are the following:

Nature of the hazard	Example of hazard
BIOLOGICAL OR MICRO-BIOLOGICAL	<p>Flora:</p> <ul style="list-style-type: none"> - Mould, bunt, <i>Bacillus cereus</i>, salmonella <p>Pests:</p> <ul style="list-style-type: none"> - Insects from cereals and oilseeds, fowl, rodents <p>Ergot</p> <p>Toxic seeds – Harmful botanical impurities</p> <ul style="list-style-type: none"> - <i>Ricinus communis</i> L. (Castor Oil plant); <i>Jatropha curcas</i> L. (Purghera, Physic nut); <i>Croton tiglium</i> L. (Croton); <i>Crotalaria</i> spp.; <i>Camelina sativa</i>(L.) Crantz. (false flax, linseed dodder, gold-of-pleasure); Mustard seeds; <i>Madhuca longifolia</i>(L.) Machr. (Mahua, Mowrah, Bassia, Madhuca and many others); <i>Prunus armeniaca</i> (Apricot) and <i>Prunus dulcis</i> var <i>amara</i> (Bitter almond); <i>Fagus silvatica</i>- unhusked beech mast; Weed seeds and unground and uncrushed fruits; Ambrosia; <p>Inherent plant toxins - Hydrocyanic acid; Free gossypol; Theobromine; Glucosinolates. The products shall be free from the following toxic or noxious seeds in amounts which may represent a hazard to human health.</p> <ul style="list-style-type: none"> • <i>Crotalaria</i> spp (Crotalaria), • <i>Agrostemma githago</i> L (Corn cockle), • <i>Ricinus communis</i> L.(Castor bean) • <i>Datura</i> spp (Jimson weed), • and other seeds that are commonly recognized as harmful to health <p>Mycotoxins (resulting from the growth of certain moulds):</p> <ul style="list-style-type: none"> - Ochratoxin A, trichotecenes (including DON and T₂ / HT₂), zearalenone, fumonisin, aflatoxins.
CHEMICAL	<p>Pesticide residues:</p> <ul style="list-style-type: none"> - Storage pesticides <p>Heavy metals:</p> <ul style="list-style-type: none"> - Cadmium, lead, mercury, arsenic

	Treated seeds Melamine (fraud) Radionucleids (nuclear plant accident or spillage) Dioxins & Furans, DL PCBs and Non BL-PCBs
PHYSICAL	Foreign bodies: - Broken bulbs, bits of gravel, pieces of metal, transport residues etc.
ALLERGENS	Allergenic products (as per Annex II of Regulation (EU) No 1169/2011 as amended): - Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut or their hybrid strains) - Soybeans and products thereof , nuts

6.2. Hazard analysis

- *Description of the hazards*

To assess the hazards in cereals, protein crops and oilseeds during the different stages of the silo diagram, we have created hazard fact sheets which can be found in Appendix 4. These sheets give a general description of the hazard, specify the origin, the conditions favourable to its persistence, proliferation or elimination and provide a reminder of the current regulations and recommendations.

- *List of the causes of the hazards*

At each stage in the operations diagram, the causes of the potential hazards are identified using the "5 Ms method". This method is extremely thorough and therefore means that no potential cause of a hazard is omitted. See below the example applied to the storage of cereals, oilseeds and protein crops:

The 5 Ms method:

Material	Cereals, oilseeds or protein crops
Environment	Atmosphere, surrounding areas
Labour	Hygiene
Method	Operating method
Equipment	Installations, transport equipment

- *Evaluating the risk relating to each hazard*

The **hazards are then prioritized** for each cause, based on:

- Severity (G) which corresponds to the consequences of the hazard on the consumer's food and feed safety,
- Frequency (F) of the hazard's appearance,
- And the likelihood of the hazard not being detected (D).

These indices are quantified using a scale of 1 to 4, based on current technical and scientific experiments. The H.A.C.C.P. study also takes into consideration the impact of the agricultural raw materials and the role played by the storage processes. The product's final destination and the data from monitoring plans are also considered.

	Severity (G)	Frequency (F)	Detection (D)
1	minor severity	practically non-existent	hazard that can always be detected
2	medium severity	possible	hazard that is detected most of the time

3	critical severity	current	hazard that is difficult to detect
4	catastrophic severity	certain	non-obvious hazard

Refer to the assessment scales used for the study of this guide in Appendix 5.

As part of the hazard analysis, to quantify the severity index, contamination, survival and multiplication factors are also taken into account if necessary.

By multiplying the marks allocated for severity, frequency and the likelihood of not being detected, a risk index $R = G * F * D$ is obtained.

R gives an indication of the significance of the risk: **the hazards for which R is high (greater than or equal to 24) and/or the severity G is equal to or greater than 3** are dealt with as a priority.

Refer to the H.A.C.C.P. plan in the following pages and the hazard analysis tables in Appendix 6.

- *Determining the preventive control measures*

Preventive control measures were defined for each cause of an identified hazard: refer to the H.A.C.C.P. plans on the following pages and the hazard analysis tables in Appendix 5.

7. Determining the critical points for controlling the hazards: the C.C.P.s

The stages constituting potential CCPs were identified using the Codex decision tree (below) when its application was relevant and the risk index was significantly high ($R \geq 24$ and/or $G \geq 3$).

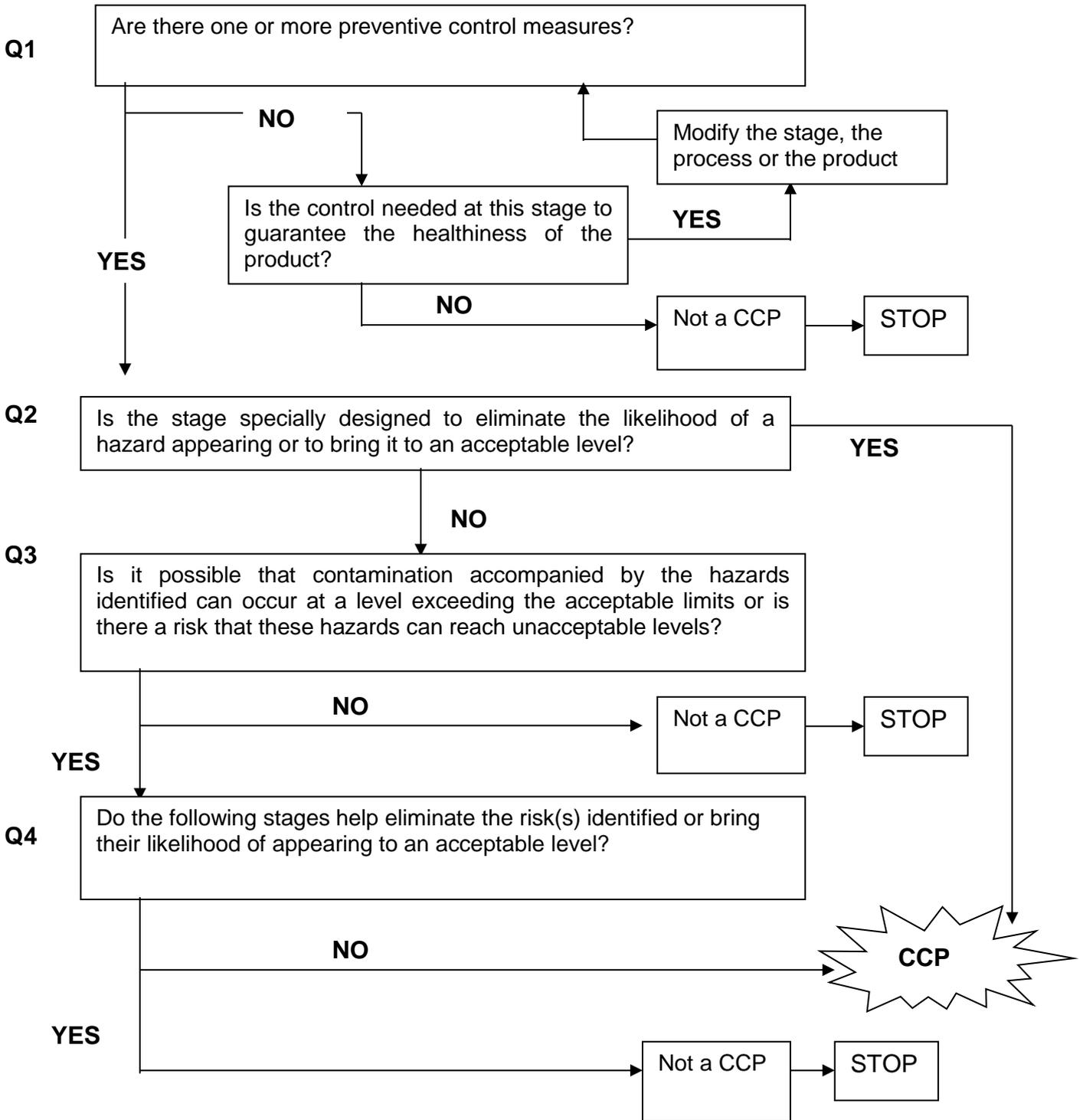
3 C.C.P.s were identified in the example diagram of §4:

	BIOLOGICAL OR MICRO-BIOLOGICAL		CHEMICAL
	Mycotoxins		Storage pesticides residues
	Field	Storage	
Receipt	(Attention point ⁷)	(Attention point)	
Pre-storage	CCP1	CCP1	
Drying			CCP4 <i>Risks Dioxins & PCBs & PAH</i>
Storage		CCP2	
Pesticide treatment			CCP3 <i>Storage pesticides residues</i>
Preparation relevant to the contractual requirements			
Dispatch - delivery	(Attention point)	(Attention point)	

⁷ The absence of a continuous (or quick result) method for monitoring the batches at receipt and dispatch does not allow these stages to be classified as CCP for field and storage mycotoxins.

Figure 1: Determining the critical control points (CCP)

Example of a decision tree for determining the CCPs (answer the questions in order)



Example of answers according to the decision tree: CCP 3

Q1: At the pesticide treatment stage, are there one or more preventive measures?

YES



Q2: Is the pesticide treatment stage specially designed to eliminate the likelihood of pesticide residues appearing or to bring it to an acceptable level?

NO



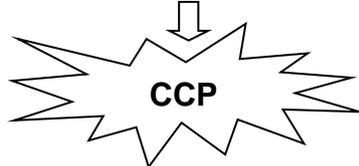
Q3: Is it possible that contamination accompanied by pesticide residues can occur at a level exceeding the acceptable limits or is there a risk that the quantity of residues can reach unacceptable levels?

YES



Q4: Do the following stages help eliminate the risk(s) identified or bring their likelihood of appearing to an acceptable level?

NO



Example of answers according to the decision tree: case of drying

Q1: At the drying stage, are there one or more preventive measures?

YES



Q2: Is the drying stage specially designed to eliminate the likelihood of storage mycotoxins appearing or to bring it to an acceptable level?

NO



Q3: Is it possible that production of storage mycotoxins can occur at a level exceeding the acceptable limits or is there a risk that the quantity of storage mycotoxins can reach unacceptable levels?

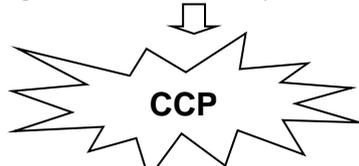
YES



Q4: Do the following stages help eliminate the risk(s) identified or bring their likelihood of appearing to an acceptable level?

NO

(the storage/preservation by ventilation stage)



Drying could be considered as a CCP or as a prerequisite program depending on the risk analysis of the company. Drying aims to reduce the food and feed materials' water content and prepare them for subsequent good storage. The drying activity is therefore an important stage in maintaining the food and feed materials' hygiene quality at the storers. However, during the storage stage, storage mould and mycotoxins can develop from sound food and feed materials due to a practice fault, poor insulation or a condensation phenomenon. According to the decision diagram, the drying stage is therefore the last stage at which the risk of mould and storage mycotoxins development can be controlled.

8. 9. and 10. Establishing the critical limits, a monitoring system and corrective actions for each CCP

For each C.C.P. determined, the working group defined criteria must be measured, critical thresholds, monitoring procedures and corrective measures established. To define them, they called upon the experience of each member of the H.A.C.C.P. team in the domain of the hazards concerned and the scientific and technical information already published. Refer to the H.A.C.C.P. plans on the following pages.

11. and 12. Defining the verification methods and establishing a documentation system

Verification of the H.A.C.C.P. system corresponds to measures for monitoring all elements of the system. It may include a review of the HACCP system (notably on the basis of non-conformities, complaints etc.), the monitoring plan results, and internal audits of the HACCP system, which may be documented as part of the quality system. This verification mainly relies on consulting registers and files provided for this purpose.

Records must be kept of monitoring actions, preventive and corrective measures. By way of illustration, examples of documentation are proposed. Refer to the H.A.C.C.P. plans on the following pages.

HACCP PLAN

Products: cereals, protein crops, oilseeds

Stage: PRE- STORAGE

CCP	Hazard / Causes of the hazard	Risk	Recommended preventive measures	Criteria	Critical thresholds	Monitoring procedures	Corrective measures	Example of HACCP documentation
CCP No.1	<p>Field and storage mycotoxins /</p> <p>Too long storage duration of a contaminated good with a high humidity level and/or high % of broken food and feed materials or level of impurities</p>	G=3 / R=24	<p>Organization of the harvests.</p> <p>Management of the time periods between collection and drying.</p> <p>Rotation of hoppers or pre-storage areas (FIFO – First In First Out principle).</p> <p>Management of the dryers.</p> <p>Raise contractors', farmers' and employees' awareness on the harvest time.</p> <p>Formation of storage mycotoxins are prevented if the product is maintained at an adequate low moisture level.</p>	Time	Variable depending on the goods and level of humidity	Monitoring of pre-storage time	Identification of the batch	Dryer internal management procedure

HACCP PLAN

Products: cereals, protein crops, oilseeds and products derived thereof

Stage: PESTICIDE TREATMENT

CCP	Hazard / Causes of the hazard	Risk	Recommended preventive measures	Criteria	Critical thresholds	Monitoring procedures	Corrective measures	Example of HACCP documentation
CCP No.3	<p><u>Residues from storage pesticides</u></p> <p>Equipment Contamination of the material by a leak in the pesticide treatment equipment.</p> <p>Method (poor regulation of the equipment, food and feed materials flow variation, multiple treatments leading to an overdose, waiting time necessary after treatment and before use of the goods is insufficient). Specific attention should be taken on the risk of cross-contamination of products during handling and storage.</p>	G = 3	<ul style="list-style-type: none"> - Maintenance of the pesticide treatment equipment. Operating method / train staff in pesticide treatment methods and the pesticide choices, servo-control of the elevator's functioning, periodic control of the flow meter. - Increase staff awareness (silo, production, drivers, boat men etc.) on complying with waiting times after treatment of the goods and before their use. 	<p>Quality of the pesticide</p> <p>Quantity of pesticide consumed</p>	<ul style="list-style-type: none"> ▪ Unsuitable product ▪ Approved dose exceeded 	<ul style="list-style-type: none"> • Purchase of authorized pesticide, verification of the pesticide's adequacy before use • Control of the flow meter's functioning and regulation • Monitoring of the pesticide's consumption <p>Control of the last treatment date</p>	<ul style="list-style-type: none"> • Curative maintenance • Isolation of the batch <p>Increase the storage duration before use</p> <p>Information to the customer on the necessary waiting time before use</p>	<ul style="list-style-type: none"> ■ Maintenance report ■ Verification report ■ Treatment records <p>Treatment records</p>

HACCP PLAN

Products: cereals, protein crops, oilseeds and products derived thereof

Stage: **DRYING**

CCP	Hazard / Causes of the hazard	Risk	Recommended preventive measures	Criteria	Critical thresholds	Monitoring procedures	Corrective measures	Example of HACCP documentation
CCP No.4	<ul style="list-style-type: none"> - Residues from Dioxins,PCBs.DL dioxins, NDL PCBs or PAH (Benzo (a) pyrene - Equipment:Leakage of dryer heat exchanger or direct contact of combustion smokes form a “bad fuels” - Other potential sources: leakage of hydraulic liquids 	G = 3	<ul style="list-style-type: none"> - Maintenance drying equipment - Use of adequate “clean” energy sources such as natural gaz 	<p>Inspection of the dryer heat exchanger</p> <p>Quality of the energy sources</p>	<p>Broken heat exchanger or direct use of combustion smoke</p> <p>Avoid using fuels of unknown sources or used motor oils or treated wood</p>	<p>Regular inspection of dryer to detect any leakage</p> <p>Regular testing of energy sources and assessment of suppliers</p> <p>Regular testing of products after drying</p>	<p>Change the dryer or repair immediately broken parts</p> <p>Install heat exchanger if fuel used is not natural gas</p> <p>Change energy sources to a “safe” one”</p>	<ul style="list-style-type: none"> ■ Maintenance report ■ Verification report ■ Analysis of fuel records

Field mycotoxins attention point

Place of appearance	Field	
Key control stage	Receipt/1 st collection point = attention point	
Stage in the process that could affect the level	Cleaning ↓	Pre-storage ↗
Control measures	<p><u>During cultivation</u> Advice/Recommendations during cultivation</p> <ul style="list-style-type: none"> • Varieties • Technical itineraries 	<p><u>During pre-storage</u> Control of the pre-storage duration (CCP1)</p>
	Field survey 5. Anticipation of the risks Allocation on receipt	
Internal checks on receipt	Take a representative sample from each trailer received (or when taken out of the dryer in the case of drying) Obtain a representative sample from each bin and analyse these samples using the risk analysis of the collector.	
Internal checks on dispatch	Take a representative sample from each dispatch and analyse these samples using the risk analysis specific to the operator	

APPENDIX 1

H.A.C.C.P.

(HAZARD ANALYSIS, CRITICAL CONTROL POINTS):

THE METHOD

H.A.C.C.P.

(Hazard Analysis, Critical Control Points): THE METHOD

1. General information and prerequisites

H.A.C.C.P. is a method used to effectively identify the critical points in a process for which control measures are essential to preventing or limiting identified hazards. It is implemented for a given product and process, step by step and hazard by hazard after the systematic assessment of all the stages in the process.

The success of its application relies on the shared will of the management and all of the staff. Another essential prerequisite consists of adhering to the general hygiene rules established for the profession; these good hygiene practices determine the effectiveness of the control measures (refer to the good hygiene practice recommendations section contained in this guide). The measures that have been included in the guide can be integrated into one of the company's management systems (ISO 9000, ISO 14000, ISO 22000 etc.), when it exists, and notably complete the documentation system. It should also be pointed out that the HACCP system, like the management system undergoes amendments aimed at improving the method, in the light of regulatory, standards, technical and scientific developments.

2. The application in 12 stages

2.1. Creating and running the H.A.C.C.P. team

- *Defining the scope of the study:*

Based on the current regulations and potentially a summary of the customers requirements, the management must:

- Identify the hazards to be considered (biological, chemical and physical),
- Determine the places and productions concerned (number of sites, types of production).

- *Creating the H.A.C.C.P. team:*

Create a group of 2 to 8 people who possess the necessary skills and know about the hazards from which the operator wants to protect itself. This team must contain at least one representative of the decision-making power, a coordinator who will guarantee the method and a storage representative, in order to group together all of the necessary skills in the different domains (storage, maintenance, regulations, food and feed safety, hygiene etc.).

- *Planning the initiative:*

Specify the different stages, the managers, the time scales and the dates on which checks will be carried out on the study's progress.

- *Training:*

The operator must train:

- All staff on food and feed safety hazards and good hygiene practices based on this guide.
- The team responsible for the study of the HACCP method in order to successfully complete the project.
- The field staff (silo, maintenance, drivers) on applying the HACCP system.

2.2. Describing the product

Describe the raw materials received and the products marketed (preparation and processing carried out, physicochemical characteristics, food and feed safety characteristics, packaging – packing, storage length, storage conditions).

2.3. Identifying the intended use of the product

Determine the normal methods of use by the end user or the consumer (animal feed, flour trade, starch industry, semolina production, oilseeds-crushing industry etc.), and any particular methods. Identify any high-risk populations (children etc.).

Take into consideration any potential subsequent processing (grinding at the flour mill or semolina factory removes the bran and reduces the microbial or mycotoxin load).

2.4. Drawing up an operations diagram

Accurately describe all of the elementary stages of the diagram. The food and feed safety management parameters of the stage must be stated (temperature, humidity, duration etc.). Traditionally each stage is represented by a rectangle and the stages are linked together by arrows.

2.5. Checking the operations diagram on site

Check that the operations diagram is accurate and complete in practice. The *Codex Alimentarius* stipulates that “the HACCP team must permanently compare the development of the activities with the operations diagram and, where appropriate, modify it”. In practical terms, the HACCP team is present on site and assists in the development of the operations from receipt of the goods from crops or transfers to dispatch or even delivery to the customer. The technique consists of questioning the silo staff with open questions on their daily work: “What are you doing?” “And then?”.

Stages 6 to 12 that follow form the 7 principles of the H.A.C.C.P. method.

2.6. Conducting an analysis of the hazards (Principle 1)

Make a list of all the possible hazards (known or conceivable) by brainstorming and by using the 5 Ms method referring to in this guide, scientific articles or works, customer requests etc.

Only retain real hazards, that is, those likely to significantly affect the consumer’s food and feed safety. For example, a dead insect in a batch of corn is not a significant hazard for the consumer.

List all of the causes of the hazards identified at each stage in the operations diagram.

At each stage, assess the relative risk of each hazard (evaluation of the severity, the frequency of its appearance and the likelihood of it not being detected).

Determine the control measures for the hazards identified.

2.7. Determining the critical points for controlling the hazards: the C.C.P.s (Principle 2)

For each hazard, apply the decision-making tree or logic diagram (refer to page 34, Figure 1 – Determining the critical points) where appropriate.

This is only a tool and is not intended to replace the team’s own expertise or thinking. There are several models. A C.C.P. should control a hazard, prevent it, or bring it to an acceptable level; if this is not the case, it is not a C.C.P. Monitoring actions carried out on the C.C.P.s ensure the control measures are implemented effectively.

For practical reasons, the C.C.P.s should be noted on the operations diagram (refer to the diagram on page 30) and a HACCP plan should be established based on the C.C.P.s identified (refer to section II in chapter 2 of this guide).

2.8. Establishing the critical limits for each C.C.P. (Principle 3)

This involves defining the measures on which the C.C.P.s’ controls will rely. Those most frequently used are: temperature, duration, humidity etc.

For each measure, quantifiable criteria are defined (and therefore critical limits) which separate a “compliant” product from a “non-compliant” product. These criteria ensure that for a given C.C.P. the corresponding control measure is correctly applied. For example, a critical limit may be the authorised pesticide dose.

For safety reasons it is important to also set a target limit or a tolerance zone. A controlled product can be “compliant”, “acceptable” or “non-compliant”.

It may be necessary to determine several quantifiable criteria and therefore several critical limits for a single C.C.P.

2.9. Establishing a monitoring system for each C.C.P. (Principle 4)

The control operations need to be defined to ensure the critical limits are respected and therefore each C.C.P. is controlled. This involves answering the following questions: Who? does What? (which control) Where? When? How often? How?

These control methods can be formalised in the form of instructions or procedures and feature in the H.A.C.C.P. plan.

Keeping a record of these controls provides internal and external proof that the controls have really been carried out.

The controls are limited in their effectiveness by:

- Human capabilities with the risks of errors this can entail,
- The rarity of the hazard's occurrence: a hazard that appears very rarely will be more difficult to detect,
- The resources available: equipment, budget.

The H.A.C.C.P. team must optimise the frequency of the controls by first targeting the C.C.P.s linked to the most significant hazards and risks.

2.10. Establishing the corrective actions for each C.C.P. (Principle 5)

The corrective actions are implemented as soon as a C.C.P. control is lost or absent. They define the future of the non-compliant product and enable the C.C.P. control to be re-established.

2.11. Defining the verification methods (Principle 6)

Establish the methods used to check that the system is working correctly.

- Initial plan of analyses confirming that the hazard is controlled by applying the H.A.C.C.P. system,
- Validation of the initial study by an expert opinion,
- Final control (verification that all of the controls have been carried out),
- Annual plan of analyses,
- Rate of "non-compliant" control results compared to "compliant" results (very interesting in the case of mycotoxin or pesticide analyses),
- Internal or external audit etc.

The management must conduct a review at least once a year to verify the effectiveness of the H.A.C.C.P. system in place.

2.12. Establishing a documentation system (Principle 7)

The documentation system contains:

- The H.A.C.C.P. documents, referring to each of the stages (control plans, procedures, operating methods etc.) forming the HACCP plan,
- The records cited in the HACCP plan.

Generally, all of the documents produced within the context of the HACCP system must be stored and archived (reports of verification actions etc.).

APPENDIX 2

PRODUCT FACT SHEETS

Cereals	Strengths in relation to the hazards studied Principal uses
Oats	<ul style="list-style-type: none"> • Hulled grain (glumes closed on the grain). <i>Use:</i> human food and animal feed
Soft wheat	<i>Use:</i> flour and starch industry, animal feed, malt industry, fermentation/alcohol
Durum wheat	<i>Use:</i> semolina production
Maize	<ul style="list-style-type: none"> ▪ Large sized grain in relation to wheat and barley, which facilitates its ventilation. <i>Use:</i> corn milling, starch industries and animal feed
Feed barley	<ul style="list-style-type: none"> • Hulled grain (glumes that stick to the grain). <i>Use:</i> animal feed
Brewing barley	<ul style="list-style-type: none"> ▪ Hulled grain (glumes that stick to the grain). <i>Use:</i> malt factories
Buckwheat	<ul style="list-style-type: none"> ▪ Black very tough husk. <i>Use:</i> flour industry/human food
Rye	<i>Use:</i> flour industry/human food, animal feed
Sorghum	<ul style="list-style-type: none"> ▪ Highly pigmented layer between the pericarp and the albumen (the “testa”) the absence or presence of which is a varietal characteristic. It seems to give the grains which have them mould resistant qualities. <i>Use:</i> animal feed
Triticale	<ul style="list-style-type: none"> ▪ Very hard glumes which stick tightly to the grain. ▪ Hardiness due to a cross between a wheat and a rye. This hardy characteristic makes it less sensitive to diseases. <i>Use:</i> animal feed
Products derived from cereals	<ul style="list-style-type: none"> ▪ Any by or co-products resulting from the primary processing of cereals and other plant products through one or several of the processes described in the glossary of process in part B of the Annex of the Feed Materials catalogue established as per the Regulation (EC) No 767/2009 as amended ▪ As non-exhaustive examples, we can mention corn gluten

	<p>feed, DDGs, cereals brans and middlings, cereals germs and flakes, etc.</p> <p><i>Use:</i> animal feed or food or industrial uses</p>
--	--

Oilseeds, protein crops and other plant products	Strengths in relation to the hazards studied Principal uses
<p>Pea, faba bean and lupin</p>	<ul style="list-style-type: none"> ▪ The thick seed coat of the pea, horse bean and lupin seeds and their low fat content (pea, horse bean) ensure good storage of the grains. ▪ The horse bean's tolerance to the <i>Aphanomyces</i> fungus of the pea (soil fungus). Moreover, its size allows for good ventilation during storage. <p><i>Use:</i> animal feed, human food (flour industry for the horse bean etc.).</p>
<p>Rape, soy, flax and sunflower</p>	<ul style="list-style-type: none"> ▪ The thick seed coat of the rape, soy, flax and sunflower seeds and their low water content ensure good storage of the grains. <p><i>Use:</i> oilseeds-crushing industry, oil industry, animal feed</p>
<p>By-products</p>	<p>Products derived from cereals, and traded by the operator</p> <p><i>Use:</i> animal feed</p>
<p>Products derived from Oilseeds and protein crops and from other plants materials</p>	<p>Any by or co-products resulting from the primary processing of oilseeds and protein crops and other plant products through one or several of the processes described in the glossary of process in part B of the Annex of the Feed Materials catalogue established as per the Regulation (EC) No 767/2009 as amended</p> <p>As non-exhaustive examples, oilseeds meals, expellers and hulls, vegetable oils, lecithin's, Sugar beet pellets, Citrus pulp pellets, Palm Kernel Expeller, Tapioca chips etc. can be mentioned</p> <p><i>Use:</i> animal feed or food or industrial uses</p>

APPENDIX 3

STAGE FACT SHEETS

Identification of the stage: RECEIPT

Purpose of the stage:

- Receive, accept and store cereals, oilseeds and protein crops.
- Identify and characterise the products.
- Classify and allocate the products received.
- Anticipate any storage problems and allow for good storage conditions.

Main hazards identified:

- Receipt of a raw material presenting a physical, chemical or biological hazard.

Nature of the process (mechanical, thermal):

- Mechanical.

Working staff (role, qualification):

- Reception manager + fixed-term contract employees under his/her responsibility during the harvest period (sampling and analyses).
- Silo manager and machinery operator + fixed-term contract employees (directing batches depending on the characteristics).

Materials entering and leaving (grains, impurities):

No separation of grains and impurities at this stage, except the most visible foreign bodies.

Environment (temperature conditions):

- Ambient/environment.

Equipment (location in the silo, characteristics):

- Vehicle.
- Sampler (sampling equipment or manual sampler).
- Collection pit with grating / flat storage platform.

Types and methods of controls carried out at this stage:

- Documents (delivery note).
- Control of the vehicle transporting the goods⁸: visual (cleanliness of the vehicle, maintenance condition, closing system), smell.
- Sample taking.
- Visual and smell analysis.
- Specific analyses of the product.
- Any control applied must be validated to ensure they are effective. For example, this means demonstrating by analytical or other means that a statement made about a control is true and the control works as intended, in particular in relation to Directive No 2002/32, to Recommendation No 576/2006 as well as to Regulation (EC) No 1881/2006 as amended. Records of this must be kept for future reference

⁸ This control of the vehicle can be carried out by the staff authorised by the operator, the owner or the receiver of the goods (e.g. the truck driver in case of self-service truck stations)

Identification of the stage: PRE-STORAGE

Purpose of the stage:

- Adjust the inflows in line with the drying capacities, while limiting the risk of alteration to the grain.

Main hazards identified:

- Development of mould.
- Development of field and/or storage mycotoxins.

Nature of the process (mechanical, thermal):

- Mechanical.

Working staff (role, qualification):

- Same staff as for receipt (logistics, time tracking).

Materials entering and leaving (grains, impurities):

No separation of the grains and impurities at this stage.

The product's moisture content if relevant.

The moisture levels refer to the moisture of grains.

For example: * Maize: 22 – 45% (approximately 35% depending on the region),

* Rape: > 11%

* Wheat: > 16%

* Pea: >16%

Environment (temperature conditions):

- Ambient conditions.

Equipment (location in the silo, characteristics):

- Handling (loader, chain conveyor, belt conveyor, bucket elevator, spiral conveyor).
- Storage bins/flat storage.

Types of controls carried out at this stage:

- Start date.
- End date (notion of time, FIFO).
- Any control applied must be validated to ensure they are effective

Identification of the stage: DRYING

Purpose of the stage:

- Bring the grain to a moisture level that allows it to remain well preserved during storage, while maintaining its technological properties.

Main hazards identified:

- Development of mould.
- Development of field and/or storage mycotoxins.
- Dioxins or Dioxins like PCBs if bad fuel and/or direct contact with burning gaz due to bad state of dryer.

Nature of the process (mechanical, thermal):

- Mechanical (pre-cleaning).
- Thermal (drying).

Working staff (role, qualification):

- Staff trained for drying.

Materials entering and leaving (grains, impurities):

- Material entering: goods presenting a humidity level higher than the standard, able to cause storage problems (moist grains at 35% on average + impurities).
- Material leaving:
 - From pre-cleaning: impurities + cleaned grains.
 - From the dryer: cleaned dry grains.

Environment (temperature, hygrometry conditions):

- High air temperature (70 – 130°C) and hygrometry (60 to 90%).

Equipment (location in the silo, characteristics):

- Lump breaker (removes the large impurities).
- Integrated dryer or external to the silo, single or multi-storey.
- Storage bin, dryeration unit, ventilators.
- Handling (bucket elevator, chain conveyor, belt conveyor, spiral conveyor etc.).

Types of controls carried out at this stage:

- Control of the grain's water content.
- Control of the grain and air temperatures.

Identification of the stage: STORAGE

Purpose of the stage:

- Store the grains or oilseeds or meals or processed products thereof.

Main hazards identified:

- Development of mould and/or storage mycotoxins and/or Salmonellas.
- Attracted insects.
- Self-heating or auto-combustion in case of excess moisture level consecutive to water leakage or not sufficiently dried products at receipt or condensation.
- Quality degradation for vegetable oils (increase of Free fatty Acids, oxidation) when long duration storage without Nitrogen capping or humidity of air.
- Cross contamination with remains of previous stored products.

Nature of the process (mechanical, thermal):

- Mechanical.
- Thermal (ventilation).

Working staff (role, qualification):

- Staff trained in storage.

Materials entering and leaving (grains, impurities):

- Material entering: dry grains or bulk processed products derived thereof (solids or liquids).
- Material leaving: cooled dry and possibly cleaned grains or bulk processed products derived thereof (solids or liquids).

Environment (temperature conditions):

- Outside temperature by ventilation to lower the temperature of the stored food and feed materials..

Equipment (location in the silo or storage site, characteristics):

- Handling (bucket elevator, chain conveyor, belt conveyor, spiral conveyor, other dedicated loading or handling equipment's such as pumps, etc.).
- Storage bin/building.
- Size grading and cleaning machine + handling equipment.
- Ventilator.
- Temperature sensor.

Types of controls carried out at this stage:

- Thermometric controls.
- Moisture if possible (in case of increasing temperature).
- Visual or even olfactory controls.
- Any control applied must be validated to ensure they are effective

Identification of the stage: PESTICIDE TREATMENT

Purpose of the stage:

- Prevent insects from being attracted (preventive treatments).
- Eliminate living insects (curative treatment).

Main hazards identified:

- The MRLs for storage pesticides are exceeded.
- Chemical contamination due to the persistence of residual fractions.
- Cross contamination between treated and non-treated grains (same or different specie) in silos/handling equipment and with residues of previous treatments of walls and floors.

Nature of the process (mechanical, thermal):

- Chemical.

Working staff (role, qualification):

- Trained staff.

Materials entering and leaving (grains, impurities):

- Material entering: grains or processed products infested with insects.
- Material leaving: treated grains or processed products.

Environment (temperature conditions):

- Ambient environment.

Equipment (location in the silo or storage site, characteristics):

- Handling.
- Pesticide treatment equipment.

Types of controls carried out at this stage:

- Sample taking.
- Visual control.

Identification of the stage: PREPARATION RELEVANT TO THE CONTRACTUAL REQUIREMENTS

Purpose of the stage:

- Provide the customer with batches of goods that comply with the regulatory and contractual specifications.

Main hazards identified:

- Batch allocation error.
- Chemical or biological contamination of a batch by a product presenting a physical, chemical or biological hazard, or by the handling and storage equipment.
- Accidental mixing of goods.
- Mixing of certified and non-certified products (or products having a different safety or contractual status).

Nature of the process (mechanical, thermal):

- Mechanical.

Working staff (role, qualification):

- Trained staff.

Materials entering and leaving (grains, impurities):

- Material entering: stored grains, meals or other processed products.
- Material leaving:
 - Grains, meals or other processed products prepared in accordance with the contractual specifications required,
 - Grains separated by sorting (small grains, tailings etc.),
 - Residues and vegetable matter.

Environment (temperature conditions):

- Ambient environment.

Equipment (location in the silo or storage cells, characteristics):

- Handling (elevator, chain conveyor, belt conveyor, spiral conveyor).
- Circuit weighing machine.
- Bin or hopper, size grading machine, cleaner-separator, pumps.

Types of controls carried out at this stage:

- Sample taking.
- Specific analyses linked to the contract.

Identification of the stage: DISPATCH - DELIVERY

Purpose of the stage:

- Transport the goods to the transfer of ownership location in compliance with the quality and quantity requirements, the delivery deadline and address.

Main hazards identified:

- Loading error.
- Chemical or biological contamination by the dispatch – delivery equipment.

Nature of the process (mechanical, thermal):

Mechanical.

Working staff (role, qualification):

- Qualified staff.
- Dispatch/laboratory manager, cereal or trading manager.
- Approver if leaving.
- Qualified transport driver, farmer aware of the hygiene rules, boat man.

Materials entering and leaving (grains, impurities):

- Goods prepared in accordance with the market demands.

Environment (temperature, hygrometry conditions):

- Ambient environment.

Equipment (location in the silo or storage site, characteristics):

- Hopper,
- Handling,
- Circuit weighing machine,
- Sampler,
- Pumps and hoses (for bulk liquid products)
- Vehicle:
 - ✓ Lorry:
 - grain carrier truck (27t), lift and carry container (12 to 13 t), bottom-dump skip, lock skip, tank, tautliner, container
 - semi-trailer, fixed or mobile skip carrier, road trailer carrier + fixed or mobile trailer
 - ✓ Train: specialised tank with hatches, opening and closing system,
 - ✓ Canal-boat or barge with a wooden or metallic bottom, one or several skids and loading hatches/hatch covers.
- Sheltered or unsheltered loading.

Types of controls carried out at this stage:

- Control of the vehicle: visual (cleanliness of the vehicle, maintenance condition, closing system), smell.
- Sampling.
- Analysis as per the contract.
- Visual control of the goods (insects, smell).
- Control of the documents (nature of the previous load, corrective actions).
- Any control applied must be validated to ensure they are effective. For example, this means demonstrating by analytical or other means that a statement made about a control is true and the control works as intended, in particular in relation to Directive No 2002/32, to Recommendation No.576/2006 as well as to Regulation (EC) No 1881/2006 as amended. Records of this must be kept for future reference

APPENDIX 4

THE HAZARD FACT SHEETS

List of the hazards

The different hazards dealt with in this code, which can be controlled by hygiene practice indicators and/or the HACCP study are the following: (non-exhaustive list⁹)

HAZARD	HAZARD IMPACT	ORIGIN OF THE HAZARD	MECHANISMS AT THE ORIGIN OF THE HAZARD	METHODS OF PREVENTING THE HAZARD	HACCP STUDY
Allergens	Toxicity	Fa: Raw materials OP: Equipment used Staff	Cross contaminations	Staff awareness raising Maintenance of the equipment	
<i>Bacillus cereus</i>	Toxicity	Fa: Raw materials Soil Env: Dust	Temperature increase – Condensation phenomenon	Ventilation – Cleaning of grains – Cleaning of the site	
Foreign bodies	Hygiene practice indicators	Fa: Raw materials OP: Equipment used Staff	Lack of awareness Maintenance defect	Staff awareness raising Maintenance of the equipment Cleaning of the grain	
Dioxins	Toxicity	Fa: Grain dryer without heat exchanger or using bad quality fuels Env: Atmospheric pollution	Proximity of a polluting site	Risk analysis and Monitoring plan if necessary	
Ergot	Toxicity	Fa: Raw materials supplied contaminated	Presence of sclerotia in the field (soil) + rainy, humid and cool weather	Recommendations of farming methods to farmers, Cleaning of the grain	Yes
Polycyclic Aromatic Hydrocarbons (PAHs)	Toxicity	Fa: Raw materials supplied contaminated	Fuel oil dryer without heat exchanger	Farmer and staff awareness raising	
Insects and dust mites	Alteration of the stored foodstuffs	Fa: Contaminated raw materials OP: Contaminated equipment	Increase in storage temperature Condensation phenomenon	Staff awareness raising Cleanliness of the equipment Cooling ventilation	Yes
Heavy metals	Toxicity	- a: Raw materials - nv: Atmospheric pollution, Soil pollution	- Accumulation - Proximity of a polluting site	- Monitoring plan - Farmer awareness raising	
Moulds including bunt	Alteration of the stored foodstuffs	Fa: Raw materials supplied contaminated OP: Poor storage methods and conditions	Condensation Increase in storage temperature Pre-storage too long	Ventilation – Cleaning of the grains Appropriate pre-storage duration Recommendations of farming methods to farmers	Yes

⁹ For specific products not indicated in this Guide, operators are advised to consult the relevant guides (http://ec.europa.eu/food/food/index_en.htm) for the specific risk analyses

Mycotoxins	Toxicity	Fa: Raw materials supplied contaminated OP: Poor storage methods and conditions	Increase in storage temperature Condensation phenomenon Pre-storage too long	Ventilation – Cleaning of the grains Temperature monitoring Appropriate pre-storage duration	Yes
Radioactivity	Toxicity	Env: Atmospheric pollution, Soil pollution	Proximity of a polluting site	Risk analysis and Monitoring plan if necessary	
Pesticide residues	Toxicity	OP: Pesticide treatment equipment leak, incorrect settings, unsuitable treatment, overdosage etc.	Maintenance defect Lack of awareness Barn storage awareness	Maintenance of the equipment Staff awareness raising	Yes
Rodents and fowl and/or their macroscopic traces	Hygiene practice indicators	OP: Poor maintenance of premises and their surroundings	No protection of premises or measures to combat the problem	Measures for protecting the premises (nets, doors etc.) and preventive measures	
Salmonellas	Toxicity and hygiene practice indicators	OP: Pests Birds, Rodents and contaminated raw materials	Presence of vectors	Staff awareness raising Protection of premises and their surroundings	
Botanical impurities	Hygiene practice indicators	Fa: Raw materials OP: Equipment used	Lack of awareness	Farmer and staff awareness raising Cleaning of the grain	

NB:

- the word staff is understood to mean the staff of the operator or any other contributor
- origin of the hazard: Fa = farmer – OP = Operator – Env. = environment

Each operator must conduct a study of the hazards linked to its outlets and its environment to ensure the food and feed safety of the products sold. Some of the hazards in this list may not be taken into account while others might be added.

With regard to pesticide residues other than storage pesticide residues, heavy metals, foreign bodies, dioxins, pathogenic flora, rodents and fowl, allergens and radioactivity, their relative risk is not specific to a given stage in the process; they are dealt with using general hygiene rules.

HAZARD FACT SHEETS

These sheets present the different hazards referred to in this guide, either because they are pathogenic and/or toxigenic, because they alter the foods stored, or because they are indicators of hygienic practices. For the purpose of clarity and to provide an overview, each hazard sheet contains the following information: nature, origin, characteristics, development conditions and applicable regulations when they exist.

There are three types of hazard:

Physical hazard

- Foreign bodies

Chemical hazards

- Heavy metals
- Residues from storage pesticides
- Dioxins & Furans, Dioxins like PCBs, Non-dioxin-like PCB
- Melamine
- Nitrites
- Radionucleides
- PAHs
- Storage insecticide residues and specific feed PPP MRLs

Biological hazards

- Insects and dust mites
- Rodents and fowl and/or their macroscopic traces
- Moulds
- Mycotoxins
- Salmonellas
- *Bacillus cereus*
- Allergens (Ambrosia)

FOREIGN BODIES

Nature of the hazard

- Physical hazard

Classification

Level of impurities is one of the qualitative criteria in commercial contracts.

Four types of impurities are distinguished:

- Broken grains
- Impurities constituted by the grains
- Sprouted grains
- Miscellaneous impurities
- Coated treated seeds¹⁰ (more a contractual issue)

The “foreign bodies” category belongs to this final type of impurity.

The main foreign bodies:

- Glass
- Plastic
- Particles of metal
- Pebbles, stones
- Plant debris
- Wood
- Soil
- Sand

Origin

- Raw materials supplied
- Maintenance of the equipment
- Loss of objects by staff

Food and feed safety risks

The presence of foreign bodies can cause risks to:

- The consumer’s safety (cut by glass)
- Their food and feed safety (transmission of bacteria)

¹⁰ Coated treated seeds means pre-treatment of seeds

HEAVY METALS

Nature of the hazard

- Chemical hazard

Classification

The term “heavy metals” is used in everyday language, but it actually refers to mineral trace elements (MTE). They are normally present in the environment as traces (< 100 mg/kg). MTEs are mainly metallic (although some such as arsenic and selenium are not). The majority is trace elements, that is, in small concentrations they are necessary to sustain life. However, lead and cadmium are not essential to sustaining life. They are toxic metallic contaminants.

Origin

They can be found in the form of trace elements in grains and their by-products following atmospheric pollution (lead) or soil pollution (cadmium).

Food and feed safety risks

Lead (Pb), Cadmium(Cd) and Mercury(Hg) are not essential to sustaining life (animals and vegetal) while Arsenic (As) is non-essential for plants but Essential for Animals. They are toxic metallic contaminants.

Pb, Cd and Hg are particularly toxic and “bio-accumulate” in the food and feed chain As (a metalloid), is essential for animals but is quickly toxic at low doses and needs a specific monitoring.

For few heavy metals, only some forms are toxic: For Mercury the organic form is more toxic than the inorganic whilst for Arsenic, the inorganic forms are more toxic.

Regulations

Concerning **foodstuffs**, Regulation (EC) No 1831/2003 as amended of 19 December 2006, as amended, sets the following maximum levels expressed in relation to fresh weight:

- Lead: - 0.20 mg/kg of cereals including buckwheat and legumes and pulses
- 0.10 mg/kg (ppm) in vegetables
- Cadmium: - 0.10 mg/kg: cereals (excl bran), wheat germ, wheat grain and rice
- 0.20 mg/kg: bran, wheat germ, wheat grain, rice, bran
- 0.20 mg/kg: soybeans (and derived products such as SBM or SBO)
- Arsenic: 0.1 ppm for vegetables and fats (based on Codex Alimentarius norm)

Concerning **raw materials for animal feed of plant origin**, Council Directive 2002/32/EC, as amended, sets the following maximum levels:

- Lead (Pb): 10 mg/kg (ppm) for feed materials
- Cadmium (Cd): 1 mg/kg (ppm) for feed materials of vegetable origin
- Mercury (Hg): 0.1 mg/kg (ppm) for feed materials of vegetable origin
- Arsenic (As): 2 ppm in feed materials and 4 ppm in PKE (Palm Kernel Expeller) (but max 2 ppm inorganic arsenic)
- Fluorine: 150 mg/kg in feed materials of vegetable origin

STORAGE PESTICIDE RESIDUES

Nature of the hazard

- Chemical hazard

Classification

A pesticide is any substance used to combat the presence or appearance of insects and mites in stored grains.

Origin

- Raw materials supplied
- Pesticide treatment
- Pesticide treatment equipment
- Cross contamination with residues of treated previous cargoes or residues of pesticides on walls/floors/handling equipments

Food and feed safety risks

- Toxicity above the regulatory concentration threshold

When products are to be used for FEED, it is important to:

- First check in the FEED Directive 2002/32/CE “undesirable substances” if the concerned Active substances are listed in the Appendix and if a specific maximum content has been fixed for them.
- If not, then check in the EU pesticide Regulation ((EC) No 396/2005 as amended) database if a specific MRL has been fixed for this simple product or group of products- If not , the default max 0.01ppm* (* = Lower Limit of Analytical Determination) will apply for simple not processed products (http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection&ch=1).
- Check whether footnote (4) of Commission Regulation (EU) No 212/2013 replacing Annex I to Regulation (EC) No 396/2005 as amended applies. The footnote (4) provides for a limited number of products that the MRLs in Annexes II and III do not apply to products or parts of the product used exclusively as ingredients for animal feed, until separate MRLs will be applicable.
- For processed products, the Regulation (EC) No 396/2005 as amended foresees the possible use of “processing factors” for the evaluation of pesticides residues. Such processing factors could be yet included in Appendix VI of Regulation (EC) No 396/2005 (concentration or dilution factors) and related to the pesticide solubility in fat (F factor) or in water (LogPow or “Octanol/water partition coefficient” which can be found in the ICSCs and also take into account the concentration or dilution factor of the product.

Article 18(3) of Regulation (EC) No 396/2005 as amended allows Member States to authorise the use of product which may contains residues of post-harvest fumigants treatments with a level above the MRLs provided:

- a) That the product is not intended for immediate consumption (this should cover the fact that some cargoes received could have a content of Phosphine above 0.1 ppm, provided that it does not present danger for the workers);
- b) Appropriate controls are in place to ensure that such products cannot be made available to the end user or consumer, if they are supplied directly to the latter, until the residues no longer exceed the maximum levels specified in Annexes II or III of Regulation (EC) No 396/2005 as amended; and

(c) The other Member States and the Commission have been informed of the measures taken.

Article 18(4) of Regulation (EC) No 396/2005 as amended also states that “In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or pursuant to obligations set out in Directive 2000/29/EC (1), a Member State may authorize the placing on the market and/or the feeding to animals within its territory of treated food or feed not complying with paragraph 1, provided that such food or feed does not constitute an unacceptable risk. Such authorizations shall immediately be notified to the other Member States, the Commission and the Authority, together with an appropriate risk assessment for consideration without undue delay with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products.”

Datura seeds must be taken into account under the food and feed safety risks because of the tropane alkaloids. Self-checking is also necessary for cereals that are not specifically intended for infants and toddlers.

The list of substances (fumigants) concerned by this Article 18(3) has been published in EU Regulation (EC) No 260/2008 as amended adding an Annex VII to EC Regulation (EC) No 396/2005 as amended, including Hydrogen phosphide, Aluminium phosphide, Magnesium phosphide (the 3 covers as well uses in cereals than in oilseeds and oilfruits) and sulfurlylfluoride (for cereals only).

Regulations and main MRLs

Characteristics of the active materials approved for the treatment of stored cereals. Only aluminium and magnesium phosphide are approved for pesticide treatment of stored oilseeds.

- Regulation (EC) No 396/2005 as amended
- For verification of EU Pesticides MRL database, consult DG SANTE web database: http://ec.europa.eu/sanco_pesticides/public/index.cfm
- Sampling methods for official controls of pesticides residues to be done according to EU Directive 2002/63/EC.
- Performance of analytical methods and the interpretation of results to be done according to Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC
- Method validation and Quality control procedures for pesticides residues analysis in Food and Feed based on Document SANCO/10684/2009 396/2005

Any numerical reference to the MRLs should be understood as subject to changes in the Regulation (EC) No 396/2005 as amended. For more information (e.g. residues of pesticides applied during cultivation), please check EU DG SANTE PPP database: http://ec.europa.eu/sanco_pesticides/public/index.cfm

DIOXINS & DIOXIN LIKE PCBs & NON-DIOXIN LIKE PCBs

Nature of the hazard

- Chemical hazard

Classification

Dioxins are Persistent Organic Pollutants (POP) that are found worldwide in any environment (ubiquitous molecules). They are molecules which can only be destroyed at a very high temperature (they are chemically and thermally stable). Moreover, they are very lipophilic (soluble in fats) and not very biodegradable. They therefore accumulate along the food chains (bioaccumulation).

Dioxins belong to a group of 75 polychlorinated dibenzo-p-dioxin (PCDD) congeners and 135 polychlorinated dibenzofuran (PCDF) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often referred to as 'dioxin-like PCBs' (DL-PCB). The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile and are referred to as 'non-dioxin like PCB' (NDL-PCB).

Each congener of dioxins or DL-PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEFs) was introduced to facilitate risk assessment and regulatory control. As a result the analytical results relating to all the individual dioxin and dioxin-like PCB congeners of toxicological concern are expressed in terms of a quantifiable unit, namely the TCDD toxic equivalent (TEQ).

The sum of the six marker or indicator PCBs (PCB 28, 52, 101, 138, 153 and 180) comprises about half of the amount of total NDL-PCB present in feed and food. That sum is considered as an appropriate marker for occurrence and human exposure to NDL-PCB. For maximum limits, directive 2002/32/EEC should be consulted.

Origin

Dioxins are released from industrial atmospheric waste and certain combustion processes. They are found in soils and in water.

PCBs were widely used for many applications, especially as dielectric fluids in transformers, capacitors and coolants. Processing and distribution of PCBs have been prohibited in almost all industrial countries since the late 1980s but they still can be released into the environment from electrical appliances, building paint and sealants and waste sites that contain PCBs.

Food and feed safety risks

The term "dioxins" encompasses 210 congeners. Among them, 17 congeners are toxic, although they do not all possess the same toxicity. To translate this difference, a toxic equivalence factor (I – TEF) has been defined (each toxin is weighted by a factor compared to the factor of 1 allocated to the most toxic dioxin).

The toxicity of a sample is quantified by the quantitative measurement of the 17 toxic congeners to which the toxic equivalence factors are applied. This shows a sample's Toxic Equivalent Level or I – TEQ.

Monitoring and controls

When products originate from areas where risks of inadequate management of dryers are known, a regular monitoring of PCBs and dioxin-like PCBs should be implemented as well as those mentioned in Regulation (EU) No 225/2012 as amended. Depending on levels found (near action limit or near max levels, actions should be taken to:

- Find source of contamination and correct it, and
- Eliminates/Recalls/Withdraws products for which levels are above MRLs (with adequate information to authorities and customers)

Regulations and EU Norms

a) For FOOD

For food products, [Regulation \(EC\) No 1881/2006](#) as amended by subsequent legal acts sets the following maximum level relative to a food:

contaminant	FOOD product concerned	EU max limits	basic EC legislation	application date
Sum of Dioxins	5.12.Vegetable Oils and fats	MRL: 0,75 pg/g fat- (Who-PCDD/F-TEQ)	Reg 1881/2006 dd 19Dec2006	01-Jan-12
sum of Dioxins & Dioxin like PCBs	5.12.Vegetable Oils and fats	MRL 1,25 pg/g fat (WHO-PCDD/F-TEQ)	Reg 1881/2006 dd 19Dec2006	in force
Non-dioxin-likePCBs (Sum of PCB 28, PCB52, PCB 101, PCB 138, PCB153 and PCB 180 (ICES – 6)	5.12.Vegetable Oils and fats	MRL : 40 ng/g fat	Reg 1881/2006 dd 19Dec2006	01-Jan-12
• Benzo(a)pyrene (BaP, a PAH “Polycyclic aromatic hydrocarbons)	Oils & fats intended for direct human consumption or use as an ingredient in foods	max 2.0 ppb (µg/kg wet weight)	Reg 1881/2006 dd 19Dec2006	in force
BAP4 (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene)	Oils & fats intended for direct human consumption or use as an ingredient in foods	MRL of 10.0 ppb (µg/kg)	Reg 835/2011 dd 19 Aug 2011	from 1 Sept 2012
contaminant	FOOD product concerned	EU max limits	basic EC legislation	application date
Dioxins + Furans	cereals & Oilseeds	MS control authorities ACTION LEVEL (WHO-TEQ-2005) ⁽¹⁾ 0,50 pg/g wet weight product	Recommendation 2013/711/EU dd 03 Dec 2013 for Food & feed as amended by Recommendation 2014/663/EU dd 11 sept 2014	as from 3 Dec 2013

Dioxin-like PCBs	cereals & Oilseeds	MS control authorities ACTION LEVEL (WHO-TEQ-2005) ⁽¹⁾ 0,35 pg/g wet weight product	Recommendation 2013/711/EU dd 03 Dec 2013 for Food & feed as amended by Recommendation 2014/663/EU dd 11 sept 2014	as from 3 Dec 2013
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⁽¹⁾: **Upperbound concentrations: Upperbound concentrations are calculated assuming that all the values of the different congeners less than the limit of quantification are equal to the limit of quantification.**

EU recommendation 2013/711/EU dd 3 Dec 2013, as amended by Recomm 2014/663/EU dd 11 sept 2014 (replaces Recom **2011/516/EU**) requests EU MS to random monitor presence of Dioxins & Furans (sum PCDDs and PCDFS) and , DL PCBs in Food and Feed products by setting some Action Levels.

EU Reg No 589/2014 of 2 June 2014 as amended lays down methods of sampling and analysis for the control of levels of dioxins (sum of PCDDs and PCDFS), dioxin-like PCBs and non-DL PCBs in certain foodstuffs and repeals Reg (EU) No 252/2012 as amended "

b) For FEED

For feed products, [Council Directive 2002/32/EC](#) as amended by subsequent legal acts sets the following maximum level relative to a feed with a moisture content of 12%:

contaminant	FEED product concerned	Maximum content or Threshold	Basic Regulation
DIOXINs (sum of PCDD & PCDF)	a) Feed materials of plant origin except veg oils and their by products	Maximum content: 0,75 ng/kg (ppt) Action threshold at 0,5 ng/kg of OMS-PCDD/F-TEQ/kg (ppt) relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012-testing base Reg 278/2012 (base 152/2009)
Dioxins + Furans	cereals & oilseeds	MS control authorities ACTION LEVEL (WHO-TEQ-2005) ⁽¹⁾ 0,50 pg/g wet weight product	Recommendation 2013/711/EU dd 03 Dec 2013 for Food & feed as amended by Recommendation 2014/663/EU dd 11 sept 2014
Sum of dioxins and dioxin-like PCBs (sum (PCDDs),PCDFs and (PCBs)	a) Feed materials of plant origin except veg oils and their by products	Maximum content 1,25 ng/kg (ppt)-of OMS-PCDD/F-PCB-TEQ/kg relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012-testing base Reg 278/2012 (base 152/2009)
Dioxin-like PCBs	a) Feed materials of plant origin except veg oils and their by products	Action Threshold 0,35 ng/kg (ppt) of OMS-PCDD/F-TEQ/kg relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012-testing base Reg 278/2012 (base 152/2009)

Dioxin-like PCBs	cereals & oilseeds	MS control authorities ACTION LEVEL (WHO-TEQ-2005) ⁽¹⁾ 0,35 µg/g wet weight product	Recommendation 2013/711/EU dd 03 Dec 2013 for Food & feed as amended by Recommendation 2014/663/EU dd 11 sept 2014
Non-dioxin-like PCBs (Sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6))	a) Feed materials of plant origin	Maximum content: 10 µg/kg (ppb) relative to a feed with moisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)

contaminant	FEED product concerned	MRIs or Threshold	Basic Regulation
DIOXINs (sum of PCDD & PCDF)	b) vegetable oils and their by products	Maximum content: 0,75 ng/kg Action threshold at 0,5 ng/kg of OMS-PCDD/F-TEQ/kg (ppt) relative to a feed with moisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Sum of dioxins and dioxin-like PCBs (sum (PCDDs), PCDFs and (PCBs))	b) vegetable oils and their by products	Maximum content 1,5 ng/kg - of OMS-PCDD/F-PCB-TEQ/kg (ppt) relative to a feed with moisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Dioxin-like PCBs	b) vegetable oils and their by products	Action Threshold 0,5 ng/kg - i- (ppt) of OMS-PCDD/F-TEQ/kg (ppt) upperbond concentration relative to a feed with 12% moisture	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
<p>Determination of the levels of dioxins and PCB in FEED products as per EU Reg 278/2012 dd 28 march 2012 amending Reg 152/2009</p> <p>EU Reg Nr 709/2014 dd 20 June 2014 amends part B of Annex V of Reg 152/2009 for "methods of Determination of the levels of Dioxins (PCDD/PCDF) and Dioxin-Like PCBs"</p> <p>EU recommendation 2013/711/EU dd 3 Dec 2013 , as amended by Recomm 2014/663/EU dd 11 sept 2014 (replaces Recom 2011/516/EU) requests EU MS to random monitor presence of Dioxins & Furans (sum PCDDs and PDCFS) and , DL PCBs in Food and Feed products by setting some Action Levels.</p>			

Sampling and analysis

For sampling and analysis of these products, please refer to:

- Regulation (EU) No 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs (**repeals** Regulation (EC) No 1883/2006).

- Regulation (EU) No 152/2009 laying down the methods of sampling and analysis for the official control of **FEED** (annex I p. 4 for sampling, annex II p. 9 general provisions on methods of analysis and Annex V (B) p. 97 for determination of dioxins (PCDD/PCDF) and DL PCBs) as amended by Regulation (EU) No 278/2012 as regards the determination of the levels of dioxins and polychlorinated biphenyls.
- Regulation (EC) No 333/2007 as amended recently by Regulation (EC) No 836/2011 lays down methods of sampling & analysis for lead, cadmium, mercury, inorganic tin, 3-MCPD and Benzo(a)pyrene in **FOOD**.

INSECTS AND DUST MITES

Nature of the hazard

- Biological hazard

Classification

Insects and mites belong to the branch of arthropods which are characterized by the presence of quite a rigid cuticle covering the body. Insects bring about an alteration in grains and other processed products derived thereof and are sources of spoiling and contamination. Mites mainly feed on grain debris or mould (secondary pests). It is not always possible to detect a batch contaminated by insects. Certain insects such as weevils develop inside the grains.

The main insects and mites found in stored grains and other processed products derived thereof:

- Insects

Grain weevil, rice weevil, tribolium castaneum, tribolium confusum, oryzaephilus surinamensis, cryptolestes, lesser grain borer, khapra beetle, wheat beetle, dried fruit moth, angoumois grain moth.

- Mites

Flour mite, rapeseed mite, hairy mite, Cheyletiella.

Origin

- Equipment (storage and handling facility)
- Raw materials supplied

Development factors in stored cereals

- Temperature
- The water level of grains and processed thereof products

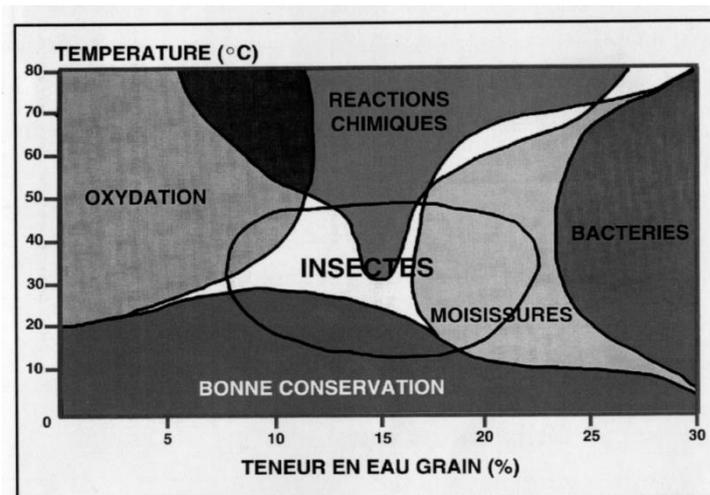
Survival of insects

- At a threshold of less than 12°C, the insects cease to develop.
- Subjected to a temperature lower than 5°C for several weeks, the insects die.
- Exposed to a temperature of 60°C for 3 minutes, the insects are destroyed.

Survival of mites

- For low temperatures, there are very large sensitivity differences between the various mite species.
- For high temperatures, exposure to a temperature of 45°C for 5 hours kills all species.

The graph below shows the risks a mass of cereals is subject to according to its temperature and water level:



FRENCH	ENGLISH
REACTIONS CHIMIQUES	CHEMICAL REACTIONS
OXYDATION	OXIDATION
INSECTES	INSECTS
BACTERIES	BACTERIA
MOISSURES	MOULDS
BONNE CONSERVATION	GOOD STORAGE
TENEUR EN EAU GRAIN (%)	GRAIN WATER LEVEL (%)

Source:
Francis Fleurat-Lessard and Bernard Cahagnier
INRA – Villenave d'Ornon and Nantes

Food and feed safety risks

Germ carriers.

RODENTS, FOWL AND/OR THEIR MACROSCOPIC TRACES

Nature of the hazard

- Biological hazard

Classification

By consuming grains or other processed products thereof, rodents and fowl cause damage, spoiling, contamination and alteration of the grains or other processed products thereof.

- The rodents likely to attack stored grains are rats, mice and squirrels.
- As regards fowl, it mainly concerns pigeons and sparrows or seagulls in port areas.

Origin

Poor maintenance or protection of:

- Premises
- External surroundings

Food and feed safety risks

Germ carriers.

Birds carry more than 60 diseases, including histoplasmosis which is an acute respiratory disease, as well as ectoparasites and salmonellas.

Dropping from birds are corrosive and can damage building roofs, walls and any outdoor machinery. Nest debris can also congest drains and gutters.

Technical interventions

The three common interventions techniques against birds are:

- Repellents: to help male socializing or breeding birds feel uncomfortable.
- Exclusion: helps preventing birds from breeding and keep them away. Doors should be kept closed when not in uses and all openings in exterior walls should be sealed with nets or other materials
- Relocation: to remove birds and nest

MOULDS

Nature of the hazard

- Biological hazard

Classification

Moulds represent a group very heterogeneous of about 11 000 species of which almost 100 are able, potentially, to produce mycotoxins. These toxicological species can be grouped in the classes of Deuteromycota and Ascomycota. Moulds are also well known allergens. Moulds growth may indicate the likely development of mycotoxins. Some moulds are also allergenic to animals or humans.

- Moulds grow a number of spores (dissemination mechanisms) which have a high longevity. These spores are disseminated by air or water and colonize new substrata.
- When the mould's growth is sufficiently advanced, it forms a mycelium (generic term used to refer to all of the filaments forming the vegetative part of fungi) that is visible to the naked eye.
- Non-photosynthetic, mould can only grow on organic media, causing damage, changing their appearance or causing organoleptic alterations.
- Types forming field fungi

The most common types are *Alternaria*, *Fusarium*, *Helminthosporium*, *Epicoccum*, *Septoria* and *Verticillium*; this flora which requires humidity to develop normally regresses in stored grains.

- Types forming intermediate fungi

Mucorales like *Rhizopus*, *Absidia* and *Mucor* and certain yeasts: these types largely predominate in specific conditions and mainly in grains that are not dry enough.

- Types forming storage fungi

Mainly *Aspergillus* and *Penicillium*.

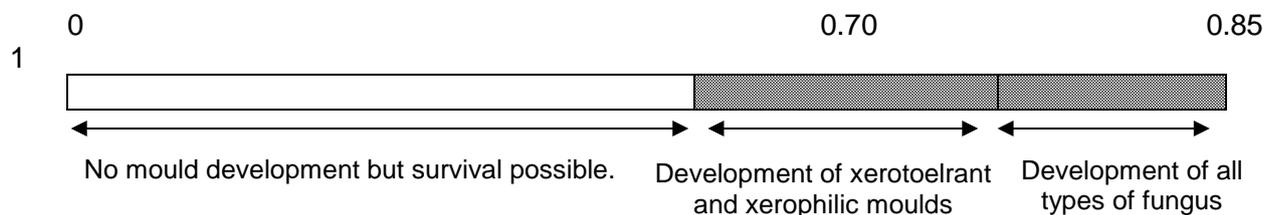
Origin

- Raw materials supplied
- Storage methods and conditions
- Equipment (storage and handling facility)

Development factors

Physical conditions influencing the growth of mould in stored cereals:

- The relative humidity which can be compared to humidity of the grains or of other processed materials thereof. An increase in the water level of products activates the growth of mould.
- The activity of water (A_w) which is equal to the relative humidity divided by 100.



- Temperature

The majority of moulds have growth optimums between 25 and 35°C and react to a rise in temperature by accelerating their growth.

- pH

Mould grows between pH 2 and pH 11.

Chemical conditions influencing the growth of mould in stored cereals:

- The composition of the atmosphere

The lower the oxygen composition of the atmosphere, the lower the growth rate of moulds, which are aerobic organisms. However, the oxygen level is unlikely to fall low enough to slow down the growth of mould.

Attention should be paid also on Ergot sclerotium.

Food and feed safety risks

Moulds present no direct food and feed safety risk but are good indicators of potential other hazards.

Regulations

- No specific regulations.

MYCOTOXINS

Nature of the hazard

- Biological hazard

Classification

Mycotoxins are “secondary metabolites” produced by certain moulds. They are molecules which have a very low molecular weight; they are not proteinic and do not therefore cause immunological reactions.

They are natural contaminants in foods and animal feed. They resist all treatments, sterilization, oxidation, acidity and alkalinity and have a lifespan in the contaminated product that is a great deal longer than that of the mould which synthesized them. However, not all moulds produce toxins and not all strains of the species that are able to, do so systematically, even if all of the conditions optimal to toxin production are combined.

Field mycotoxins

Mycotoxins	Moulds	Main media
Trichothecenes	<i>Fusarium</i>	Maize, barley, wheat, oats
Zearalenone	<i>Fusarium graminearum</i>	Maize, wheat, sorghum
Fumonisin	<i>Fusarium moniliforme</i>	Maize
Aflatoxins*	<i>Aspergillus flavus</i> and <i>Aspergillus parasiticus</i>	Maize
Ergot alkaloids	<i>Claviceps purpurea</i>	Rye and wheat

* Aflatoxins are mainly storage mycotoxins but under extreme climatic conditions and pest attacks they may be produced during cultivation.

In March 2012, the EU published a Commission Recommendation 2012/154/EU of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food asking Member States to perform with the active involvement of feed and food business operators monitoring on the presence of ergot alkaloids in cereals and cereal products intended for human consumption or intended for animal feeding, in pasture/forage grasses for animal feeding and in compound feed and food.

Member States should analyse the samples for at least the following ergot alkaloids:

- Ergocristine/ergocristinine,
- Ergotamine/ergotaminine,
- Ergocryptine/ergocryptinine,
- Ergometrine/ergometrinine,
- Ergosine/ergosinine,
- Ergocornine/ergocorninine.

Member States should determine, whenever possible, simultaneously the sclerotia content in the sample in order to be able to improve the knowledge on the relation between the content of sclerotia and the level of individual ergot alkaloids.

On March 27th 2013, the EU published a Commission Recommendation 2013/165/EU on the presence of T-2 and HT-2 toxin in cereals and cereals products) asking Member States to perform with the active involvement of the feed and food business operators monitoring on the presence of T-2 and HT-2 toxin in cereals and cereals products intended for human consumption or intended for animal feeding (rice and rice products are not included). The

purpose is to encourage that samples are simultaneously analysed for the presence of T2 & HT-2 and other fusarium-toxins such as DON, ZEA and FUMOMO B1+B2 and to allow the extent of co-occurrence to be assessed. For the sampling and testing of FOOD products, operators should use Regulation (EC) No 401/2006 (annex I part B and Annex II point 4.3.1(g) and for FEED products, the Regulation (EC) No 152/2009 as amended should be used. The Recommendation 2013/165/EU provides recommended LOD and detection limits. In case of (repetitive) findings of levels above the recommended ones, Member States with the active involvement of the food and feed operators should perform an investigation to identify the measures to be taken in order to avoid or reduce such presence in future as well as effects of feed and food processing on the presence of T-2 and HT-2 toxins. Member States should provide on a regular basis (at least every year) to EFSA the analytical results compiled into a single database.

Storage mycotoxins

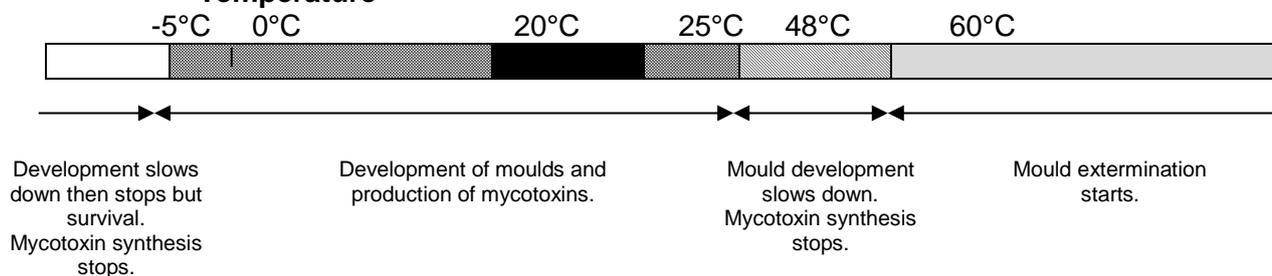
Mycotoxins	Moulds	Main media
Ochratoxins	<i>Aspergillus ochraceus</i> <i>Penicillium viridicatum</i>	Maize, barley, wheat
Citrinin	<i>Penicillium citrinum</i>	Barley, rye, oats, maize
Sterigmatocystin	<i>Aspergillus versicolor</i>	Wheat
Aflatoxins	<i>Aspergillus parasiticus</i> <i>Aspergillus flavus</i>	Maize, sorghum, Oilseeds

Origin

- Raw materials supplied
- Storage methods and conditions

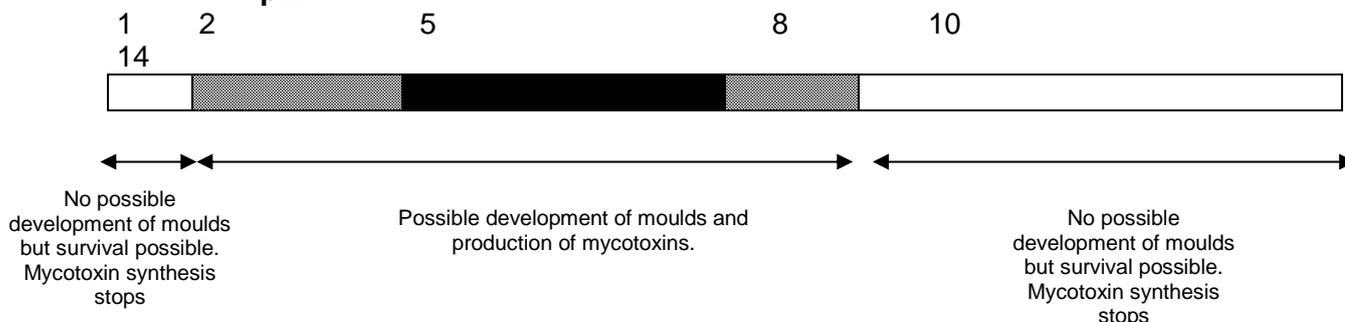
Development factors

- Temperature

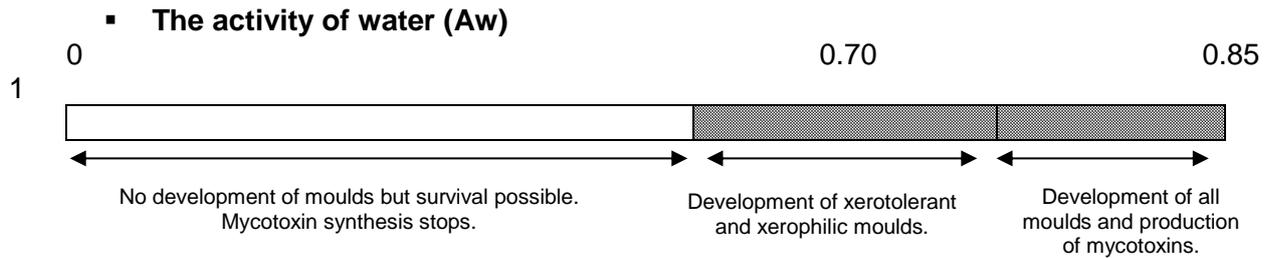


Mycotoxins are not very sensitive to heat; they are resistant to all the heat treatments currently used in the food-processing industries.

- pH.



Mycotoxins are stable, regardless of the pH.



The greater the grains' Aw the higher the mycotoxin production even for species classed as xerotolerant or xerophilic.

Food and feed safety risks of aflatoxins and ochratoxins

- Nephrotoxicosis
- Carcinogenesis
- Immunosuppressant

Regulations

- The mixing of products compliant with the set maximum levels for mycotoxins with non-compliant products is prohibited (Non Dilution Rule)
- Maximum mycotoxin levels for foodstuffs: (basic text: Regulation (EC) No 1881/2006 of 19 December 2006 as amended)

▪ **Aflatoxins:**

Concerning cereals and oilseeds (excluding maize):

- 2 µg/ kg for aflatoxin B1,
- 4 µg/ kg for the sum of the aflatoxins (B1+B2+G1+G2).

Concerning maize to be subjected to sorting or other physical treatment before direct human consumption or use as an ingredient in foodstuffs:

- 5 µg/ kg for aflatoxin B1,
- 10 µg/ kg for the total of the aflatoxins (B1+B2+G1+G2).

Regulation (EC) No 165/2010 has modified Regulation (EC) No 1881/2006 as amended by introducing some MRLs for aflatoxins in oilseeds for food uses

- 2.1.1-Groundnuts (peanuts) and other oilseeds (*), to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs with the exception of - groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production: Aflatoxin B1: 8,0 ppb - and Aflatoxin B1+B2+G1+G2 : 15,0 ppb
- 2.1.5-Groundnuts (peanuts) and other oilseeds (*) and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of - crude vegetable oils destined for refining - refined vegetable oils

Note: Crude vegoils for direct Human consumption are concerned also: aflatoxin B1: 2,0 ppb - and Aflatoxin B1+B2+G1+G2 : 4,0 ppb

▪ **Ochratoxin A:**

- 5 µg/kg for unprocessed cereals (including untreated rice and buckwheat),
- 3 µg/kg for cereal by-products (including processed cereal products and the grains of cereals intended for direct human consumption).
- 8 µg/kg for wheat gluten not sold directly to the consumer,

Regulation (EU) No 844/2011 introduces specific pre-export certification rules on OTA controls by CANADA of exports of Wheat and wheat flour to the EU

- **Deoxynivalenol (also called vomitoxin):**
 - 1250 µg/kg for unprocessed cereals other than durum wheat, oats and maize,
 - 1750 µg/kg for durum wheat, oats and maize (with the exception of unprocessed maize intended to be processed by wet milling).
- **Zearalenone:**
 - 100 µg/kg for unprocessed cereals other than maize,
 - 350 µg/kg for maize (with the exception of unprocessed maize intended to be processed by wet milling).
- **Fumonisin:**
 - 4000 µg/kg for unprocessed maize (with the exception of unprocessed maize intended to be processed by wet milling)
 - 1000 µg/kg for maize intended for direct human consumption
- **T2 and HT2:**

EU Recommendation 2013/165/EU sets indicative levels for the sum of T-2 and HT-2 (µg/kg – ppb) in cereals and cereals products (rice excluded) from which onwards/above which investigations should be performed, certainly in case of repetitive findings (indicative levels are NOT feed and food safety levels!):

- For unprocessed cereals: 200 ppb for barley (incl. Malting Barley) and maize, 1000 ppb for oats (with husks) and 100 ppb for wheat, rye and other cereals
- For cereals grains for direct human consumption (i.e. which have undergone drying, cleaning, de-husking and sorting processes and on which no further cleaning and sorting processes will be performed before their further processing in the food chain): 200 ppb for oats, 100 ppb for maize and 50 ppb for other cereals

▪ Maximum mycotoxin levels for products intended for feed (basic text: Directive 2002/32 as amended)

- **Aflatoxin B1:**
 - 0.02 mg/kg for all raw materials
- Recommended maximum mycotoxin levels for cereals intended for animal feed (Commission Recommendation 2006/576/CE):
 - **Deoxynivalenol:**
 - 8 mg/kg for all cereals and max 12 ppm for maize by products (DDGS/CGF)
 - **Zearalenone:**
 - 2 mg/kg for all cereals and max 3 ppm for maize by products (DDGS/CGF)
 - **Ochratoxin A:**
 - 0.25 mg/kg for all cereals
 - **Fumonisin B1 + B2:**
 - 60 mg/kg for all cereals (affects mainly maize and maize BP)
 - **T2 and HT2:**

EU Recommendation 2013/165/EU sets indicative levels for the sum of T-2 and HT-2 (µg/kg – ppb) in cereals and cereals products (rice excluded) from which onwards/above which

investigations should be performed, certainly in case of repetitive findings (indicative levels are NOT feed and food safety levels!):

- For unprocessed cereals : 200 ppb for barley (incl. Malting Barley) and maize, 1000 ppb for oats (with husks) and 100 ppb for wheat, rye and other cereals
- For cereals products for feed and compound feed (base 12% moisture): 2000 ppb for oats milling products (husks), 500 ppb for other cereals products and 250 ppb for compound feed

Sampling and testing

- For **FOOD**, Regulation (EC) No 401/2006 as amended lays down the methods of sampling and analysis for official controls of the levels of mycotoxins in FOOD.
- For contractual large lot sampling it is recommended to use the norm AFNOR NF XP V03-777 or the ISO CEN 24333 standard (for grains). Operators, can also use, for internal or contractual monitoring some sampling Rules such as GAFTA 124 (for grains and products thereof and oilseeds meals) or FOSFA methods (for oilseeds and vegetable oils.).
- Regulation (EC) No 882/2004 as amended on official controls also applies.
- An EU guidance document for the sampling of cereals for mycotoxins has also been published by the EU Commission.
- In Nov 2010, the EU Commission also released a Guidance Document for competent authorities for the control of compliance with EU legislation on aflatoxins.
- For **FEED**, Commission Regulation (EC) No 152/2009 as amended laying down the methods of sampling and analysis for the official control of feed.
- Commission decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results.

SALMONELLAS

Each operator is advised to follow EU and current national requirements. It is recognised that the requirements regarding Salmonella vary by Member State within the EU.

Nature of the hazard

- Biological hazard

Classification

Salmonellas are bacteria that belong to the family of Enterobacteriaceae, which are pathogenic for humans and animals.

Salmonellas have characteristics which explain their very widespread distribution:

- They are carried by a large range of hosts (humans, mammals, birds, reptiles, insects etc.).
- They have a very high survivability in the environment.

From an epidemiological point of view salmonellas can be classed into three main groups:

- Strains that only infect humans and are responsible for typhoid fever with septicaemic dissemination, which are not pathogenic for other animal species.
- Strains specifically adapted to particular species of vertebrates (poultry, sheep etc.), some of which are pathogenic for humans.
- Strains that do not have a specific preferred host and infect both humans and animals. This is the reservoir in which the main agents of the salmonellas currently encountered are found.

Salmonellas can be dangerous for humans or animals.

Origin

The principal habitat of Salmonella is the intestinal tract of humans and animals. Salmonella is disseminated in the natural environment through human or animal excretion. It should be described as follows: "Fecal contamination by pests (mainly birds and rodents) but also contaminated dust or remains of previously transported/handled or stored materials."

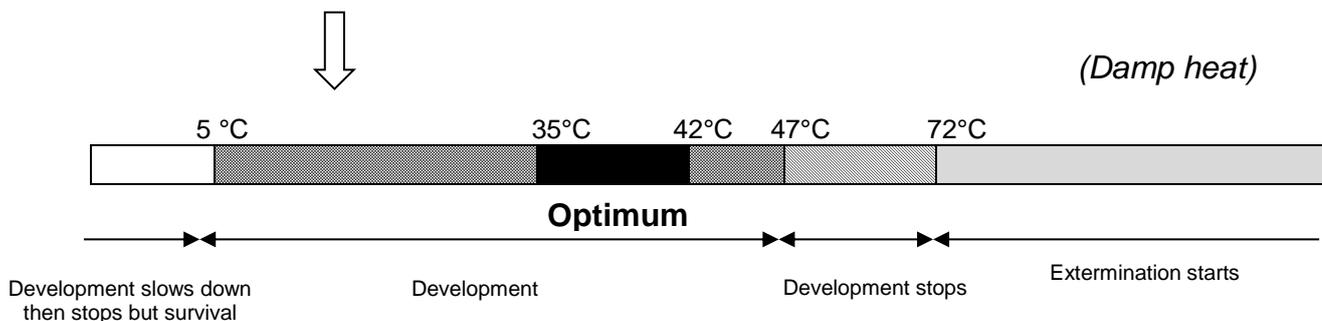
- Pests (mainly birds and rodents) but also contaminated dust or remains of previously transported/handled or stored materials
- Staff hygiene

Development factors

- Temperature

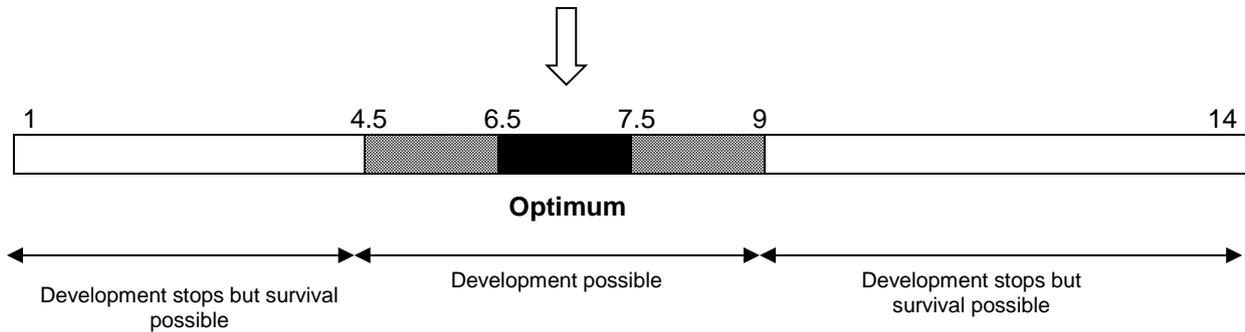
In case a heat treatment is necessary, the operator is advised to work according to the EU, local and national legislations or according to a recognised methodology.

Salmonella is sensitive to heat.



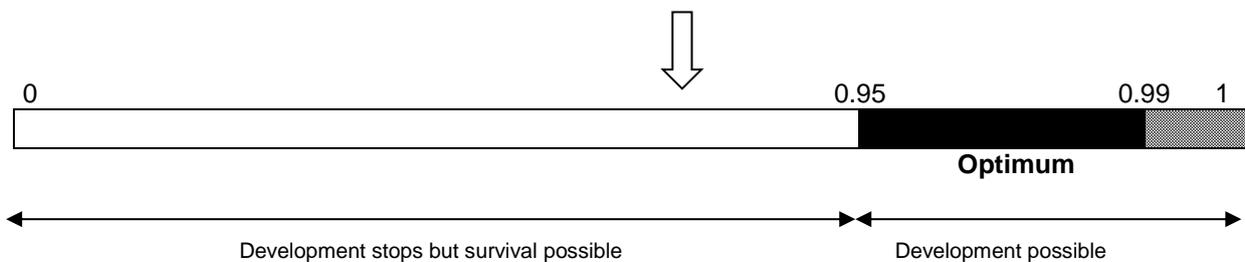
- pH

Acid treatment should be done according to the applicable current EU and national legislation. When such a methodology is used, appropriate labelling and information should be provided to the customers.



- Activity of water

Special attention should be taken in assuring that products are in an adequate low moisture level and that condensation is avoided as much as possible.



Control and Monitoring

With reference to products at risk such as oilseeds meals, and depending on the origin and the reported alerts, a regular monitoring and testing of products must be done while using adequate sampling and testing procedure (see & 3.1 and 3.2 of chapter 1 of this Guide). In case of a positive testing, procedures of serotyping, communications to customers & authorities, information on preventive treatments (chemical and/or by heat), disinfection of equipments and stores and labelling should be implemented, depending on the local national applicable rules or regulations. Research of the origin/source of contamination should be undergone in order to reduce/eliminate the contamination. An experienced person should pay attention in order to prevent condensation via proper ventilation system. The storekeeper should check on regular basis that storage and handling facilities are maintained as to prevent the occurrence of salmonella. This should be done applying appropriate sampling and testing methods and procedures. Contaminated products can be treated using a thermic treatment (with adequate duration and temperature level above 72°C) in approved facilities, if required at national level. Other treatments such as approved organic acids can help in preventing salmonella's development.

Food and feed safety risks

Mainly intestinal disorders.

Regulations and norms

There is no EU harmonised legislation for salmonella in feed materials. Each Member State has its own legislation and rules fixing the occurrence status and the actions to be taken in case of detection (who should be informed, which treatment, etc).

For more information, please refer to Article 15 (2) of Regulation (EC) No 178/2002 as amended. Please refer also to EFSA 2008 Scientific opinion regarding further information about Salmonella.

Regulation (EC) No 2160/2003 targets mainly 5 dangerous serotypes (strains) although attention should also be paid to other serotypes: S. Enteritidis – S. Typhimurium – S. Infantis – S. Hadar – and S. Virchow. Presence of any of those 5 serovars must usually be notified at animal production levels (primary and breeding). This Regulation applies to feed.

BACILLUS CEREBUS

Nature of the hazard

- Biological hazard

Classification

- *Bacillus cereus* belongs to the family of Bacillaceae, formed of bacilli which produce heat resistant spores. It is pathogenic for humans and animals. This micro-organism is frequently found in products rich in starch (rice, cereals etc.).
- *Bacillus cereus* is capable of producing two types of toxins one of which is heat stable. It is responsible for food poisoning due either to ingestion of the preformed toxin in the food, or ingestion of the bacterium.
- *Bacillus cereus* produces spores which give it a high survivability (form of heat, pressure and low Aw etc. resistance).

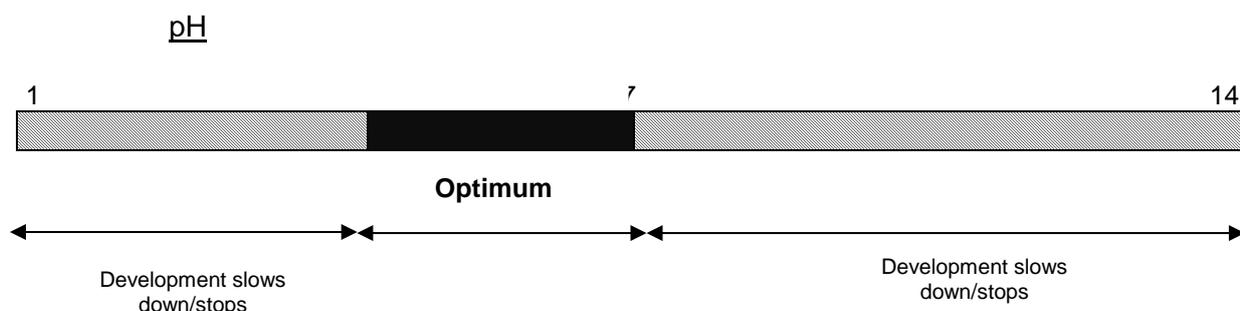
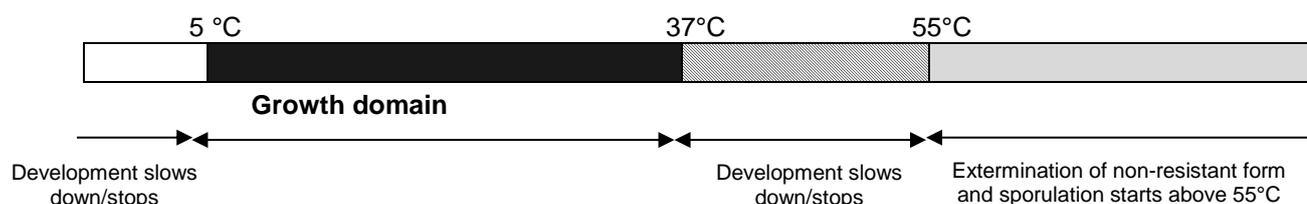
Origin

- Dust
- Soil
- Raw materials supplied

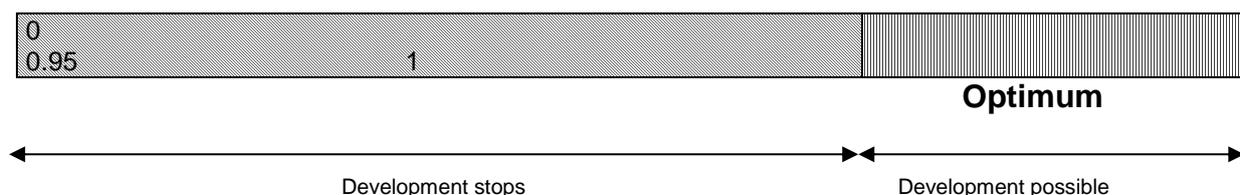
Factors in the development of *Bacillus cereus* and toxin production

- Temperature

Certain strains are capable of multiplying in the cold.



- Activity of water (Aw)



Food and feed safety risks

Gastro-intestinal disorders.

ALLERGENS (AMBROSIA)

Various botanical impurities can be found in food and feed materials as a consequence of not being fully removed during harvesting or because of cross contamination during handling and storage or transport operations. Some of these seeds do present some risks when consumed by humans or by animals.

Nature of the hazard

- Allergen hazard

Classification AMBROSIA

The genus Ambrosia (Asteraceae family) is distributed worldwide. Ambrosia artemisiifolia (common ragweed) has heavily colonised several areas of South-East Europe. Ambrosia spp., both in their native range and in invaded areas, are of public health concern due to the allergenic properties of their pollen.

A. artemisiifolia is a weed of waste ground and agricultural land that flourishes wherever soil is newly disturbed. Dispersion of Ambrosia occurs naturally through seed drop, movement by animals and surface water, and often follows human activities entering the different regions by transport with agricultural machines and excavated material.

Inhalation of the plant pollen causes rhino-conjunctivitis and asthma, with skin allergies and food allergy playing minor roles. Ambrosia may cross-sensitize patients to other allergens, including food allergens. There is some evidence for allergenicity of Ambrosia pollen in animals. However, there are some indications that **A. artemisiifolia** could become highly invasive in certain environmentally-valuable habitats and might be linked to an impoverishment of species richness; therefore further ecological studies are needed. The EFSA CONTAM Panel focused on the relative importance of animal feed, bird feed in particular, on the dispersion of Ambrosia. Ambrosia seeds may contaminate feed.

Animal feeds, including **maize, wheat, sunflowers, millet, peanuts, soybean, peas and beans** may contain seeds of Ambrosia. Commercial feed for livestock is processed prior to use and the procedures of grinding, pelleting and/or heating almost completely destroy the Ambrosia seeds. In contrast, bird feed used for the feeding of wild and ornamental birds, which is often contaminated with seeds of *A. artemisiifolia*, is generally not processed and hence may contribute to the dissemination of viable ragweed seeds. Therefore, bird feed seems to play an important role in introducing Ambrosia to new, previously not infested areas.

Origin of hazard

- Botanic impurities not fully removed during harvesting or during cleaning at reception silos
- Cross contamination during handling and storage or transport operations

Regulations and EU norms

a) For FEED

Section VI of EU Directive 2002/32/EC on undesirable substances in FEED sets the following limits AMBROSIA in Feed materials

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
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6. Seeds from Ambrosia spp.	Feed materials (¹¹), with the exception of:	50
	— Millet (grains of <i>Panicum miliaceum</i> L.) and sorghum (grains of <i>Sorghum bicolor</i> (L) Moench s.l.) not directly fed to animals (³)	200
	Compound feed containing unground grains and seeds	50

¹¹ “In case unequivocal evidence is provided that the grains and seeds are intended for milling or crushing, there is no need to perform a cleaning of the grains and seeds containing non-compliant levels of seeds of *Ambrosia* spp. before milling or crushing on the condition that

- the consignment is transported as a whole to the milling or crushing plant, and
- the milling or crushing plant is informed in advance of the presence of high level of *Ambrosia* spp. seeds in order take additional prevention measures to avoid dissemination into the environment, and
- solid evidence is provided that prevention measures are taken to avoid dissemination of *Ambrosia* spp. seeds into the environment during transport to the crushing or milling plant, and
- the competent authority agrees to the transport, after having ensured that the abovementioned conditions are fulfilled.

In case these conditions are not fulfilled, the consignment must be cleaned before any transport into the EU and the screenings must be appropriately destroyed.”

MELAMINE

Nature of the hazard

Melamine is a substance can react together with cyanuric acid to produce melamine cyanurate. This is a crystalline complex which is highly insoluble in water and which causes kidney problems which may result in death.

Classification:

- Chemical

Origin

Melamine is produced in high volumes mainly for the synthesis of melamine-formaldehyde resins used in the manufacture of laminates, plastics and coatings, including food contact materials such as kitchenware. In addition, melamine and a number of related compounds are used as flame retardants. The WHO1 (2009) reports the use of melamine containing sanitizing agent, like trichloromelamine and the use of sodium dichloroisocyanurate as disinfection agent of drinking-water. The latter can contain residual cyanuric acid, which can form an insoluble complex with melamine.

Control Measures

Products of Chinese origin need to be particularly monitored as well as those having an high protein content (such as oilseed meals, protein concentrate of SKM).

The following products trigger a higher risk to contain hazardous levels or exceeding maximum limits of melamine:

- Of vegetal origin, where during cultivation, cyromazine containing pesticides are / were used or where during cultivation melamine containing fertilizers are / were used.
- Where during sanitizing, products got into contact with melamine or melamine analogues containing sanitizing agents (e.g. trichloromelamine).
- Where during processing, water is used which is disinfected with sodium dichloroisocyanurate (being degraded to, amongst others, melamine).
- Products susceptible / of risk for adulteration by adding of melamine, are high protein products, like wheat gluten, rice protein, soy bean products, dairy products, fish meal, high protein concentrates.

Food and feed safety risks

Illegal adulteration of food and feed with melamine has resulted in illness and deaths of human infants and pet animals (cats and dogs), primarily as a result of kidney damage caused by crystals or stones in the urinary tract. The pets were given feed adulterated with crude (“scrap”) melamine also containing its analogues, and the crystals consisted of complexes of melamine with cyanuric acid. In the human infants, who were given infant formula adulterated with a relatively pure preparation of melamine, the crystals consisted of complexes of melamine with uric acid which occurs naturally in urine. Crystals have also been reported in livestock given feed contaminated with melamine and in experimental animals dosed with melamine either alone or together with cyanuric acid (EFSA3, 2010). The adulteration occurs, because commonly used methods for protein analysis cannot distinguish between nitrogen from protein sources and nitrogen from non-protein sources.

It results in incorrectly high protein measurements for products containing non-protein nitrogen sources like melamine and provides an economic incentive for their (illegal) addition (WHO1, 2009). Up to mid-2010 still batches of melamine contaminated milk products were found in China, originating from the incident in 2008. These batches should have been destroyed, but were not offered for destruction and again illegally mixed into food products

A specific risk in humans is the lack of uric acid oxidase (WHO1, 2009). Co-precipitation of melamine with uric acid is likely to occur in humans because they excrete more uric acid in the urine than most mammals due to a lack of the enzyme urate oxidase.

Regulations and norms

Melamine content in **FEED** is EU Regulated by Directive 2002/32/EC as amended by Regulation (EU) No 574/2011, with the following MRLs:

- Max 2.5 ppm (mg/kg) for all feed materials with 12% moisture for feed materials (except GAA guanidine acetic acid, urea and biuret)

Melamine content in **FOOD** is EU Regulated by Regulation (EC) No 1881/2006 as amended by Regulation (EU) No 594/2012, with the following MRLs:

- Max 2.5 ppm (mg/kg) for food, with the exception of infant formulae and follow-on formula (¹²)

¹² The maximum level does not apply to food for which it can be proven that the level of melamine higher than 2,5 mg/kg is the consequence of authorized use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine.

NITRITE

Nature of the hazard

Nitrate (formula NO₃) and nitrite (formula NO₂) are nitrogen compounds which are part of the nitrogen cycle. Through human activity (especially excess use of fertiliser) large amounts of extra nitrogen are added to certain phases of the natural nitrogen cycle. This leads to leaching and acidification. Nitrite is the conversion product of nitrate.

Nitrite is formed naturally by the nitrogen cycle during the process of nitrogen fixation and it is subsequently converted to nitrate, a major nutrient assimilated by plants. Two main nitrite salt forms occur, namely sodium and potassium nitrite.

Classification

- Chemical

Severity:

- High

Origin

- Excess uses of nitrates/nitrogen fertilisers. Nitrite in drinking water is regulated in Europe, with a maximum level of 0.5 mg/L. Nitrate levels in forages are naturally high and the inter-conversion of nitrate to nitrite is the largest contributor to nitrite exposure in food-producing animals.

Control measures:

- Establish purchasing requirements
- Expert use of fertilisers
- Monitor cultivation area (certified)
- Plot history
- Prevent overdosing of nitrate
- Received product analysis
- Soil history
- Water management

The control measures specified in this fact sheet are all control measures which can be used depending on the product and/or process step.

Food and feed safety risks

It may act as a carcinogen for chronic exposure. Acutely, nitrite is approximately ten-fold more toxic than nitrate and three main toxicological endpoints have been identified: methaemoglobin formation (in a wide range of species including man), hypertrophy of the adrenal zona glomerulosa (rats), and equivocal evidence for carcinogenesis (female mice). In monogastric animals, most nitrite is formed and absorbed in the upper digestive tract. In contrast in ruminants, nitrite and nitrate is metabolised by the rumen flora. Reports of adverse effects after excessive nitrite exposure in livestock exist, and pigs and ruminants, as major food producing animals, are particularly susceptible: this is because of relatively low nitrite reductase activity and high levels of rumen conversion of exogenous nitrate to nitrite, respectively.

Regulations

Nitrites content in **FEED** is EU Regulated by Directive 2002/32/EC as amended, with the following MRLs:

- 15 ppm (mg/kg) (expressed in sodium nitrite) for feed with 12% moisture for feed materials (except fishmeal, silage and complete feedingstuffs)

RADIONUCLEIDS

Nature of the hazard

Radioactivity is the special characteristic of a chemical substance that emits radiation. We call that a radioactive substance. This may be a gas, vapor, liquid or solid substance. Known radioactive substances are: Cobalt, Caesium, Iodine, Radium, Uranium and Plutonium.

It is necessary to make a distinction between radioactive contamination and Irradiation

Radioactive contamination occurs when radioactive materials deposits on products or animals or is eaten/breathed by an animal, while Irradiation occurs when a living animal/human or an object is submitted to a ionising emission. Contamination is legally defined by an undesirable presence, at a significant level, of radioactive substances in or on a specific mean. In case of irradiation, the objet or animal/human needs just to be put at a greater distance from the emitting source for the irradiation to stop while in case of contamination, especially in case of ingestion of radioactive substance, the internal irradiation is much more difficult to eliminate. In worst case, if the amount of ingested radioactive substance is high, the human or animal or vegetal can become himself a source of irradiation.

Radioactive contamination can propagate in the food and feed chain, and a living being becomes contaminated after having eaten a contaminated plant or animal.

Classification

- Chemical

Severity

- High

Origin

Spillage or explosion of a plant using nuclear fuels or use of plants grown on land having been contaminated by nuclear residues (wastes or atmospheric deposits)

Control measures

Avoid risk areas (such as Japan “Fukushima” area or Ukraine “Tchernobyl area”)

Measuring radioactivity

Ionizing radiation is ubiquitous in the environment, and also comes from radioactive materials, X-ray tubes, and particle accelerators. It is invisible and not directly detectable by human senses, so instruments such as Geiger counters are usually required to detect its presence.

There are four different but interrelated units for measuring radioactivity, exposure, absorbed dose, and dose equivalent. These can be remembered by the mnemonic R-E-A-D, as follows, with both common (British, e.g., Ci) and international (metric, e.g., Bq) units in use:

- Radioactivity refers to the amount of ionizing radiation released by a material. Whether it emits alpha or beta particles, gamma rays, x-rays, or neutrons, a quantity of radioactive material is expressed in terms of its radioactivity (or simply its activity), which represents how many atoms in the material decay in a given time period. The units of measure for radioactivity are the curie (Ci) and becquerel (Bq).
- Exposure describes the amount of radiation traveling through the air. Many radiation monitors measure exposure. The units for exposure are the roentgen (R) and coulomb/kilogram (C/kg).
- Absorbed dose describes the amount of radiation absorbed by an object or person (that is, the amount of energy that radioactive sources deposit in materials through which they pass). The units for absorbed dose are the radiation absorbed dose (rad) and gray (Gy).

- Dose equivalent (or effective dose) combines the amount of radiation absorbed and the medical effects of that type of radiation. For beta and gamma radiation, the dose equivalent is the same as the absorbed dose. By contrast, the dose equivalent is larger than the absorbed dose for alpha and neutron radiation, because these types of radiation are more damaging to the human body. Units for dose equivalent are the roentgen equivalent man (rem) and sievert (Sv), and biological dose equivalents are commonly measured in 1/1000th of a rem (known as a millirem or mrem).

For practical purposes, 1 R (exposure) = 1 rad (absorbed dose) = 1 rem or 1000 mrem (dose equivalent).

Note that a measure given in Ci tells the radioactivity of a substance, while a measure in rem (or mrem) tells the amount of energy that a radioactive source deposits in living tissue. For example, a person would receive a dose equivalent of 1 mrem from any one of the following activities:

The becquerel (symbol Bq) is the SI-derived unit of radioactivity. One Bq is defined as the activity of a quantity of radioactive material in which one nucleus decays per second. The Bq unit is therefore equivalent to s⁻¹

In a fixed mass of radioactive material, the number of becquerels changes with time. Therefore, a sample radioactive decay rate is always stated with a timestamp for short-lived isotopes, sometimes after adjustment to some specific date of interest (in the past or in the future).

Food and feed safety risks

Radiations, depending on their strength, have clear genetic effects, including the effect on cancer risk.

Ionizing (or ionising) radiation is radiation with sufficient energy to remove an electron from an atom or molecule. This ionization produces free radicals, atoms or molecules containing unpaired electrons, which tend to be especially chemically reactive.

The degree and nature of such ionization depends on the energy of the individual particles (including photons), not on their number (intensity). Exposure to radiation causes damage to living tissue, and can result in mutation, radiation sickness, cancer, and death. If the dose is sufficient, the effect may be seen almost immediately, in the form of radiation poisoning.

Regulations

For FEED products:

- Regulation No 770/90/Euratom fixes an MRL of 500 Bq/Kg (basis 12% moisture) for Sum of Cs-134 and Cs-137-

However, in order to ensure consistency with MRL applies in Japan, the following values replace on a provisional basis those fixed by Regulation 770/90 as from 1st April 2012 and until 31 March 2014 (Regulation (EU) No 996/2012 as amended)

Reg EU 996/2012 dd 26 oct 2012				
<i>repeals EU Reg 284/2012 repealing Reg 961/2011 repealing Reg 351/2011)</i>				
value applicable until 31 march 2014				
maximum levels for FEED with 12% moisture in Bq/Kg as provided by Japanese legislation				
radionucleides	Feed intended for cattle and horses	Feed intended for pigs	Feed intended for poultry	Feed for fish
Sum of caesium-134 & caesium-137	100	80	160	40
<i>in order to ensure consistency with MRL currently applied in Japan, these values replace on a provisional basis the values laid down in Reg (Euratom) 770/90</i>				

For FOOD products:

- Regulation (EEC) No 3954/87 as amended by Regulation (EU) No 996/2012 fixes MRLs for Sum of Cs-134 and Cs-137

However, in order to ensure consistency with MRL applies in Japan, the following values replace on a provisional basis those fixed by Regulation (EC) No 3954/87 as from 1st April 2012 and until 31 March 2014:

Reg EU 996/2012 dd 26 oct 2012				
<i>repeals EU Reg 284/2012 repealing Reg 961/2011 repealing Reg 351/2011)</i>				
value applicable until 31 march 2014				
maximum levels for FOOD in Bq/Kg as provided by Japanese legislation				
radionucleides	Food for infants and young children	Mil and milk-based drinks	other food, with the exception of mineral water & similar drinks- tea brewed from unfermented leaves	mineral water & similar drinks & tea brewed from unfermented leaves
Sum of caesium-134 & caesium-137	50	50	100	10
<i>in order to ensure consistency with MRL currently applied in Japan, these values replace on a provisional basis the values laid down in Reg (Euratom) 3954/87</i>				
Transitional measures maximum levels for FOOD in Bq/Kg as provided by Japanese legislation				
radionucleides	Milk & dairy products, mineral water & similar drinks produced before 31 March 2012	Other Foods, except for rice, soybean & processed products thereof produced before 31 March 2012	Products made from rice, produced before 30 Sept 2012	Soybean harvested before 31 Dec 2012 and Products made from soybean produced 31 dec 2012
Sum of caesium-134 & caesium-137	200	500	500	500

PAH & BAP

Nature of the hazard

- Chemical hazard

Classification

Benzo(a)pyrene belongs to the group of polycyclic aromatic hydrocarbons (PAH) and is used as a marker for the occurrence and effect of carcinogenic PAH in food including also benz(a)anthracene, benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(k)fluoranthene, benzo(g,h,i)perylene, chrysene, cyclopenta(c,d)pyrene, dibenz(a,h)anthracene, dibenzo(a,e)pyrene, dibenzo(a,h)pyrene, dibenzo(a,i)pyrene, dibenzo(a,l)pyrene, indeno(1,2,3-cd)pyrene and 5-methylchrysene. C₂₀H₁₂, is a five-ring polycyclic aromatic hydrocarbon whose metabolites are mutagenic and highly carcinogenic. Benzo[a]pyrene is listed as a Group 1 carcinogen by the IARC. A certain number of polycyclic aromatic hydrocarbons (PAH) are genotoxic carcinogens. PAH can contaminate foods during smoking processes and heating and drying processes that allow combustion products to come into direct contact with food. In addition, environmental pollution may cause contamination with PAH, High levels of PAH were found in dried fruits, olive pomace oil, smoked fish, grape seed oil, smoked meat products, fresh molluscs, spices/sauces and condiments.

Origin

Benzo[a]pyrene is a product of incomplete combustion at temperatures between 300 and 600 °C. Benzo[a]pyrene is found in coal tar, in automobile exhaust fumes (especially from diesel engines), in all smoke resulting from the combustion of organic material (including cigarette smoke), and in charbroiled food.

Regulations and EU norms

a) For FOOD

Regulation (EU) No 835/2011 of 19 August 2011 amends Regulation (EC) No 1881/2006 as amended as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs.

	Foodstuffs	Maximum levels (yg/kg)	
6.1	Benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene	Benzo(a)pyrene	Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene ⁽⁴⁵⁾
6.1.1	Oils and fats (excluding cocoa butter and coconut oil) intended for direct human consumption or use as an ingredient in food	2.0	10.0
6.1.8	Processed cereal-based foods and baby foods for infants and young children ⁽³⁾ ⁽²⁹⁾	1.0	1.0
⁽⁴⁵⁾ Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.			

Storage insecticide residues and specific feed PPP MRLs

Nature of the hazard:

- Chemical hazard

Classification

An insecticide is any substance used to combat the presence or appearance of insects and mites in stored grains.

Origin

- Raw materials supplied
- Insecticide treatment
- Insecticide treatment equipment
- Cross contamination with residues of treated previous cargoes or residues of pesticides on walls/floors/handling equipment's

Food and feed safety risks

Toxicity above the regulatory concentration threshold.

When products are to be used for FEED, it is important to:

- First check in the FEED Directive 2002/32/CE “undesirable substances” if the concerned Active substances is listed in the Appendix and if a specific MRL has been fixed for it ([see table next page](#))
- If not, then check in the EU pesticide Regulation (EC/396/2005) database if a specific MRL has been fixed for this simple product or group of products- If not , the default max 0.01ppm * (* = Lower Limit of Analytical Determination) will apply for simple not processed products.(see http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection&ch=1) Please check the possible existence of some footnotes which allows some having an MRLs higher than the one fixed in the Regulation (EC) No 396/2005 provided the product is to be used only for feed (concerns sorghum, millet, palm fruits and palm kernels feed products)
- For processed products, the Regulation (EC) No 396/2005 as amended foresees the possible use of “processing factors” for the evaluation of pesticides residues. Such processing factors could be yet included in Appendix VI of Regulation (EC) No 396/2005 (concentration or dilution factors) and related to the pesticide solubility in fat (F factor) or in water (LogPow or “Octanol/water partition coefficient” which can be found in the ICSCs and also take into account the concentration or dilution factor of the product.

Article 18(3) of Regulation (EC) No 396/2005 allows MS to authorise the use of product which may contains residues of post-harvest fumigants treatments with a level above the MRLs provided a) that the product is not intended for immediate consumption (this should cover the fact that some cargoes received could have a content of Phosphine above 0.1 ppm, provided that it does not present danger for the workers) and b) appropriate controls are in place to ensure that such products cannot be made available to the end user or consumer, if they are supplied directly to the latter, until the residues no longer exceed the maximum levels specified in Annexes II or III of EC Erg 396/2005 and (c) the other Member States and the Commission have been informed of the measures taken.

Article 18(4) of Regulation (EC) No 396/2005 also states that “In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or pursuant to obligations set out in Directive 2000/29/EC (1), a Member State may authorise the placing on the market and/or the feeding to animals within its territory of treated food or feed not complying with paragraph 1, provided that such food or feed does not

constitute an unacceptable risk. Such authorisations shall immediately be notified to the other Member States, the Commission and the Authority, together with an appropriate risk assessment for consideration without undue delay with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products.”

The list of substances (fumigants) concerned by this Art 18(3) has been published in Regulation (EU) No 260/2008 of 18/3/2008 adding an Annex VII to Regulation (EC) No 396/2005, including Hydrogen phosphide, Aluminium phosphide, Magnesium phosphide (the 3 covers as well uses in cereals than in oilseeds and oilfruits) and Sulfurylfluoride (for cereals only)

Regulations

Characteristics of the active materials approved for the treatment of stored cereals.

Only aluminium and magnesium phosphide are approved for insecticide treatment of stored oilseeds. Nevertheless, there is an MRL for the following insecticides:

Insecticide active material	Authorized dose in substance (g/ t)	Persistence or duration of the product's action after application	Maximum Residue Limit (mg/ kg) <u>Cereals</u>	Maximum Residue Limit (mg/ kg) <u>Oil and protein seeds</u>
Bifenthrin	Non authorised for use in the EU		Wheat,Oats, triticale, barley: 0.5 Other: 0.05*	Oilseeds: 0.1* Pulses, dry: 0.05
Malathion (can be used until 01/12/2008)-re authorised 01 May2010 at EU level but not yet at MS level)	8	< 3 months	8	Oilseeds: 0.02* Pulses: 0.02*-
Pirimiphos-methyl	4	> 6 months	5 (could be reduced at 0.5 ppm in Maize/rice/rye)	0.05* for pulses and oilseeds (could be raised at 0.5 ppm)
Chlorpyriphos-methyl	2.5	> 6 months	3	0.05* for pulses and oilseeds
Deltamethrin	0.5-1	> 6 months	2	0.05 for oilseeds (0.1 for rape and 1.0 for pulses)
Cypermethrin		18 months	Barley, oats, Rye, Wheat: 2 ppm Maize, Sorghum, millet: 0.3 ppm	Rape, Sunflower, Linseeds: 0,2 ppm Soybean, other oilseeds and pulses: 0,05 ppm
Butoxide Pyperony (a synergisant of delatmethrin or pyrethroids)	Not EU regulated	Could become regulated with the implementation of the new endocrine disruptor rules	10 ppm in France for cereals	
Natural pyrethrins		< 1 month	3	pulses: 3 oilseeds: 3

Phosphines and phosphides (* :sum of aluminium phosphide, aluminium phosphine, magnesium phosphide, magnesium phosphine, zinc phosphide and zinc phosphine)	2	No persistence	0.1*	0.1 for oilseeds and peas 0.05for oilseeds and pluses Except Rape, Sun,peas: 0.1
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Main regulations

- **Regulation (EC) No 149/2008 as amended and Regulation (EC) No 396/2005 as amended.**
- for verification of **EU Pesticides MRL database** , consult DG SANTE web database:
 - http://ec.europa.eu/sanco_pesticides/public/index.cfm
- **Sampling methods** for official controls of pesticides residues to be done according to EU Directive 2002/63/EC of 11 July 2002.
- **Performance of analytical methods and the interpretation of results** to be done according to Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC.
- **Method validation and Quality control procedures for pesticides residues analysis** in Food and Feed based on Document SANCO/10684/2009.
- **A new Regulation (EU) No 691/2013 of 19th July 2013** amends Annexes I and II of Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed as regards methods of sampling

APPENDIX 5

ESTABLISHING THE SCALES FOR ANALYSING HAZARDS

Appearance scale

The appearance scale corresponds to the likelihood of occurrence of a hazard, ranging from technically not existent to certain.

NOTE	CRITERIA
1	Practically non-existent. The likelihood of the hazard being present is very small and has never occurred to date.
2	Possible. An occasional defect or fault has appeared in the past. If the product's control is poor at this point, the hazard will only be present in one part of a single batch.
3	Common. The hazard is regularly present. If the product's control is poor at this point, the hazard will be present in an entire product batch.
4	Certain. The hazard is always present. If the product's control is poor at this point, the hazard will affect several product batches.

Detection scale

The detection scale corresponds to the probability/likelihood of the hazard within the frame of normal monitoring actions taken according to the operator's risk assessment.

NOTE	CRITERIA
1	The hazard can always be detected during controls.
2	The hazard is detected most of the time during controls carried out. A few defects may escape detection but will be systematically located before the product is released (dispatch).
3	A large proportion of defects will not be detected during controls but the majority will be located during the product's release (final control before dispatch).
4	The hazard is not apparent. The hazard requires significant investigations in order to be detected.

Severity scale

The severity of a hazard corresponds to the significance of its consequences.

NOTE	CRITERIA
1	Minor severity: Consumption of the hazardous product may have a negative effect on the product's taste but does not affect the consumer's food and feed safety. Where regulatory thresholds have been set, the results from analyses show zero or low values.
2	Medium severity: Consumption of the hazardous product may have a slight effect on the consumer's food and feed safety (sensitive people) if subject to prolonged exposure to the hazard. Where regulatory thresholds have been set, the results from analyses show low values.
3	Critical severity: Consumption of the hazardous product may affect the consumer's food and feed safety (although without the need for hospitalization) if subject to prolonged exposure to the hazard. Where regulatory thresholds have been set, the results from analyses are close to the maximum levels.
4	Catastrophic severity: Consumption of the hazardous product may cause serious food and feed safety problems (hospitalization, death) for some people (or the

	entire population). Where regulatory thresholds have been set, the results from analyses are higher than the regulatory standards.
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APPENDIX 6

HAZARD ANALYSIS TABLES (EXAMPLES¹³)

¹³ For various food and feed processed products, it is recommended to consult the hazard analysis tables developed within the respective sectorial Guides as approved by the EU Commission and published on their website at:

http://ec.europa.eu/food/food/animalnutrition/feedhygiene/guide_goodpractice_en.htm

Product Cereals, oilseeds and protein crops						
Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
Ergot	Receipt of contaminated goods	3	1	2	6	Advisory approach with farmers (use of certified seeds or graded farm seeds, compliance with the good practices guide for field crops). Carry out controls on receipt – Train staff in detecting ergot.
Moulds including bunt	Contaminated goods: Receipt from a storage crib (maize) Receipt of wet goods (inflows) Receipt of contaminated goods	1 1 1	2 2 2	2 1 2	4 2 4	Choose a variety adapted to its environment. Advisory approach with farmers (crib drying, ripeness, previous crop, cultivation (labour), phytosanitary protection), compliance with the good practices guide for field crops. Adjust the threshing equipment (broken seed problem). Carry out controls on receipt and make corrective action decisions. Train staff in detecting bunt.
Mycotoxins <i>Fumonisin, DON, Zearalenone</i> Aflatoxins (in case of special dry and hot weather during flowering of maize)	Contaminated material: Receipt of <u>contaminated goods</u> Receipt from a storage crib Receipt of wet <u>goods</u> (inflows)	3	2	4	24	Advisory approach with farmers (variety chosen, previous crop, cultivation (labour), phytosanitary protection, ripeness, harvest date, crib drying, storage, cleaning / maintenance of the equipment etc.). Combat borer insects to limit the development of fumonisins. Comply with the good hygiene practices guide for field crops.
Ochratoxin A	Goods contaminated following barn storage Receipt from a storage crib	3	2	4	24	Raise farmers' awareness on controlling their storage.

Product Cereals, oilseeds and protein crops, other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Insects</u>	Infested goods:					
	Goods delivered during harvest time	1	1	2	2	Train silo/warehouse staff in insect detection. Increase the farmer's awareness on controlling his storage. Controls on receipt.
	Goods delivered outside harvest time	1	2	2	4	
	Infested equipment:					
Pitt	1	1	3	3	Cleaning of the operator's pits and transport equipment. Increase silo staff's awareness on cleaning the pits. (Pesticide treatment on the pits). Increase the farmer's and driver's awareness on cleaning the transport equipment.	
Transport equipment (farmer, collection/storage organizations, service provider)	1	1	3	3		
<u>Residues from storage pesticides</u>	Goods already treated by the farmer or collection/storage organization (transfer):					
	Goods delivered during harvest time	3	1	4	12	Monitoring/recording of treatments on the delivery note. Training and awareness raising for silo staff and farmers on approved treatment methods and their consequences.
	Goods from storage	3	2	4	24	
	Goods treated with an unapproved product (e.g. oilseeds)	3	1	4	12	

G severity index

F frequency of appearance index

D detection index

R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Moulds</u>	<p>Method: Too long storage duration of a contaminated good with a high humidity level and/or high % of broken grains or level of impurities) e.g. for maize with a humidity level > 30 - 32% > 72 hr</p>	1	2	3	6	<p>Organization of the harvests. Management of the time periods between collection and drying. Rotation of hoppers or pre-storage areas (FIFO – First In First Out principle). Management of the dryers. Raise contractors', farmers' and employees' awareness on the harvest time.</p>
<u>Mycotoxins</u>	<p>Method: Too long storage duration of a contaminated good with a high humidity level and/or high % of broken grains or level of impurities) e.g. for maize with a humidity level > 30 – 32% > 72 hr</p>	3	2	4	24	<p>Organization of the harvests. Management of the time periods between collection and drying. Rotation of hoppers or pre-storage areas (FIFO – First In First Out principle). Management of the dryers. Raise contractors', farmers' and employees' awareness on the harvest time.</p>

G severity index

F frequency of appearance index

D detection index

R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Insects</u>	No conceivable cause					
<u>Residues from storage pesticides</u>	No conceivable cause					

G severity index

F frequency of appearance index

D detection index

R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Moulds</u>	Equipment / Method: Poor operation of the dryer Discontinuous operation of the dryer	1	2	3	6	Maintenance of the dryer. Management of the dryers. Awareness raising/training for staff in operating a dryer.
<u>Mycotoxins</u>	Equipment / Method: Poor operation of the dryer Discontinuous operation of the dryer	3	1	4	12	Maintenance of the dryer. Management of the dryers. Awareness raising/training for staff in operating a dryer. Control the humidity of the goods.
Dioxins and DL-PCBs	Direct drying can pose a significant risk to feed (and food) safety in regard to dioxins when improper fuel is used in the process or due to poor maintenance of the dryer).	3	2	4	24	Maintenance of the dryer.. check leakage of heat exchanger Management of the dryers. Awareness raising/training for staff in operating a dryer.- Forbid use of “dangerous” fuels such as used engines lubricants, pyralene, treated woods, ect.. and favour use of natural gaz when possible

G severity index
 F frequency of appearance index
 D detection index
 R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures						
		G	F	D	R							
Moulds	<u>Equipment:</u> Unloading points too high (broken grains)	1	2	3	6	Maintenance – Cleaning of the bins – Cleaning of the silo / pesticide treatment. Good storage design.						
	Poor bin sealing (infiltration of water)											
	Ineffective ventilation (performance of the ventilator, height of the bins, extraction)											
	Insufficiently clean bins											
	Dryeration bins not isolated from the other bins											
	Lack of thermometry											
<u>Method:</u> Poor bin rotation	Ineffective cleaning of the grains	1	2	3	6	Staff training. Cleaning of the grains - Projected storage plan Storage management: temperature reading – ventilation method Visual control						
	Lack of or unsuitable ventilation											
	Mixing of goods											
	Damp raw material											
	Mycotoxins <i>(Ochratoxin A and/or Aflatoxins)</i>						<u>Equipment:</u> Unloading points too high (broken grains)	3	2	4	24	Staff training. Cleaning of the grains - Projected storage plan Storage management: temperature reading – ventilation method
							Poor bin sealing (infiltration of water)					
Ineffective ventilation (performance of the ventilator, height of the bins, extraction)												
Insufficiently clean bins												
Dryeration bins not isolated from the other bins												
Lack of thermometry												
<u>Method:</u> Poor bin rotation	Ineffective cleaning of the grains	3	2	4	24	Maintenance – Cleaning of the bins – Cleaning of the silo / pesticide treatment. Good storage design.						
	Lack of or unsuitable ventilation											
	Mixing of goods											

G severity index

F frequency of appearance index

D detection index

R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures	
		G	F	D	R		
Insects	Equipment infested (bin and handling equipment) or faulty (thermometry, ventilator). Cereals Oilseeds	1 1	2 1	2 2	4 2	Cleaning and pesticide treatment if required of the storage bins and handling equipment. Control of the equipment's correct operation (thermometry, ventilator). Temperature control. Visual control Train silo staff in storage methods. Operating methods adapted to the silo facilities (example: ventilation operating method).	
	Environment: Temperature and humidity conditions favouring the proliferation of the insects. Cereals Oilseeds	1 1	2 1	2 2	4 2		
	Method/labour (absence of or poor ventilation, long storage duration): Cereals Oilseeds	1 1	2 1	2 2	4 2		
Salmonella	Contamination by bird's or rodents or bad hygiene practices	2	2	3	12	Check regularly goods when receipt- Ensure that all entrances of the stores are well closed by nets or other materials and ante- rodents measures well implemented. Stores to be maintained well clean and dry and appropriately decontaminated when salmonellas are detected	

G severity index
 F frequency of appearance index
 D detection index
 R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Residues from storage pesticides</u>	Contamination of the goods by a leak in the pesticide treatment equipment. Contamination or cross-contamination of the goods by the circuits and/or bins.	3	1	4	12	Maintenance and verification of the pesticide treatment equipment. Control of the drum levels. If possible, dedicate the circuits for oilseeds goods or drain the circuits.
	Method Poor regulation of the equipment, grain flow variation, multiple treatments leading to an overdose, waiting time necessary after treatment and before use of the goods is insufficient. <i>Product not approved for oilseeds</i>	3	2	4	24	Operating method/train staff in pesticide treatment methods, the product choices and the dose applied. Increase staff awareness (silo, production, drivers, boat men etc.) on complying with waiting times after treatment of the goods and before their use. Servo-control for the elevator's functioning, Monitoring / recording Periodic maintenance and control of the treatment equipment Periodic verification of the handling equipment's flow.
<u>Insects</u>	Method (unsuitable treatment, under dosage).	1	2	2	4	Monitoring / recording Periodic maintenance and control of the treatment equipment Periodic verification of the handling equipment's flow. Operating method/train staff in pesticide treatment methods, the product choices and the dose applied. Servo-control for the elevator's functioning.

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Moulds</u>	Accidental mixing of goods with non-compliant raw materials.	1	1	3	3	Cleaning / Identification of the batches.
<u>Mycotoxins</u>	Accidental mixing of goods with non-compliant raw materials.	3	1	4	12	Identification of the batches / Cleaning.
Insects	Contamination during mixing by an infested good.	1	2	2	4	Identification of the contaminated batches. Sampling control
	Infested equipment (handling equipment, bins or hoppers, size grading machine, cleaner - separator).	1	1	2	2	Cleaning and pesticide treatment of equipment, if required.
GMOs	Accidental mixing of goods					Not a food or feed safety issue but more a contractual and/or labelling issue (case of product contained or derived from Approved GMOs)

G severity index

F frequency of appearance index

D detection index

R risk or criticality = G * F * D

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Moulds</u>	Wet goods loaded:					
	• Because of loading in the rain (unprotected loading)	1	2	1	2	Instructions to stop loading in bad weather or to protect the goods.
	• Because goods were wet when loaded	1	2	1	2	Goods inspections: humidity, visual, smell. Limit the transport time.
	Cleaning difficult due to equipment design.	1	2	2	4	Raise staff awareness on cleaning and inspections (driver, boat man, silo operator etc.).
	The container has a faulty seal Container remains wet after cleaning.	1	2	3	6	Specifications with the transport service providers requiring cleaning of the transport equipment.
	Rotting residue from the previous transport:	1	2	3	6	Inspections: visual, smell, documentary.
	• Lorry / Barge • Train	1	1	1	1	Maintenance of the transport equipment.
carriage of undried goods: duration too long (barge / wagon). Duration > 72 hr (e.g. for maize with a humidity level > 30-32%)	1	2	3	6	Raise the transporters awareness on transport times.	

Product Cereals, oilseeds and protein crops, other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Mycotoxins</u> <i>Fumonisin</i> , <i>DON</i> , <i>Zearalenone</i> , <i>Ochratoxin A</i>	Wet goods loaded:					Instructions to stop loading in bad weather Goods inspections: humidity, visual, smell – Limit the transport time. Raise staff awareness on cleaning and inspections (driver, boat man, silo operator etc.). Specifications with the transport service providers requiring cleaning of the transport equipment. Inspections: visual, smell, documentary. Maintenance of the transport equipment. Raise the transporter's awareness on transport times.
	<ul style="list-style-type: none"> Because of loading in the rain (unprotected loading) 	3	1	4	12	
	<ul style="list-style-type: none"> Because goods were wet when loaded 	3	1	4	12	
	Cleaning difficult due to equipment design. The container has a faulty seal	3	1	4	12	
	Container remains wet after cleaning.	3	1	4	12	
	Rotting residue from the previous transport:	3	1	4	12	
	<ul style="list-style-type: none"> Lorry / Barge Train 	3	1	4	12	
	carriage of undried goods: duration too long (barge / wagon).	3	2	4	24	
<ul style="list-style-type: none"> Duration > 72 hr (e.g. for maize with a humidity level > 30-32%) 	3	1	4	12		

Product Cereals, oilseeds and protein crops , other plant products and products derived thereof

Hazard	Causes of the hazard	Hazard analysis				Recommended preventive measures
		G	F	D	R	
<u>Insects</u>	Infested goods	1	2	2	4	Good storage practices.
	Infested handling equipment.	1	2	3	6	Cleaning and pesticide treatment of handling equipment, if required.
	Infested vehicle:					
	<ul style="list-style-type: none"> Container design which favours residues (lorries: moving bases, locks, tyres, tarpaulin; boat: floor, hatches, wooden panels; train: hatches, corners of the wagon) 	1	2	3	6	Specifications with the transporters with a requirement to avoid using certain containers.
	<ul style="list-style-type: none"> Container contaminated by a previous transport – residue from contaminated goods: 	1	2	3	6	Control of the container: visual, smell, documents – Verification that this control has been carried out by the approver. Specifications with the transporters with a requirement regarding the vehicle's cleanliness. Cleaning of his/her vehicle by the storage organization.
Poor cleaning – lack of staff controls	1	1	3	3	Increase staff awareness (silo, drivers) on cleanliness and vehicle cleaning.	
Loaded carriage: duration too long (barge / wagon).	1	1	3	3	Increase the transporter's awareness on transport times – preventive treatment of the batch.	

G severity index
D detection index

F frequency of appearance index
R risk or criticality = G * F * D

APPENDIX 7

ACRONYMS & ABBREVIATIONS

- **AFNOR** (Association française de normalisation / French Standards Association)
- **AFSSA** (Agence française de sécurité sanitaire des aliments / French Food Safety Authority) : created by law no. 98-535 of 01 July 1998, OJ of 02/07/1998, the new Agency is mainly responsible for assessing the sanitary and nutritional risks that may be present in foods intended for humans or animals, including water intended for human consumption.
- **ARVALIS-Institut du végétal / Plant Institute** Technical centre for research and development of cereal production procedures in France, merger of the ITCF and the AGPM (Association Générale des Producteurs de Maïs / General Association of Maize Growers) Technique.
- **CETIOM** (Centre Technique Interprofessionnel des Oléagineux Métropolitains / Technical Centre for Oilseeds Crops) Technical centre for research and development of oilseeds production procedures in France.
- **COCERAL** (Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures)
- **Codex Alimentarius** FAO (Food and Agriculture Organisation) / WHO (World Health Organization) joint committee, the Codex Alimentarius Commission whose aim is to create standards to protect consumer safety and ensure fair practices in the foodstuff trade, these standards are used as a reference by the World Trade Organization (WTO) when assessing the extent to which the national regulations and their methods of application are an excessive hindrance.
- **Coop de France - Métiers du Grain** (French Agricultural Cooperative Union for Collection, Supply and Processing)
- **COPA-COGECA** (European Farmers And European Agri-Cooperatives)
- **FNA** (Fédération du Négoce Agricole / Union of Agro-Businesses)
- **ISO** (International Organization for Standardization)
- **ITCF** (Institut Technique des Céréales et des Fourrages / Technical Institute for Cereals and Forage)
- **ONIGC** (Office National Interprofessionnel des Grandes Cultures / National Interprofessional Office for Crops)
- **ONIDOL** (Organisation Nationale Interprofessionnelle des Oléagineux / National Oilseeds Interprofessional Organization)
- **SYNACOMEX** (Syndicat National du Commerce Extérieur des Céréales)
- **UNIP** (Union Nationale Interprofessionnelle des Plantes Riches en Protéines / National Protein crops Interprofessional Union)
- **UNISTOCK** (European Association of Professional Portside Storekeepers for Agribulk Commodities within the European Union)

APPENDIX 8

REGULATORY REFERENCES

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- [Council Regulation \(EEC\) No 315/93](#), of 8 February 1993, laying down Community procedures for contaminants in food.
- [Regulation \(EC\) No 999/2001](#) of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.
- [Regulation \(EC\) No 178/2002](#) of the European Parliament and of the Council 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.
- [Regulation \(EEC\) No 852/2004](#) of the European Parliament and of the Council of 29 April 2004, on the hygiene of foodstuffs.
- [Regulation \(EEC\) No 882/2004](#) of the European Parliament and of the Council of 29 April 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- [Regulation \(EEC\) No 183/2005](#) of the European Parliament and of the Council of 12 January 2005, laying down requirements for feed hygiene.
- [Directive 2001/96/EC](#) of the European Parliament and the Council of 4 December 2001 establishing harmonised requirements and procedures for the safe loading and unloading of bulk carriers.
- [Regulation \(EC\) No 767/2009](#) of the European Parliament and of the Council 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.
- [Regulation \(EC\) No 1774/2002](#) as repealed by [Regulation \(EC\) No 1069/2009](#) of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption.
- [Commission Regulation \(EU\) No 790/2010](#) of 7 September 2010 amending Annexes VII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption.
- [Commission Regulation \(EC\) No 152/2009](#) of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed.
- [Commission Regulation \(EU\) No 709/2014](#) of 20 June 2014 amending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls.
- [Commission Regulation \(EU\) No 225/2012](#) of 15 March 2012 amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof.
- [Regulation \(EU\) No 1169/2011](#) of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

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- [Directive 2000/59/EC](#) of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residues - Commission declaration.
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- [Commission Regulation \(EU\) No 579/2014](#) of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea.
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Contaminants in food

- [Commission Regulation \(EC\) No 1881/2006](#) of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs [Heavy metals and Mycotoxins in particular].
- [Commission Regulation \(EU\) No 2015/1006](#) of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs.
- [Commission Regulation \(EU\) No 165/2010](#) of 26 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins.
- [Commission Recommendation No 2006/583/EC](#) of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products.
- [Commission Regulation \(EC\) No 401/2006](#) of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.
- [Regulation \(EC\) No 2160/2003](#) of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents.
- [Commission Regulation \(EC\) No 333/2007](#) of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs.
- [Commission Regulation \(EU\) No 589/2014](#) of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012.
- [Commission Regulation \(EC\) No 1882/2006](#) of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs.

Undesirable substances and products in feed

- [Commission Regulation \(EU\) No 278/2012](#) of 28 March 2012 amending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls.
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APPENDIX 9

TRANSPORT

TRANSPORT: Procedures for cleaning and categorising products

This appendix proposes a categorization procedure for bulk products transported by land, sea or river, based on the risk levels they present for the subsequent load.

It also defines the required cleaning levels according to the nature of the previous load and describes the procedure to be followed to reallocate and validate containers that have transported “very high-risk” products in the previous load.

On this basis the operator can:

- Verify the risk category of the products transported during the previous load
- And ensure that appropriate cleaning and/or washing and/or disinfection procedures are applied to bring the risks of contamination to an acceptable level.

Any packed and/or packaged product can be transported in accordance with current regulations.

1. Definition of the different cleaning procedure levels

Level A: Dry cleaning

Application:

In the case of transport of dry „neutral“ substances only, dry cleaning may be sufficient and beneficial both practically and microbiologically.

The general cleaning regime is as follows:

1. Clean the means of transport by extraction, blowing out or sweeping.
2. Manual cleaning of places which are difficult to reach.
3. If there are still remains after dry cleaning then use additional wet cleaning.

Any parts that are still dirty after drying quickly, cleaning can be cleaned locally using a wet process.

EXPLANATION

In dry cleaning the preference is for suction because there is then no spreading of dust or dirt.

Level B: Cleaning with clean water

Application:

After the transportation of products with cleaning regime B there should always be wet cleaning before the first transport of animal feeds.

Companies carrying out transportation using bulk tankers should wet clean these tankers at least once per quarter unless it can be demonstrated that there are no remains present in the bulk tanker.

Cleaning with water is necessary after transport of, for instance, damp or sticky substances or possibly harmful chemicals.

The general cleaning regime is as follows:

1. Remove residue from the previous load as much and as dry as possible.

2. Pre-rinse with cold water, or warm if necessary, and clean difficult places manually.
3. Manual cleaning.
4. High-pressure cleaning with water.
5. Dry quickly through ventilation or hot air dryer.

Explanation

With open vehicles it is best to use a high-pressure cleaner with a flat nozzle with at least 25 bar pressure or higher. If chemicals need to be removed, (e.g. chemical fertilizers) warm water should be used at a temperature of at least 60°C, to dissolve the chemicals more easily. Places that are difficult to reach should if necessary be cleaned separately with additional means such as brushes. It is important that the water can be drained.

Level C: Cleaning with water + cleansing agent

Application:

In case of load containing protein or grease, it is necessary to use a cleansing agent.

The general cleaning regime is as follows:

1. Remove residue from the previous load as much and as dry as possible.
2. Pre-rinse with hot water (max. 60 °C) and clean difficult places by hand.
3. Foam or gel with a cleaning agent for tippers open wagons or flush with CIP cleaning agent at 80 °C in the event of tank cleaning.
4. Rinse with water at approx. 60°C.
5. If necessary dry quickly through ventilation or hot air dryer.

Explanation:

A raised water temperature is required to remove fats more easily. This may however not be higher than 60 degrees Celsius to prevent the protein from coagulating and thereby sticking to surfaces. To facilitate the removal of protein and greases it is advisable to use a medium to strong alkaline cleansing agent, using the dosage prescribed by the manufacturer.

In open systems it is best to use a foaming degreasing agent. In the case of tank cleaning with spray balls, no foaming agents may be used. It is then better to use a so-called Cleaning in Place (CIP) agent at a high temperature. In specific cases, such as the removal of calcareous substances, an acid cleansing agent is preferable.

Cleaning and disinfection agents must be appropriate for the purpose for which they are used. They must also not form any risk to the safety of the food or feed which are being carried in the means of transport. The residues of cleaning and disinfecting agents must be kept as small as possible.

Level D: Cleaning regime D (Cleaning with water and cleansing agent and disinfection)

Application:

After the transportation of products with cleaning regime D there should always be cleaning and disinfection before the first load of animal feeds or food in bulk. Disinfection is only necessary if preceding loads are microbiologically unacceptable (detectable signs of decay), or if it is known that they carry micro-organisms that cause disease, such as Salmonella.

The general cleaning regime is as follows:

1. Cleaning in accordance with cleaning regime A, B or C

2. Disinfection with a legally-permitted disinfectant (approved for the foodstuff industry) at a dosage indicated in the instructions for use.
3. If necessary wet rinsing
4. If necessary dry through ventilation or hot air dryer.

As guidance, operators are recommended to make use of some existing database or lists which provide the relevant cleaning regime for many products (e.g. the IDTF database available on <http://icrt-idtf.com/en/links.php>).

Explanation:

Another form of disinfection (e.g. dry) may only be applied if its effectiveness has been established.

A distinction can be made between disinfectants tested for bactericidal and fungicidal effect and those tested for bactericidal, fungicidal and virucidal effect. The latter may only be used in the livestock sector. For food or animal feed transport vehicles, use of a disinfectant approved for the food industry is the only other alternative.

Use of a combined cleansing and disinfecting agent containing active chlorine is only possible on smooth surfaces that are easy to clean, such as stainless steel.

In all other cases it is better to clean first and then disinfect, in which case, for the disinfection of open vehicles disinfectants containing active chlorine are advised. In some cases it is not advisable to use agent containing chlorine, such as for materials which corrode easily or after an acid cleansing due to the forming of toxic chlorine gases. In this case quaternary ammonium compounds may be used, except for tank cleaning with spray balls due to foam forming. Their advantage is that they adhere better and therefore work longer. The disadvantage is that they are more difficult to remove.

For closed tankers, the use of acetic acid can be considered. Its advantage is that it activated less by residues than active chlorine is. The penetrating odour and the harm it does to rubber are a disadvantage. Disinfectants must be given at least five minutes to take effect.

The food industry prescribes rinsing after disinfecting. In order to avoid the risk of residues, it is advisable to apply this to transport vehicles as well, unless it can be demonstrated that residues do not constitute a risk. In some cases, removing the disinfectant can lead to the development of surviving bacteria if the surface re-mains wet for too long.

After cleaning loads containing animal proteins, a check may be carried out for residues of components of animal origin in animal feeds according to the microscopic screening methods laid down in the legal requirements.

Other additional checks will be carried out to assess the effectiveness of the cleaning and/or disinfection method used. In order to assess the cleaning, ATP (Adenosine Tri Phosphate) measurements can be used. ATP is present in all animal and vegetable cells and can thus be used as an indicator for the extent of biological contamination left on surfaces. The ATP measurement itself is very easy and can yield a result within minutes. The application of ATP is not useful in most cases of transport of chemicals. In order to verify the effectiveness of a particular disinfection technique in use, agar stamps can be used, which can determine the numbers of surviving micro-organisms. This technique takes a day to produce results, which means that any necessary adjustments to the disinfection process can only be made afterwards. This technique provides results only after a period of one day so that any required modification of the disinfection process can only take place later.

More advanced methods may be used for checking on chemical residues and pesticides such as HPLC and Mass Spectrometry (MS).

2. Instructions for transport sequence, cleaning and disinfection

Rules of cleaning and disinfection based on previous loaded cargo				
Instructions for transport sequence, cleaning and disinfection				
Cleaning regime	Previous load		Following load	
	Description of the product	State of the bulk loading compartment	Animal Feed or Food Product	Animal feed products for laying poultry
Forbidden load	Very high-risk materials	n/a	Not allowed.	
Cleaning method approved by the competent authority or inspection by the competent authority	"(Products containing) certain animal products as per Regulation (EC) No 999/2001 (*)	n/a	Feed for Ruminants. Requirements for the release of transport means for the transport of animal feed are set in Re. (EC) No 999/2001 and by the competent authority	
Cleaning method approved by the competent authority or inspection by the competent authority	"(Products containing) certain animal products as per Regulation (EC) No 999/2001 (*)		Feed for non-ruminants	
		After unloading	A	
		Residue after dry cleaning	B	
		(odour) residue after cleaning with water	C	
D	Microbiologically contaminated materials (for example Salmonella) or perceivable signs of decay (for example abnormal odours)	After unloading	A+D	
		Residue after dry cleaning	B+D	
		(odour) residue after cleaning with water	C+D	
C	Material constituting a physical and/or chemical risk, not or badly soluble in water load containing protein or grease	After unloading	C	
		(odour) residue after cleaning with water and cleaning agent	Additional cleaning until (odour) residues are removed	
B	Material constituting a physical and/or chemical risk	After unloading	B	
		(odour) residue after cleaning with water	C	
A	Neutral materials	After unloading	A	
		Residue after dry cleaning	B	

		(odour) residue after cleaning with water	C	
	Compound feeds and premixes with nicarbazine and medicated feeds with sulpha agents	After unloading	A	A **
		Residue after dry cleaning	B	B**
		(odour) residue after cleaning with water	C	C**
Cleaning regime				
A. Dry cleaning		C. Cleaning with water + cleansing agent		
B. Cleaning with water		D. Disinfection after applying cleaning regime A, B or C		

(*) By "(Products containing) certain animal products in accordance with Regulation (EC) No 999/2001" is meant:

- Processed animal proteins(as defined in Regulations (EC) No 1069/2009 as amended and 142/2011 as amended)
- Blood products
- Hydrolysed proteins
- Dicalcium phosphate and tricalcium phosphate (of animal origin)
- Gelatin from ruminants
- Feeds which contain these animal products

This does not include (if designated as processed category 3 material):

- Milk and products on the basis of milk and colostrum
- Colostrum
- Eggs and egg products
- Hydrolysed proteins from parts of non-ruminants or from skins of ruminants (the hydrolysed protein must be produced in an establishment or plant which has been approved as per Regulation (EC) No 1069/2009 as amended, using a method that meets at least the standards referred to in Regulation (EC) No 142/2011 as amended, Section 5, sub. D (Hydrolysed protein derived from ruminant shall have a molecular weight below 10,000 Dalton)
- Gelatin from non-ruminants
- Collagen

Definition of processed animal proteins:" according to Regulation (EC) No 142/2011 Annex I as amended:

Animal proteins that were derived fully from category 3 material and that were processed in accordance with Section 1 of Chapter II of Annex X (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen.

As a general rule, the operators must comply with legal requirements as laid down in (EC) Regulation No 999/2001 of 22 May 2001 as amended laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies as amended.

()** The specified cleaning instructions only apply when the manufacturer can show that the end feed remains under the total carry-over norms (factory carry-over including the carry-over during transport). For the carry-over of nicarbazine/sulpha's during transport 0.03% may be assumed if

use is made of a bulk tanker where the compartments are pressurised during unloading. If an operator is unable to show that the end feed remains under the total carry-over norms then a very penetrating and strict cleaning procedure should be used. It must be demonstrated with very clear documentation in what manner the carry-over is controlled (for example by way of flush batches).

3. Categorising products transported in bulk

General principles

Each product transported must be categorised based on the type and severity of the risk it presents. The transport conditions and cleaning sequences must be adapted to the risk level presented. For class LR1 products, the loading compartment cannot be used until the necessary cleaning procedures determined by the risk analysis have been carried out by the operator.

Category LR1 – Very high-risk products *Non-exhaustive list (such as, without limitation)*

Type of Products	Example
Animal faeces	Slurry, manure, droppings etc.
Other (inorganic substances)	Asbestos, asphalt, gas, petroleum, mineral clay used for detoxification, petroleum cokes, mineral oils, radioactive material, active carbon used. Toxic oxidant materials, metal shavings and turnings (not degreased, not washed and not dried)
Other (organic substances)	Domestic waste, untreated food residues, sewage sludge, unpackaged grains treated with toxic substances
Products of animal origin banned in feed for production animals¹⁴	Treated and untreated materials from Category 1 or 2 (see Regulation (EC) No 1069/2009)

Category LR2 – Microbiologically contaminated products *Non-exhaustive list (such as, without limitation)*

Type of Products	Example
Other (inorganic substances)	Dirty glass etc.
Other (organic substances)	Organic compost, organic fertilizer, material contaminated by salmonella or other pathogens, materials that have perceptible signs of deterioration etc.
Products of animal origin authorized for use in feed for production animals, excluding dairy and egg products	Animal and marine animal fats and oils etc.

Category LR3 – Products with a chemical and/or physical risk *Non-exhaustive list (such as, without limitation)*

Type of Products	Example
Chemical fertilizers and liquid minerals	Nitrogen solutions etc.
Products containing soil	Green compost, garden soil, soil-based compost, heath earth
Additives	All additives included in the list of additives approved by the EU (transported in bulk in accordance with Regulation (EC) No 1831/2003 as amended)
Solid mineral combustible fuel oil	Anthracite, bituminous coal, black coal, cokes etc.

¹⁴ The classification for products of animal origin banned in feed for production animals (C1 or C2) depends on national legislations

Other substances/products (inorganic)	Construction and demolition waste, miscellaneous chemical products, clean glass, metal shavings and turnings, residues, (copper, brass, aluminium) etc.
Other substances/products (organic)	Miscellaneous organic substances (alcohols, acids, wax, vegetable and hydrogenated oil and fat, fatty acid esters, grape derivatives, white mineral oil, acid oils and fatty acid distillates etc.)

Category LR4 – Neutral products

Non-exhaustive list (such as, without limitation)

Type of Products	Example
Products or raw materials intended for human food	Products or raw materials for human food, such as grains, oilseeds, protein crops and their by-products
Raw materials intended for the production of animal feed and animal feed of mineral or plant origin	Products or raw materials for animal feed, such as grains, oilseeds, protein crops and their co-products, sugar beet pulp, lucerne etc. Sodium chloride (salt) Feed for animals
Raw materials of animal origin intended for the production of feed for production animals and foods containing them	Milk and dairy products, egg products etc.
Foods for animals containing animal proteins (excluding dairy and egg products)	Animal feed with fish meal, dibasic calcium phosphate, tribasic calcium phosphate of animal origin and blood products from non-ruminants, if the following load is made up of animal feed for non-ruminants (in accordance with Regulation (EC) No 999/2001 as amended)
Chemical fertilizers and solid minerals	Ammonium sulphates, potassium sulphate, urea, calcium etc.
Pre-packed and/or packaged products	Packaged agricultural supplies, pallets, Big Bag, additives in solid/dry form etc.
Products containing soil	Garden peat, garden compost/soil (treated with artificial fertilizers)
Minerals	Granite, mining stone etc.
Other substances/products (organic)	Miscellaneous silicates, gravel, pebbles, clinker, synthetic materials, mortar, cement, gypsum, ethanol, vermiculite, talc, tree bark, grasses, wood shavings, coffee husk, (waste) paper etc.

4. Recommended sequences for transport, cleaning and disinfection

	Products in the previous load (N-1)	Products to be loaded (N)	
	Very high-risk products	n.a. (not applicable) Transport not authorized (unless procedure E is applied)	
	Microbiologically contaminated products (p.e. salmonella, putrefaction etc.)	Cleaning after unloading	A+D
		Residues remaining after dry cleaning	B+D
		Residues (odour) after cleaning with water	C+D
	Products representing a physical or chemical risk	Clean after unloading	B
		Residues (odour) after cleaning with water	C

	Neutral products	Clean after unloading	A
		Residues remaining after dry cleaning	B
		Residues (odour) after cleaning with water	C

Particular case of precedents concerning the transport of animal products:

Regardless of the category to which they belong (LR1, LR2, LR3 or LR4), it is important to ensure that, in addition to the rules described in the above table, the transport complies with the national and community rules specific to the transport of these products (Regulation (EC) No 1774/2002 as amended and (EC) No 999/2001 in particular).