



The European
Pet Food Industry

Guide to Good Practice for the Manufacture of Safe Pet Foods

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Introduction

PURPOSE AND OBJECTIVE

Feeding **pet animals** with safe **pet food** for a long healthy life is the prime objective of the European Pet food Industry. This applies to the entire manufacturing process from the selection of feed materials/**additives** to the **finished product**.

Regulation (EC) No 1831/2003 on feed additives acknowledges the importance of good hygiene practices and encourages the development of EU and national Guides to good practice to ease the interpretation and implementation of the EU legal framework.¹

This Guide to Good Practice for the Manufacture of Safe **Pet Food** (hereafter “the Guide”) developed by FEDIAF² lays down good practices on the safety and hygiene of **pet food** processes and products. This document is meant to be a practical and useful tool for **pet food** manufacturers to help them in developing a robust **pet food safety management system** and complying with safety and hygiene legal requirements.

SCOPE

The scope of the Guide covers the production, storage and distribution of **wet pet food** (e.g. cans, trays and **pouches**), **dry or semi-moist pet food** and **dog chews** in Europe as well as third country imports into the EU. The target species covered by this Guide are as follows: cats, dogs, ornamental fish and birds as well as small animals (e.g. rodents, reptiles, rabbits, etc.). Products destined to horses are excluded from the scope of this Guide.

Moreover, the production, storage and distribution of medicated **pet food** are not part of the scope of this guide either. Considerations related to quality aspects not related to product safety & hygiene are out of the scope of the document and can be found in relevant certification codes.

The guide does not replace national regulatory requirements and is based on full self-responsibility of the individual **pet food** manufacturer using the following reference documents and legal acts:

- Current best practices in the **pet food** industry,
- Existing European legislation including the Regulation of the European Parliament and the Council laying down requirements for Feed hygiene affecting **pet food**,
- Requirements of **Hazard Analysis Critical Control Points (HACCP)** as mentioned within **CODEX Alimentarius** Commission, Recommended International Code of Practice, CAC/RCP 1-1969, Rev. 4-2003
- EN ISO 9001:2015 (E) and EN ISO 22000:2005 (E)
- Requirements of standards developed by other stakeholders e.g. related business sectors, retailers.

UPDATE

The need for update of this document is assessed every year at the FEDIAF's Annual General Meeting. When an in-depth review of the document is carried out in the light of relevant technological, scientific or legislative developments for the production of safe **pet food**, the document is officially submitted to the European Commission and the Member States for assessment.

The European Commission on its own initiative or at the request of the Member States, within the framework of the SCoPAFF (Standing Committee on Plants, Animals, Food and Feed), may also request FEDIAF to review and update the Guide. FEDIAF is responsible for informing the European Commission and the **pet food** industry whenever the Guide is updated. The first version of the document was approved in 2007. A second version was developed and approved in 2010. This is the third version subject to approval.

Glossary

The glossary contains definitions of key words used in this Guide followed by the source of the definition. Whenever appropriate, definitions are adapted to **pet food**. All

defined terms are written in red throughout the Guide to facilitate the reading of the document.

A

Additives: Substances, micro-organisms or preparations, other than feed material and **premixtures**, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3):

- Favourably affect characteristics of feed;
- Favourably affect characteristics of animal products;
- Favourably affect the colour of ornamental fish and birds;
- Satisfy the nutritional needs of animals;
- Favourably affect the environmental consequences of animal production;
- Favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of **feedingstuffs**;
- Have a coccidiostatic or histomonostatic effect.

(Regulation (EC) No 1831/2003, art. 2.2 (a))

Animal by-products (for **pet food production):** Entire bodies or parts of animals, products of animal origin or other products obtained from animals referred to in Article 10 (a to m) of Regulation 1069/2009/EC, which are not intended for human consumption, including oocytes, embryos and semen *(Regulation (EC) No 1069/2009 on animal by-products, art. 3.1)*

B

Batch:

- A unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together as a shipping unit *(Regulation (EU) No 142/2011, Annex I, no. 50)*
- an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together *(Regulation (EC) No 183/2005, Annex II, a and Regulation (EC) No 767/2009, Article 3 (2) (r))*

Audit: Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which **audit** criteria are fulfilled.

Internal, first party **audits** – are conducted by, or on behalf of, the organization itself for management review and other internal purposes.

External **audits** are second- and third-party **audits**. Second-party **audits** are conducted by parties having an interest in the organization such as customers, or by other persons on their behalf.

Third-party **audits** are conducted by external independent organizations providing certification.

(EN ISO 9000:2015)

C

Calibration: Set of operations required to ensure that measuring equipment conforms to the requirements for its intended use (*EN ISO 9000:2015*)

Canned pet food: Heat-processed pet food contained within a hermetically sealed container (*Regulation (EU) No 142/2011, Annex I, no. 16*)

Carry-over: transfer of any substance or product from one production batch to the immediate subsequent batch in a particular section of the plant, for example, a mixer or a hand tip point.

Codex Alimentarius: Internationally recognized food and hygiene standards of which HACCP is one such standard which are published in the Codex Alimentarius. These non-binding (voluntary) global references become enforceable when accepted as national standards by the member countries. It works under the auspice of FAO/WHO (*"Understanding of Codex Alimentarius Third Edition", WHO, FAO, Rome 2006 ISBN 978-92-5-105614-1*)

Competent authority

- The central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country (*Regulation (EC) No 882/2004 (art. 2(4))*)
- The central authority of a Member State competent to ensure compliance with the requirements of legislation or any authority to which that central authority has delegated that competence, in particular for the control of feedingstuffs; it shall also include, where appropriate, the corresponding authority of a third country (*Regulation (EC) No 999/2001 (art. 3(1)(e) and Regulation (EC) No 1069/2009 (art. 3 no. 10)*)
- The authority of a Member State or of a third country designated to carry out official controls (*Regulation (EC) No 183/2005, art. 3(e)*)

Complete feed/pet food: A compound feed/pet food which, by reason of its composition, is sufficient for a daily ration (*Regulation (EC) No 767/2009 (art 3 (2) (i))*)

Complementary feed/pet food: A compound feed/pet food which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed/pet food (*Regulation (EC) No 767/2009 (art 3 (2) (j))*)

Commissioning: Process by which equipment, machinery, production line, facility or plant (which is complete or near completion) is tested and optimized in order to function according to its objectives or specifications (*Internal Definition of Fediaf*)

Contamination:

- The presence or introduction of a hazard (*Regulation (EC) No 852/2004*)
- Hazard may be posed by any contaminant (e.g. biological or chemical agent, foreign matter, or other substance) not intentionally added to food which may compromise food safety or suitability (*Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969, Rev. 4-2003*)

Control measure: Action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (*Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969, Rev. 4-2003*)

Correction: Action to eliminate a detected non-conformity (*EN ISO 9000:2015*)

Corrective action: Action to eliminate the cause of a detected nonconformity or other undesirable situation (*EN ISO 9000:2015*)

Critical Control Point (CCP): A step at which it is essential that a specific control measure is applied to prevent or eliminate a food safety hazard or reduce the risk to an acceptable level (*Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969, Rev. 4-2003 and ISO 22000:2005 E*)

Critical Limit: Criterion which separates acceptability from unacceptability (*Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969, Rev. 4-2003 and ISO 22000:2005(E)*)

C

Cross-contamination: The passing of microorganisms, chemicals or other harmful substances indirectly from one material to another through improper design and layout ,

unsterile equipment, air, procedures, or products (*Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969, Rev. 4-2003*)

D

Dog chews: Products for **pet animals** to chew, produced from untanned hides and skins of ungulates or from other material of animal origin (*Regulation 142/2011/EU, Annex I, no. 17*)

Dry pet food: **Pet food** with a moisture content that does not exceed 14 % (*Internal definition of Fediaf*)

E

Exposure assessment: Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives) (*OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44*)

F

F value of 3: Fc3 is a processing standard that specifies that the core temperature of the product has reached 121 degrees Celsius for 3 minutes. – Equivalent time-temperature parameters to 121 degrees Celsius for 3 minutes (Fc3) involve the product reaching one of the following minimum core temperature/time parameters (*Internal definition of Fediaf*)

110 degrees Celsius for 40 minutes; or
111 degrees Celsius for 32 minutes; or
112 degrees Celsius for 25 minutes; or
113 degrees Celsius for 20 minutes; or
114 degrees Celsius for 16 minutes; or
115 degrees Celsius for 13 minutes; or
116 degrees Celsius for 11 minutes; or
117 degrees Celsius for 9 minutes; or
118 degrees Celsius for 7 minutes; or
119 degrees Celsius for 6 minutes; or
120 degrees Celsius for 5 minutes; or
121 degrees Celsius for 3 minutes; or
122 degrees Celsius for 3 minutes; or
123 degrees Celsius for 3 minutes; or

124 degrees Celsius for 3 minutes; or
125 degrees Celsius for 2 minutes; or
126 degrees Celsius for 1 minute; or
127 degrees Celsius for 46 seconds; or
128 degrees Celsius for 37 seconds; or
129 degrees Celsius for 29 seconds; or
130 degrees Celsius for 23 seconds; or
131 degrees Celsius for 18 seconds; or
132 degrees Celsius for 15 seconds; or
133 degrees Celsius for 12 seconds; or
134 degrees Celsius for 9 seconds; or
135 degrees Celsius for 7 seconds; or
136 degrees Celsius for 6 seconds

Feed hygiene: Measures and conditions necessary to control food safety **hazards** and to ensure fitness for animal consumption of a feed, taking into account its intended use (*Regulation (EC) No 183/2005, art. 3(a)*)

Feed materials: Products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not

containing feed **additives**, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of **premixtures** (*Regulation (EC) No 767/2009, art. 3 (2) g*)

Feed materials of animal origin: Those feed materials, as defined in Article 3(2)(g) of *Regulation (EC) No 767/2009*, that are of animal origin, including processed animal proteins, blood products, rendered fats, egg products, fish oil, fat derivatives, collagen, gelatine and hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, milk, milk-based products, milk-derived products, colostrum, colostrum products and centrifuge or separator sludge (*Regulation (EU) No 142/2011, Annex I, no 3*)

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*)

Feedingstuffs: Products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing **additives**, for oral animal feeding (*Directive 2002/32/EC, art. 2(a)*)

F

F.I.F.O. (first in first out): Stock rotation based on the principle of despatching earliest received products first (PAS 222)

F.E.F.O (first expired first out): stock rotation based on the principle of despatching earliest expiration date first.

Finished (end) product: Product that will undergo no further processing or transformation by the organisation. (EN ISO 22000:2005 E)

Flow diagram: Schematic and systematic presentation of the sequence of, and interactions of steps. (EN ISO 22000:2005 E)

Feed grade: Lubricants, cleaning agents and heat transfer fluids formulated to be suitable for use in animal food processes where there may be incidental contact between the lubricant, cleaning agents and heat transfer fluids and the animal food (PAS 222)

Feed safety management system: A system to define **feed safety policy**, related objectives, documented procedures, records, and responsibility to ensure that all products will not harm the consumer when prepared and/or eaten according to the intended use. (EN ISO 22000:2005 E)

Feed safety policy: Overall intentions and direction of an organization related to food safety (3.1) as formally expressed by top management. In particular, a commitment to the implementation and ongoing maintenance of its **Feed Safety Management System**. (EN ISO 22000:2005 E)

G

Genetically Modified Organisms (GMO):

- An organism, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination (Directive 2001/18/EC (Article 2(2))
- Organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC are excluded from the scope of definition (Regulation (EC) No 1829/2003)

Genetically modified feed (pet food): Feed containing, consisting of or **produced from GMOs**. For **pet food** products which are not required to be labelled “contains GMO” or “**produced from GMO**”, the operator is required to ensure that the **pet food** product does not contain, consists of or is **produced from GMO** in excess of 0.9% per incorporated feed material provided that this presence is adventitious (accidental, non-intentional) or technically unavoidable (Regulation (EC) No 1829/2003)

H

HACCP (Hazard Analysis and Critical Control Point):

A system which identifies, evaluates, and controls **hazards** which are significant for food safety (Codex Alimentarius Commission Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003)

HACCP plan: A document prepared in accordance with the principles of **HACCP** to ensure control of **hazards** which are significant for food safety in the segment of the food

chain under consideration Codex Alimentarius Commission Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003)

Hazard: A 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, art. 3(14))

H

Hazard assessment: A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed. The process includes **hazard identification** and **hazard characterization** (*OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44*)

Hazard characterization: The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties (*OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44*)

Hazard identification: The identification of the type and nature of adverse effects that an agent has inherent capacity to cause in an organism, system or (sub) population (*OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44*)

Hermetically sealed container: A container that is designed and intended to be secure against the entry of micro-organisms (*Regulation (EU) No 142/2011, Annex I, no. 51*)

M

Moist/wet pet food: Pet food with a moisture content of 60 % or more (*Internal definition of Fediaf*)

Monitoring: Conducting a planned sequence of observations or measurements to assess whether **control measures** are operating as intended (*EN ISO 22000:2005 E*)

N

Non-conformity: Non-fulfilment of a requirement (*EN ISO 22000:2005 E*)

O

Operational Prerequisite Programme (OPRP): Prerequisite programme identified by a **hazard** analysis as essential in order to control the likelihood of either the **pet food** product or the process environment being exposed

to safety **hazards**, that either will be contaminated, or that the **hazards** will proliferate. It will not eliminate the **hazard** on its own (*EN ISO 22000:2005 E*)

P

Pesticide residue: means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2, point 1 of Directive 91/414/EEC, which are present in or on the

products covered by Annex I to this Regulation, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide (*Regulation (EC) No 369/2005*)

P

Pet or pet animal:

- Any animal belonging to species normally nourished and kept but not consumed, by humans for purposes other than farming (*Regulation (EC) No 1069/2009, art. 3(8)*)
- Any non-food-producing animal belonging to species fed, bred or kept, but not normally used for human consumption in the Community (*Regulation (EC) No 767/2009, Article 3 (2) (f)*)

Pet food: Any product produced by a **pet food** manufacturer, whether processed, partially processed or unprocessed, intended to be ingested by **pet animals** after placing on the market. The legislator sometimes uses “feed” or “feedingstuff” as synonyms (*Regulation (EC) No 178/2002*)

(Pet) food chain: Sequence of the stages and operations involved in the processing, distribution, and handling of a **pet food** and its **feed materials/additives**, from production to consumption (*EN ISO 22000:2005 E*)

(Pet) food safety: Assurance that (pet) food will not cause harm to the animal, human or environment when it is prepared and/or eaten according to its intended use. (*EN ISO 22000:2005 E*)

(Pet) food safety hazard: Biological, chemical or physical agent in, or condition of, (pet) food with the potential to cause an adverse health effect (*EN ISO 22000:2005 E*)

Potable water: Water meeting the minimum requirements laid down in Council Directive 98/83/EC on the quality of water intended for human consumption (1) (*Regulation (EC) No 852/2004*)

Pouch: A sealed plastic, foil or composite **hermetically sealed container** used in packaging **pet food** (*Internal definition of Fediaf*)

Premixtures: Mixtures of feed **additives** or mixtures of one or more feed **additives** with feed materials or water used as carriers, not intended for direct feeding to animals (*Regulation (EC) No 1831/2003, art. 2(2)(e)*)

Prerequisite Programme (PRP): “Food safety” basic conditions and activities that are necessary to maintain a hygienic environment throughout the (pet) food chain suitable for the production, handling and provision of safe end products and safe food for **pets**. **PRP** is a combination of all of good practices like GMP, GHP, GLP (*EN ISO 22000:2005 E*)

Preventive action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation (*EN ISO 22000:2005*)

Processing aids: Any substance intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residue of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on finished feed (*Regulation (EC) No 1831/2003*)

Produced from GMOs: Derived, in whole or in part from **GMOs** but not containing or consisting of **GMOs** (e.g. refined oils directly derived from GM soy are “**produced from GMOs**” even if the end product does not contain **GMOs**; vitamins using **processing aids** such as GM microorganisms are not “**produced from GMOs**” but indirectly produced with **GMOs**) (*Regulation (EC) No 1829/2003 on **genetically modified food and feed** FEDIAF Guide to Good Practice for the communication on **Pet Food** 2015*)

Product Recall: Any measures aimed at achieving the return of an unfit product from consumers and customers (*Internal definition of Fediaf*)

Product Withdrawal: Any measures aimed at achieving the return of an unfit product from customers but not final consumers (*Internal definition of Fediaf*)

R

RASFF: The Rapid Alert System for Food and Feed (RASFF) is a system established as a network between the Commission and Member States for the notification of a direct or indirect **risk** to human, animal health and environment deriving from food and feed which provide the control authorities an effective tool for exchange of information on measures taken to ensure food and feed safety. (Regulation (EC) No 178/2002 and Regulation (EC) No 183/2005)

Raw pet food: Pet food containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing. (Regulation (EU) No 142/2011, Annex I, no. 21)

Rework: Utilization of nonconforming and returned materials suitable for reprocessing (e.g. pellet fines, screenings, quality defects and customer returns) (PAS 222)

Risk: Function of the probability of an adverse health effect and the severity of that effect, consequential to a **hazard** (Regulation (EC) No 178/2002, art. 3(9))

Risk analysis: Process consisting of three interconnected components: **risk assessment**, **risk management** and **risk communication** (Regulation (EC) No 178/2002, art. 3(10))

Risk assessment: Scientifically based process consisting of four steps: **hazard identification**, **hazard characterization**, **exposure assessment** and **risk characterization** (Regulation (EC) No 178/2002, art. 3(11))

Risk characterization: The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub) population, under defined exposure conditions (OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44)

Risk communication: The interactive exchange of information and options throughout the **risk analysis** process as regards **hazards** and **risks**, **risk**-related factors and **risk** perceptions, among **risk** assessors, **risk** managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of **risk assessment** findings and the basis of **risk management** decisions. (Regulation (EC) No 178/2002, art. 3(13))

Risk evaluation: Establishment of a quantitative relationship between **risks** and benefits of exposure to an agent, involving the complex process of determining the significance of the identified **hazards** and estimated **risks** to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the agent (OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44)

Risk management: The process, distinct from **risk assessment**, of weighing policy alternatives in consultation with interested parties, considering **risk assessment** and other legitimate factors, and, if need be, selecting appropriate prevention and control options (Regulation (EC) No 178/2002, art. 3(12))

Risk monitoring: Process of following up the decisions and actions within **risk management** in order to ascertain that **risk** containment or reduction with respect to a particular **hazard** is assured (OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44)

S

Sample (representative sample): Set composed of one or several items (or a portion of matter) selected by different means in a population (or in an important quantity of matter). It is intended to provide information on a given characteristic of the studied population (or

matter), and to form a basis for a decision concerning the population or the matter or the process, which has produced it. A **representative sample** is a **sample** in which the characteristics of the lot from which it is drawn are maintained. It is in particular the case of a simple random

S

sample where each of the items or increments of the lot has been given the same probability of entering the **sample** (*Codex Alimentarius General Guidelines on Sampling CAC/GL 50-2004*)

Semi-Moist pet food: **Pet food** with a moisture content exceeding 14 % and not exceeding 60 % (*Internal definition of Fediaf*)

Shelf-life: The period during which the product maintains its microbiological safety, nutritional and sensory qualities

at specific storage conditions. It is based on identified **hazards** for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used (*Internal definition of Fediaf*)

Supplier: Organization or person that provides a product like a producer, distributor, retailer, vendor of a product, contractor. **Suppliers** can be internal or external to the organization (*EN ISO 9000:2015*)

T

Traceability:

- The 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/EC, art. 3(15)*)

- **Traceability** means the ability to trace **GMOs** and products **produced from GMOs** at all stages of their placing on the market through the production and distribution chains (*Regulation (EC) No 1830/2003*)

U

Undesirable substance: 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, art. 2(l)*)

Updating: Immediate and/or planned activity to ensure application of the most recent information (*EN ISO 22000:2005 E*)

V

Validation: Obtaining evidence that the **control measures** managed by the **HACCP plan** and by the operational **PRPs** (3.9) are capable of being effective (*EN ISO 22000:2005 E*)

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. It involves the application of methods, procedures, tests and other evaluations, in addition to **monitoring**, to determine compliance with the specifications laid down in the **HACCP plan** and the effectiveness of the **HACCP**-based Food Safety System. (*EN ISO 22000:2005 E*)

1. Pet food safety management system

1.1. MANAGEMENT RESPONSIBILITIES AND RESOURCES

1.1.1. Management commitment, responsibility and policy

The management (from the higher management to the lower management) must be committed to the implementation of EU legislation, national law and the present good practices in order to help ensure the pet food safety of the products.³

The management must ensure that responsibilities and authorities are defined, documented and communicated within the organisation.

The management must:

- Establish a pet food safety policy, ensure that objectives are established and communicate the policy throughout the organisation.
- Ensure that these objectives and policies are in compliance with regulatory requirements as well as with the good practices laid down in this Guide.
- Define and document the scope of the pet food safety management system, by identifying the product categories, production sites/ process lines and outsourced activities which are covered by the system.

- Identify all other relevant activities at the location which might cause a **risk** for **pet food** production
- Ensure crisis management is in place with defined responsibilities.

The management must continuously improve the effectiveness of the pet food safety system.

Staff appointed by the management must have defined responsibility and authority to:

- Identify and record any problems with regard to product safety and the operator's pet food safety management system.
- Initiate preventive or corrective measures to anticipate or remediate to product safety.

1.1.2. Pet food safety organization

1.1.2.1. Organisational chart

The management must establish an organisational chart.⁴
The responsibilities regarding pet food safety must be documented and kept up-to-date.

1.1.2.2. Competency, awareness and education

All personnel carrying out activities affecting pet food safety must be competent and have the appropriate education, training, skills and experience according to the job description. The job description will be communicated to the employees responsible. Training programmes must be routinely reviewed and updated, where necessary.

The management must:

- Identify and define clearly the necessary skills and competences for personnel whose activities have an impact on pet food safety in the job description.
- Provide the necessary education and/or training according to the job description to ensure and maintain the fulfilment of these necessary skills, including an

introduction to HACCP principles.

- Ensure that personnel responsible for monitoring pet food safety processes are trained in proper monitoring techniques and the necessary actions to be taken when there is a loss of control of the processes.
- Evaluate the effectiveness of the activities above.
- Ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to pet food safety.
- Ensure that personnel are aware of the necessity of effective communication.
- Maintain appropriate records of education, training, skills and experience of all personnel having an impact on pet food safety.

1.1.2.3. Pet food safety leader: responsibility, authority and communication

Management must appoint a pet food safety leader who, irrespective of other responsibilities, must implement and maintain a pet food safety management system of which HACCP is part (see also chapter 3 on HACCP).

1.1.3. Management review

The management must document verification measures taken to ensure that the pet food safety management system is working effectively. These must include planning, implementation and monitoring of processes which demonstrate product safety. Monitoring processes must include collection of measurements, analysis of data and, if relevant, measures to improve the effectiveness of the system.

A documented procedure must define the structure(s) to identify and manage corrective measures, including:

- Analysis of the cause of the non-conformity.
- Definition of the corrective measure.
- Tracking of the realisation of the measure.
- Verification of the effectiveness of the measure, where appropriate.

All of the above steps must be demonstrable by e.g. records or minutes of meetings.

Annually, the management must review the implementation, effectiveness and validity of the pet food safety management system by evaluating:

- Actions resulting from previous management reviews.
- Results of internal and external audits.
- Results of the HACCP verification.
- Complaints and other customer feedback.
- Implementation of major corrective and preventive measures.
- Changes that could have an impact on the validity of the feed safety management system.

The output of the review must address:

- Conclusions on the implementation, effectiveness and validity of the feed safety management system.
- Actions and objectives to improve the feed safety management system.
- Changes needed in the HACCP study.

The report of the review must be readily available.

1.2. TRACEABILITY

1.2.1. Definition, scope and boundaries

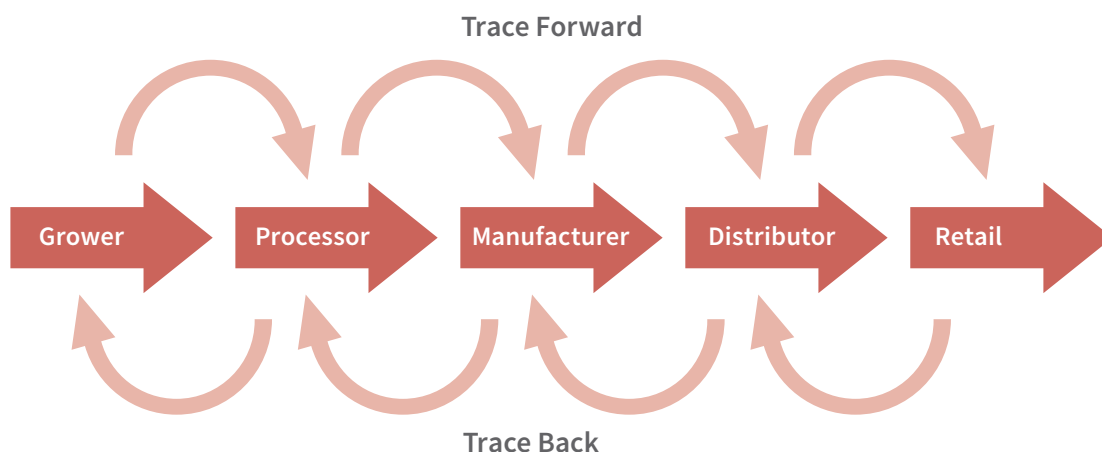
Traceability is the ability to track feed materials, additives, packaging material or any substances used at all stages of production, processing and distribution of pet food.⁵ To this end, it is recommended to follow the F.I.F.O or F.E.F.O principles.

Traceability must apply and be the responsibility of each operator of the entire pet food chain (“from farm to feeding bowl”).

Traceability must be ensured through the full process:

- From the finished pet food back to the source of the respective feed material, additives, packaging material or other substance,
- From a respective feed material, additive, packaging material or other substance to the finished pet food for which each of the substance is used,
- From the finished pet food to the retailer.

Figure X: The supply chain



1.2.2. Registration and approval of operators

The pet food manufacturer must apply for registration and/or approval to the competent authority for its relevant activities.⁶ The following activities require mandatorily an approval:

- Manufacturing and/or placing on the market of following authorised feed additives:
 - All nutritional additives;
 - All zootechnical additives;
 - Technological additives: antioxidants with a fixed maximum content;
 - Sensory additives: carotenoids and xantophylls.
- Manufacturing and/or placing on the market of premixtures prepared using following feed additives:
 - Nutritional additives: A- and D-vitamins, Cu and Se;
 - Zootechnical additives: all antibiotics, all coccidiostats and histomonostats, all growth promoters.
- Manufacturing for placing on the market, or producing for the exclusive requirements of their holdings, compound feedingstuffs using feed additives or premixtures containing antibiotics, coccidiostats and histomonostats, growth promoters.

Establishments producing feed materials or complementary feed exceeding 100 times the relevant fixed maximum content in complete feed for a particular nutritional purpose in respect of the relevant intended use shall also be approved.⁷

The pet food manufacturer must provide the competent authority with up-to-date information on any establishments under its control, including notifying the competent authority of any significant change in activities and any closure of an existing establishment.⁹

The manufacturing of pet food which makes use of animal-by-products requires an additional approval procedure.⁸

1.2.3. Documentation system

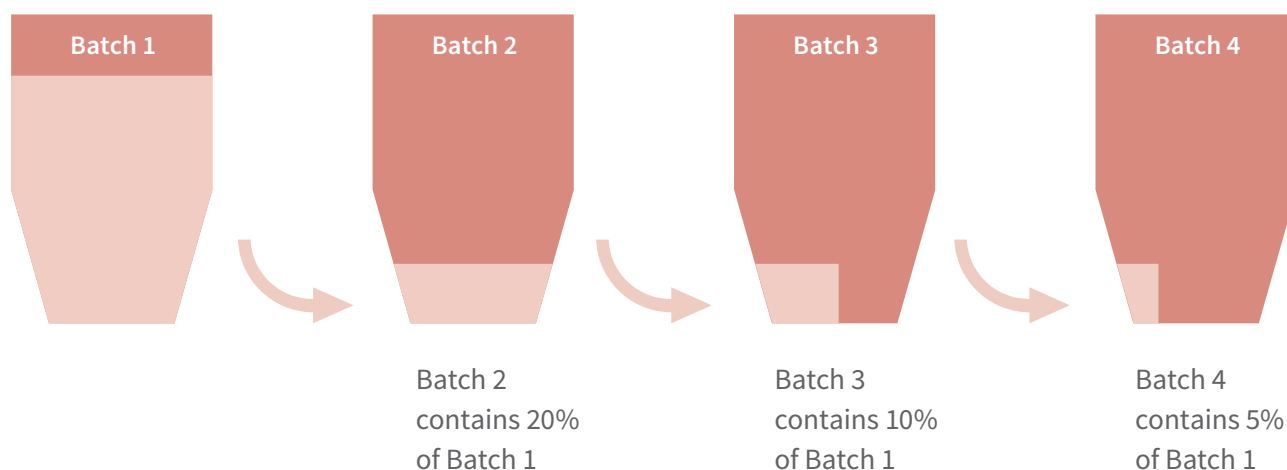
The pet food manufacturer must work with a system of documentation designed to ensure an adequate level of traceability.¹⁰ Traceability implies the use of unique batch number which gives the capability to identify feed materials during the process and the finished products. In order to ensure product traceability, the pet food manufacturer must record¹¹ and keep the following information till the end of shelf life and any event at least two years¹² (the European Commission recommends up to five years) when the pet food contains animal-by-products (or five years if the product contains GMOs):¹³

- The name and address of the suppliers (e.g. feed materials, additives/premixtures, packaging/finished products) and the sources of these feed materials/packaging/finished goods, including the batch number, quantity and delivery date.

- The approval or registration number of the suppliers of feed materials/additives covered by an approval or registration procedure according to EU feed legislation.
- The nature, formulation and quantity of the finished products manufactured, along with the manufacturing date and batch number. Samples and records of each batch must be retained in accordance with the feed hygiene regulation.
- The name and address of the site where the batch of semi-finished or finished products are delivered.

The pet food manufacturer must establish procedures and describe the way of working in case batches cannot be segregated from each other, e.g. feed materials in silos, rework, co-packed products. Each of these cases need dedicated way of working and procedures.

Figure X: Example of the non-segregation principle



1.2.4. Review and verification

The implemented **traceability** system (upstream/forward and downstream/backward) must be regularly reviewed, tested and recorded in order to assess if its defined objectives are met. The review of the system must consider

the reconciliation of the mass balance between inputted materials and rendered **finished products**. The review may lead to the establishment of improvement actions.

1.2.5. Complaints and product recall¹⁴/product withdrawal

The **pet food** manufacturer must implement procedures for the handling of pet owners' complaints related to the safety of a pet food product. These procedures must include:

- Defined responsibilities for the management of complaints;
- Recordings of name of the complaining customer;
- Recordings of the finished pet food under complaint;
- An investigation into the cause of the complaint;
- A reply to the customer; and
- All necessary corrective actions in a timely and effective manner.

When there are signs of a pet food safety issue, immediate action must be taken by the **pet food** manufacturer according to the defined procedures (**risk assessment**, consideration of **recall** or **withdrawal** actions, definition of the volume of products impacted by the **recall/withdrawal** procedure).

The **pet food** manufacturer must also implement a system (procedures, responsibilities, tools, etc) for the prompt **recall** or **withdrawal** of products in the distribution network.

The manufacturer must keep control of the retrieved affected products and to implement the appropriate disposal protocols in order to avoid that these products come back to the market.

The **pet food** manufacturer must inform and collaborate with the **competent authority** in case of a serious **risk** to human or animal health or to the environment.¹⁵ The procedure must be regularly tested and revised where needed in a manner that is appropriate to ensure its effective operation. These tests need to be recorded.

2. Pre-requisite programmes

2.1. FACILITIES AND PLANT DESIGN

2.1.1 Exterior

The site must be located and maintained so as to prevent **contamination** and enable the production of safe and legal **pet food**. The measures to prevent **contamination** must be reviewed to ensure they continue to be effective.

All buildings must be surrounded by a clear space. All immediate surrounding areas must be kept clean, vegetation must be maintained and effective pest control programmes must be implemented.

Where external storage is necessary, items must be protected from contamination and deterioration; e.g. pallets intended to be used for **dry pet food** must be kept dry.

Waste collection must take place in a well-defined area and must be managed in a way there is no **risk** for **contamination**.

Appropriate drainage must be in place to prevent standing water and avoid the **risk** of **contamination** of feed materials and pet food.

2.1.2 Food defence, biovigilance and bioterrorism

The site boundaries must be clearly defined, and access to the site must be managed.

must put in place protective measures. Critical areas need to be identified and access needs to be controlled (e.g. inlet of silos).

A **risk assessment** on pet food safety needs to be conducted to define reasonably expected occurrence by potential acts of sabotage, vandalism or terrorism and

2.1.3 Interior¹⁶

The construction of the site, buildings and facilities must be suitable for the intended purpose. In line with foreign body management, the use of materials such as glass, plastic, wood should be avoided as needed to prevent **risks** of **contamination**.

There must be sufficient working space and storage to enable all operations to be carried out properly under safe and hygienic conditions.

The production process from reception to dispatch must be designed to permit adequate cleaning and/or disinfection in order to prevent **contamination** and **cross-contamination** to personnel, product, facilities and equipment.

Possibilities to segregate between unprocessed, processed materials and waste must be in place to minimise the **risk** of product **cross-contamination**.

Adequate facilities for disposing of unused **animal by-products** remaining after the production of the products must be available.

2.1.4. Construction

Wall/floor junctions and corners must be covered to facilitate cleaning and disinfection. Cavities in the surface of walls must be avoided, where necessary, to prevent debris from accumulating and pest harbourage. Structural materials must be resistant to the cleaning system applied.

Floors must have adequate falls to cope with the flow of any water or effluent towards suitable drainage. This drainage must be designed and maintained to avoid build-up of debris and standing water.

Ceilings and overhead fixtures must be designed, constructed, finished and maintained to prevent the accumulation of dirt, to reduce condensation, minimise mould growth and to prevent the accumulation of dust.

The use of glass close to production machinery must be avoided and wherever necessary it must be protected

against breakage.

Where windows are designed to be opened for ventilation purposes, they must, where necessary, be adequately screened to prevent the ingress of pests. External openings (incl. doors intended for transfer of materials must be managed to prevent entry of foreign matter, moisture and pests.

Adequate ventilation and air flow must be provided in product storage and the processing environment to prevent condensation or excessive dust.

Facilities must have adequate natural and/or artificial lighting. Shatterproof plastic diffusers or sleeve covers must protect all fluorescent lights, bulbs and strip lights, including those on electric fly killer units, where they constitute a **risk** to the product.

2.1.5. Sanitary facilities

Personnel hygiene facilities (e.g. hand washing, toilets and showers) must be available, clearly designated and

maintained as necessary for pet food safety. These facilities should not directly be accessed from a production area.

2.2. UTILITIES

2.2.1. General requirements

Design and lay-out of utilities must take into account the prevention of product **contamination**. Utilities include:

- Supply of water or steam, as product ingredient or for product contact;
- Supply of air (or gas), as ventilation (natural or

mechanical) or as compressed air or gas system;

- Supply of energy (for example electricity, light, or heat).

Whenever applicable, utilities units must be placed away from walls to allow easy access for operation, cleaning and maintenance, and to prevent pest infestation.

2.2.2. Water

Water or steam used as product ingredient, or in contact with materials, products or product-contact surfaces must meet specified pet food safety requirements relevant to the product. The same applies to water for cleaning or applications where there is a **risk** of indirect product contact.

Potable water should be used when available.

Proper labelling and segregation between potable and non-potable supplies must be made.

Use of recycled water must be justified by a **hazard**

assessment. Recycled water must have a separate supply system to prevent from refluxing into **potable water** system.

In case chemicals are used for boilers that supply water or steam for direct inclusion or product contact, such chemicals must be either approved pet food **additives** or

approved by relevant **competent authority** as safe for use.

The quality of water, steam or ice, that comes in contact with **pet food** must comply with applicable quality regulations and be regularly monitored in order to assure that it presents no **risk** to product safety or quality and comply with governmental regulations.

2.2.3. Air (or gas)

Ventilation and aspiration of sufficient capacity must be provided to keep rooms free of excessive steam, condensation and dust.

Exterior air intake ports must be examined periodically for physical integrity.

Air systems (incl. compressed air or gas) must be suitable to prevent **contamination**.

Hazards related to applications that use compressed air (or gas) to convey materials must be given special consideration.

Use of oil-free compressors is recommended. Where oil compressors are used, food-grade oil must be used and, in case there is a potential for compressed air (or gas) to come into contact with the product, the air must be filtered.

2.2.4. Lighting¹⁷

Sufficient lighting must be provided throughout the facilities and production areas in order to allow personnel to operate in a hygienic manner and to carry out their pet food safety responsibilities.

Contamination with glass or hard plastic due to breakage of lighting equipment must be prevented by means of a convenient lay out of lighting equipment, by protecting light fixtures or by using shatterproof lighting equipment.

2.3. WASTE DISPOSAL

2.3.1. General requirements

There must be adequate systems for the identification, collection, removal and disposal of waste materials, in

a manner that prevents **contamination** of products or production areas.

2.3.2. Containers for waste

All waste containers must be:

- Clearly identified;
- Located in a designated area;
- Designed to be effectively emptied and allow effective cleaning;

- Used for holding waste only; and
- Kept closed.

2.3.3. Waste management and removal

Provision must be made for the segregation, storage and removal of waste.

Waste and materials not suitable as feed material or **pet food** (due to e.g. **cross-contamination**) must be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other **hazards** must be disposed of in an appropriate way and not used as pet food.¹⁸

Systems must be in place to avoid accumulation of waste in production areas, and must prevent the use of unfit materials.

Defined waste areas and removal frequencies must be established in a manner to prevent waste becomes a source of food to pests.

Waste disposal must meet legislative requirements and, where appropriate, removed by licensed contractors.

External waste collection containers and compactors must be closed and/or covered and emptied at appropriate frequencies.

2.3.4. Drains and drainage

Drains must be designed, constructed and located so that the **risk** of **contamination** of materials or products is avoided.¹⁹

Drains must have sufficient capacity to remove expected

flow loads and not be located in a manner that would contaminate if a leak occurred.

Drainage direction must not be from a contaminated area to a clean area.

2.3.5. Spoilage and dust

Spoilage and dust must be cleaned and controlled to avoid pests to be attracted.

2.4. EQUIPMENT

2.4.1. Equipment

Equipment must be designed and be positioned such as to avoid **contamination**, **cross-contamination** and to be effectively cleaned and disinfected. When appropriate, machinery coming into contact with feed materials/**pet food** must be dried following any wet cleaning process.

All equipment must be properly specified prior to purchase and **commissioning** (e.g. paragraph 2.5 on mixing & homogeneity). **Commissioning** activities must verify that the new equipment is capable of producing safe, quality and legally compliant **pet food**.

All equipment surfaces coming into contact with the product should be impervious and non-reactive. All potential pet food contact lubricants must be of **feed grade** quality.

Equipment must undergo appropriate and regular maintenance, in accordance with written procedures pre-established by the equipment manufacturer, to minimize the **risk** of **contamination**.²⁰

Safety, quality or legality of product must not be jeopardised during and after maintenance operations.

Particular attention should be drawn to the **risk** of foreign body **contamination**. Third party contractors must be under the supervision of a designated person.

Measurement equipment must be safeguarded from adjustments that would invalidate the measurement results.

2.4.2. Calibration

When it is necessary to verify **monitoring** results (in case of **CCPs**, **OPRPs**, product legality or critical Quality) equipment used must be calibrated and traceable.²¹

- a. The equipment must be fit for the intended use. For instance, to weigh 500 grams, the balance used should not be one that is able to weight 100 kg with a 500 gram interval.
- b. A system needs to be in place to ensure that equipment must:
 - Be calibrated or verified at specified intervals or prior to use and the basis used for **calibration** or **verification** must be recorded;
 - Be calibrated following a defined method using more than 2 measurement points to be able to determine the linear **calibration** graph;

For the control of pre-packages placed on the market, procedures implemented have to be recognised by the competent authorities in the Member State.

- Be adjusted or re-adjusted as necessary when outside the allowed deviation (**corrective action**);
 - Be able to track to the reference used;
 - Be identified to enable the **calibration** status to be determined;
 - Be safeguarded from adjustments that would invalidate the measurement results;
 - Be protected from damage and deterioration.
- c. Procedures must be in place to ensure that products produced under not controlled conditions should be checked and assessed as safe before release.
 - d. Records of the results of **calibration** and **verification** must be maintained.
 - e. For the control of pre-packages placed on the market, procedures implemented have to be recognised by the competent authorities in the Member State.

Measuring instrument/equipment calibration compliance overview										Date:			
Identification number	Name of instrument	Location	CCP/ RCP/CP	Range of Measurement	Accuracy required	Deviation allowed	Calibration Frequency	Calibration Body	Reference instrument	Certificate number	Last calibration	Next calibration	Calibration status
12345	Static thermometer	Hydrostat	CCP	100-150° C	± 0,1°C	0,5°C	6 months	STORK	T98765	QC5436	15-Nov-16	May 2017	OK

2.5. MIXING & HOMOGENITY

All mixers used in the manufacture of pet food must be appropriate for the range of weights or volumes being mixed, and must be capable of manufacturing homogeneous mixes or homogenous solutions.

Cleanliness of the mixer is essential for efficacy and pet food safety.

Written maintenance schedules should exist for examination of the mixer to ensure that worn equipment parts do not lead to the build-up of residues when the mixer is emptied.

The mixers must operate for a pre-set time, determined by pre-production trials to ensure homogenous mixes and/or solutions.

The efficiency of the mixing process must be regularly checked to ensure that additives are evenly dispersed throughout the mix, using a tracer to be dosed following an appropriate procedure.

The method used should consist in:

- **Selecting a tracer:** the tracers can be selected from additives or medicaments, trace elements or specific

external tracer. It must be possible to dose the tracer with the aid of an exact, it should be repeatable and there have to be a sensitive analysis method to determine the quantity of the tracer in the mixture. The characteristics of the added tracer must not be influenced by the process which takes place between adding the tracer and the sampling point. The quantity of the mixture to be tested on the homogeneity should be representative of the production, according to internal recipes.

- **Producing a mix in which the tracer is contained:** the conditions (quantity, time, etc) during the homogeneity validation must coincide with the normal practices of the production plant.
- **Sampling:** the recommended sampling point is therefore a point which is as close as possible to output of the mixing point. Not fewer than 10 samples should be taken from a mixture. Results will improve if samples are taken from several locations at several different times.

More samples is always better, but the cost of sampling should also be considered in determining the number of samples taken. The mass of a sample should simply be any mass that is convenient to collect and analyse. The size of the samples could be between 100 and 1000g. It may be noted that in the same test all the samples should have the same size.

- **Analysing the tracer in the samples**
- **Evaluating (or assessing) the results achieved:** a statistical interpretation on the conformity of the homogeneity has to be done based on the coefficient of variation.

An unacceptable **carry-over** of additives, veterinary medical substances or any other undesirable substance must be defined, prevented and monitored. Operators must demonstrate the effectiveness of mixers with regard to homogeneity.

2.6. MANAGEMENT OF INCOMING MATERIALS

2.6.1. General requirements

The safety and legal compliance of feed materials, **additives** and packaging materials must be controlled and ensured at delivery. A vendor/**supplier** approval system must be in place in order to manage the sourcing of safe feed materials (see section 2.6.2).

The parameters describing the safety and legal compliance of **feed materials**, **additives** and packaging materials must be defined in written specifications, which need to be timely updated whenever necessary.

Procedures must be in place to define how to register, inspect, analyse, accept or reject incoming materials, including how to effectively handle and track the rejected deliveries.

The information obtained by controlling the **feed materials**, **additives** and packaging materials at delivery should be utilized to drive preventative actions and continuous improvement.

EU approved feed materials of GMO origin do not pose a **feed safety** hazard. When used, they are subject to specific regulations and must be declared in the label. For this purpose, the pet food manufacturer must have effective procedures in place to control the presence of feed materials containing, consisting of or produced from genetically modified organisms.

2.6.2. Vendor/supplier approval system

A vendor/**supplier** approval system must be in place in order to approve **suppliers'** site and to control the purchase of **feed materials/additives** and packaging materials, **additives**, finished and semi-finished product.

This approval system must document all standards and **monitoring** procedures dealing with primary production, inbound feed materials and packaging and transport. A list of approved **suppliers** and services must be maintained.

The procedures must define how materials/suppliers which are not covered by the above mentioned are handled. Additionally, the procedures must define how exceptions are handled e.g. the use of products or services where audit or monitoring has not been undertaken.

In order to approve a supplier's site, the following actions should be considered by the pet food manufacturer:

- Check the registration/approval of the supplier's site;
- Check the history of pet food incidents of the supplier's site;
- Check pre-filled questionnaires (as defined by the pet food safety management);
- Check the (pet) food safety management system of the supplier's site (e.g. audit to be carried out)

2.6.3. Specifications

Each feed material, additive and packaging material must have a written specification, which is regularly updated.

The specification should include:

- Name, coding or other identification of the concerned material;
- Origin and production method;
- Composition;
- Relevant chemical, physical and microbiological characteristics regarding safety, including characteristics determined in the hazard analysis, and regarding quality attributes;
- Packaging (if any);
- Shelf life/storage conditions;
- Directions for application/intended use;

2.6.4. Handling of incoming material

Vehicles, documentation and materials must be inspected prior to unloading to verify that the material is the correct one and it is in suitable conditions: for example, damaged, infested or dirty transports/containers will be rejected; materials shipped in damaged, infested or dirty vehicles will be rejected as well.

The conformance of incoming materials to specifications must be verified, for example by checking the Certificate of Analyses provided by the supplier and/or by analyzing the material. A documented procedure of inspection, sampling

To maintain the supplier's site approval, assessment/inspection and monitoring of suppliers must be performed with the frequency and type of assessment being determined by risk evaluation as provided in Annex III of this Guide.

Assessment may take the form of monitoring performance through in-house checks, certificates of analysis or extend to supplier inspection, as appropriate.

Supplier assessment must include the suppliers' ability to trace back to their supplier, evaluation of HACCP systems, product safety information and legislative requirements. The methods and frequency of assessment should be based on formal risk assessment.

- Relevant legislation, incl. labelling and claims, types of feedstuffs in which usage is approved, notes on any hazards or limitations about usage.

Any specification must be formally agreed with relevant parties, and signed off by the concerned supplier(s).

Such specifications will reflect the outcome of the preliminary risk analysis (about physical, chemical and biological risks) carried out for each incoming item in accordance with the HACCP study (see Chapter 3.2).

There must be a documented procedure for the amendment and approval of specifications for all parts of the process.

and analysis must exist, addressing products and hazards, methods, frequency, qualifications and responsibilities. Such procedure will take into account the risk assessment (HACCP), for example with regard to the frequency of a specific analysis.

Validated procedures for sampling incoming materials must exist.²² Adequate qualification and training of anyone dealing with sampling must be ensured. A procedure must be established to deal with non-conforming materials and their rejection. Such procedure should be designed to

prevent unintended use of non-conforming materials (e.g. holding). Documentation of rejected shipments, including reason for rejection, must be maintained.

Perishable or frozen materials meet specific minimum temperature requirements at points of shipment, transportation and receipt. Documentation of temperature checks for perishable goods at receiving points must be maintained.

2.7. CLEANING AND SANITATION

2.7.1. Cleaning & sanitising procedures

Appropriate standards of hygiene and housekeeping must be established to maintain hygienic conditions. Programmes must be monitored for continuing suitability and effectiveness.

Documented cleaning and/or disinfection programmes must cover the building, utilities, plant and equipment and must be validated and verified for their effectiveness in reducing the **risk of contamination**.

Only approved **feed grade** cleaning and sanitizing agents should be used.

Periodic cleaning and sanitizing activities must be recorded.

Cleaning and sanitizing tools must be designed and maintained in a condition that does not present a potential source of extraneous matter.

Cleaning staff should be trained according to guidelines mentioned in section 2.8.2.1 of this Guide.

2.7.2. Integrated pest management system

The **pet food** manufacturer is responsible for implementing hygiene, cleaning, incoming materials inspection and **monitoring** procedures to minimise the **risk** of pest infestation on the site.

Permanently operational electric fly killers and other pest trap methods must, when in use, be positioned so as to avoid **risk** of contaminating the product.

Pest control programmes must be implemented and be regularly reviewed for effectiveness. When applied, programmes must include a list of chemicals which are approved for use in specified areas of the site.

Incoming feed materials must, where appropriate, be thoroughly checked on arrival for the absence of pests.

The **pet food** manufacturer must either contract the services to a competent, and where appropriate licensed, pest control organisation, or must have trained personnel, for the regular inspection and treatment of premises to stop and eradicate pest infestation. Where the services of a pest control contractor are employed, the service contracted must be clearly defined and reflect the activities of the site.

Feed materials, packaging and **finished products** must be stored so as to minimise the **risk** of pest infestation. Where stored product may attract pests, appropriate measures must be included in the control programme.

Pet food production and storage buildings must be maintained in a good repair. Holes, drains and other potential access points must be sealed. Drains must be fitted with screens and traps to prevent pest entry.

Documentation must provide detailed information on the safe use and application of baits. The location of all pest **control measures** must be identified on a plan/diagram of the site.

Detailed records of the pest control inspections, recommendations and necessary action undertaken must be kept.

2.7.3. Chemicals control policy

The **pet food** manufacturer must adopt all measures to comply with the maximum permitted levels of physicochemical residues (including veterinary drugs) laid down in Community legislation and as mentioned in Annex I of this Guide.

Appropriate storage facilities must be provided for the control and storage of any hazardous chemicals.

2.7.4. Foreign bodies control policy

The use of glass or other brittle material (such as hard plastic components in equipments) close to production machinery must be avoided and, wherever necessary, it must be protected against breakage.

processing, packing and storage areas must be in place to ensure the necessary precautions are taken. These procedures should form part of a formal foreign bodies control policy.

Where identified by the **hazard assessment**, a zoning plan must be implemented.

Measures must be put in place to prevent, control or detect potential contaminants identified by the **hazard assessment**. For more details, please refer to table of hazards n° 1, 2 and 3.

Written procedures for wood, metal, glass and hard clear plastic breakages in feed material handling, preparation,

2.7.5. Pathogens monitoring

When a **pet food safety risk** linked to pathogens is defined in the **HACCP** study, a **monitoring** program should be implemented in order to proactively control the safety of products.

Pathogens **monitoring** control programmes must be implemented and be regularly reviewed.

Zoning and a pre-defined flow of product and personnel is an important **prerequisite programme** to proactively prevent pathogen presence.

Pathogens **monitoring** should include environmental **samples**, line **samples** and **samples** of finished products.

Pathogen **monitoring** is a way to ensure the safety of **pet food** and is one of the programs aimed at measuring the effectiveness of the implementation of the pre-requisite programs, in particular for products which are not sterilised in hermetic package. In order to monitor the microbiological state of a factory, **samples** are collected and analysed according to a pre-defined plan (location, frequency, number). Data obtained from the **monitoring** should be routinely trended and the information obtained will drive subsequent sampling and product release protocols as well as **corrective actions**.

a. **Environmental samples** are taken by swabbing from non-product contact surfaces; the routine plan should include fixed (or pre-defined) locations and random locations; in case of need (e.g. new cracks detected in a floor, any troubleshooting), a specific investigation should be conducted by taking 'investigative' **samples** in the concerned location(s). The number, frequency and location of environmental sampling will be defined by the **HACCP plan** and tend to be proportional to the factory size and complexity. As part of the **HACCP plan**, every factory is supposed to be split into zones related to their microbiological 'cleanness', and the environmental sampling plan (and results management) will be designed in accordance to zoning.

The type of pathogen (and indicator) microorganisms to be monitored will be defined by the **hazard** analysis (**HACCP plan**) and it is expected to include typically Salmonella.

b. **Line samples** are taken by swabbing from product contact surfaces (e.g. internal surface of processing equipment, transport belts, nozzles etc.) and by

collecting fines from build ups (for example, at the base of a conveying system) into sterile packs – after collecting the **samples** all materials should be removed and the area sanitised in order to make sure that the next sampling will represent the current status. Again, the number, frequency and location of line **samples** will be defined by the **HACCP plan**.

c. Samples of finished products are taken when packed products are ready to be placed on the market. Frequency should be set according to legislation and/or customer's requirements (e.g. retailer).

In all cases (environmental, line and **finished products**), **monitoring** will have different levels triggered by the microbiological status of the factory; typically, there are three levels:

- 'Standard' or 'minimum': whenever the results of **monitoring** are consistently showing that the microbiological status is 'clean' and in control (i.e. absence of pathogens and indicator microorganisms within specified limits)
- 'Heightened' or 'medium': if the microbiological status is not consistently in control, (i.e. due to occasional detection of pathogens or to indicator microorganisms above specified limits); and
- 'Elevated' or 'maximum', in case the microbiological status is consistently not in control, (i.e. due to the recurrent detection of pathogens and of indicator microorganisms above specified limits).

Every level corresponds to a different **monitoring** plan: by increasing the level, the number and frequency of sampling will increase accordingly.

When the routine monitoring reveals a positive result, the pathogen **monitoring programme** should be adapted as to be more stringent. The number of **samples**, the foreseen time needed to demonstrate that the situation is again under control and the final date for re-instating the routine pathogen **monitoring programme** should be defined and documented.

The limits of pathogen (and indicator) microorganisms which trigger the different **monitoring** levels need to be defined by the manufacturer, taking into consideration the safety of **finished products**. Also, the results of **monitoring** (including trending) may trigger preventative and **corrective** actions, which could include destroying some **finished products** and/or shutting down all or parts of the concerned production line(s) for cleaning and sanitizing. In such a case, a specific additional microbiological testing plan is required to verify the effectiveness of the **corrective actions**.

A plan should describe:

- The frequency of sampling,
- The number and location of **samples** to be taken,
- The micro-organism(s) to be looked for.

When required, the plan should be adapted as to investigate any new potential **risk** specific to the plant of the manufacturer.

The **pet food** manufacturer must have specific trained personnel to set up a plan and to take **samples**.

Sampling must be done by trained personnel in a way as to avoid:

- **Cross-contamination** of **samples**;
- **Contamination** within/between the production line(s).

Samples need to be stored and transported in a way as to ensure that the conditions of the **samples** are stable until analyses are carried out

It is essential that all staff dealing with pathogens **monitoring** (taking, transporting and analysing **samples**) are properly trained and well equipped, to prevent any **risks** of affecting the analysis results (e.g. by cross contaminating or by mixing up **samples**) and any **risks** about their own safety.

2.8. PERSONNEL

2.8.1. Training

The **pet food** manufacturer must ensure that all employees are adequately trained, instructed and supervised, in line with their activity.

Good manufacturing practice requires that all employees involved in the production of **pet food**, including storage and transport, be aware (e.g. clearly informed in writing of their duties, responsibilities and powers) that they contribute to the quality and safety of the **finished products**.

All personnel, including temporary personnel and contractors, must be in sufficient number, possess the skills and qualifications necessary for the manufacturing process and be appropriately trained prior to commencing work. They must be adequately supervised throughout the working period.

The staff must be adequately trained for **feed safety management system**. The person responsible for supervising **quality control** and product safety must furthermore be in a position to carry out his/her tasks independently and to take the appropriate decisions.

The **pet food** manufacturer must have full training programmes and maintained records (e.g. programme content, name of the trainer, final assessment of trainees, and establishment of the requirement of retraining).

The company must ensure that in particular the personnel responsible for **feed safety monitoring, corrections, corrective actions, preventive actions** is trained and must routinely review the competencies of staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, **monitoring** or on- the-job-experience.

2.8.2. Hygiene and health

2.8.2.1. Personnel hygiene

The **pet food** manufacturer's personnel hygiene standards must be documented and adopted by all personnel, including contractors and visitors to the factory. These standards must be designed with due regard to the **risk** of product **contamination**.

The requirements for personnel hygiene must be documented and communicated to all personnel in a document policy, describing the behaviours required of personnel receiving, processing, packaging, loading and storage areas. Compliance with the requirements must be checked regularly.

Based on **risk assessment** the company must document its jewellery policy including the rules for watches and rings or studs in exposed and visible parts of the body (e.g. noses, tongues, eyebrows). The exception could be a plain wedding ring unless identified as a **feed safety hazard** or occupational safety **hazard** to the individual.

All cuts and grazes on exposed skin must be covered (e.g. by a coloured bandage or detectable blue metal strip plaster, different from the product colour). If metal detection is implemented, a **sample** from the bandage must be successfully tested through a metal detector and records must be kept.

Smoking, eating (including chewing gums and sweets) and drinking are not allowed in production areas.

Hand cleaning must be performed in an appropriate manner and frequency. A document detailing the hand cleaning policy must require to wash and/or sanitize hands (if deemed appropriate by the management) in the following cases:

- Before starting any working shift,
- Immediately after using the toilet,
- Immediately after handling potential contaminants and
- When moving from one area to another.

Personnel (including visitors) known, or suspected, to be suffering from a disease likely to be transmitted to pet food, should not be allowed to enter any pet food area where direct contact with pet food is possible and there is

a likelihood of contaminating the pet food, posing a risk to the safety of the product, the target animal and to humans handling the pet food.

2.8.2.2. Workwear & Personnel protective clothing

Pet food handlers, visitors, and contractors working in, or entering the pet food handling areas, must wear suitable pet food manufacturer-issued protective clothing.

obligation for the personnel to wash hands (see section on 2.7.5 on pathogens monitoring).

Personnel who work in, or enter into, areas where exposed materials are handled must wear work clothing that is fit for purpose and in good condition.

All protective clothing must be laundered effectively at intervals suitable for the intended purpose.

Where appropriate, all hair must be fully covered to prevent product contamination.

Based on risk assessment, the company must document and communicate to all employees, contractors and visitors the rules regarding the wearing and changing of protective clothing in work areas. Protective clothing must be available in sufficient numbers for each employee and in suitable design to prevent contamination of the product (e.g. no external pockets or sewn on buttons).

Suitable safety footwear must be worn within the factory environment.

Gloves, if worn, should be subject to adequate control to avoid product contamination. This does not replace the

2.8.3. Staff facilities

Personnel hygiene facilities must be available, clearly designated and maintained as necessary for pet food safety.

Consumption of food and drinks as well as smoking must only be allowed in segregated and dedicated areas.

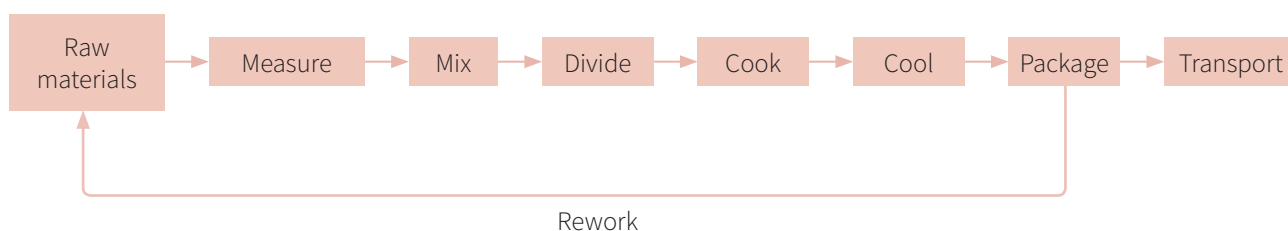
2.9. REWORK

Rework must be treated as a raw material and therefore the basic principles must be applied:

- Where rework or any reworking operation is performed, traceability must be maintained.
- Where re-processing is used, or reworking operations

carried out, procedures must be implemented to ensure the safety, legality and quality of the finished product.

- The use of rework must be part of the HACCP study (e.g. part of the flow diagram, hazards by contamination of the finished product, etc...).



2.10. TRANSPORT AND STORAGE

2.10.1. General requirements

All vehicles or warehouses used for the transportation or storage of feed materials (including **additives** and packaging), intermediates/semi-processed products and **finished product**, must be suitable for the intended purpose, and be maintained in good repair and in a hygienic condition.²³

A **hazard assessment** must be conducted to determine when cleaning is required. Cleaning procedures must be documented, and cleaning actions between loads must be recorded.

Containers used for transporting, or warehouses used for storing, feed materials and **finished products** should be kept free of potential contaminants, whether chemical, odour, pests (e.g. microorganisms, rodents, insects, birds) and domestic animals.

Feed materials, additives and packaging materials, as well as **finished products**, must be stored and transported in

such a way as to make them easily identifiable (product name, number, date and time of manufacture) and to prevent **cross-contamination** and deterioration.

Refrigerated and humidity-controlled transport or storage must be capable of maintaining product, feed material or **additive** temperature within specification, under maximum load, and whilst the product, feed material or **additive** is stored on the vehicle or in the warehouse.

Where appropriate, procedures must be in place in the case of equipment failure (e.g. refrigeration); these procedures must ensure product safety, legality and quality.

Where required, bulk containers and vehicles must be dedicated to a specified material, class of materials or animal food or ingredient used only.

2.10.2. Transport

All transportation conveyances must be inspected prior to loading to ensure they are consistent with specification requirements.

Based on a **risk assessment**, measures must be taken to ensure that the loading and transportation of the product is adequate in order to minimize the **risk** of chemical, microbiological and/or physical **contamination** of the product. **Risk assessments** must consider any potential **hazards** and ensure that controls effectively preclude any serious risk of **contamination**.

For the transport of feed materials carried out by a sub-contractor, requirements on transportation must be communicated to the transporter; these requirements must be documented.

Where the **feed material/additive**, packaging materials or **finished product** transported is susceptible to damage by the weather, vehicles must be weather proofed and must

be loaded and unloaded in covered bays to protect the material.

Animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.²⁴

Unprocessed Category 3 material destined for the production of feed material or pet food must be transported chilled or frozen, unless processed within 24 hours of the time at which it was generated.²⁵ Vehicles, containers, or packaging must have a label attached that says: 'category 3 material - not for human consumption'.²⁶

Vehicles and reusable containers and all reusable items of equipment or appliances that come into contact with animal by-products or processed products must be:

- cleaned, washed and disinfected after each use;
- maintained in a clean condition; and
- checked for cleanliness and dryness before new use.²⁷

History of previous loads and cleaning procedures must be known and considered.

Reusable containers must be dedicated to the carriage of a particular product in order to avoid **cross-contamination**.

2.10.3. Storage

Materials (including **additives** and packaging) as well as **finished products** must be stored in dry, clean, well-ventilated spaces protected from dust, condensation, fumes, infestation or other sources of **contamination**.

- Packed materials must be stored in appropriate packaging.

Storage segregation²⁸ procedures must be in place to prevent the **cross-contamination** of **finished products**, packaging and feed materials.

- A separate area or other means of segregating materials identified as non-conforming must be provided. Non-conforming materials or **finished products** must be clearly identified.
- Product returned from distribution must be assessed for

animal **feed safety hazards** and handled accordingly.

- Waste materials and chemicals (cleaning products, lubricants and pesticides) must be clearly identified and stored separately.

Procedures must be in place to ensure that materials and products are used in the correct order and within the allocated **shelf life** (e.g. **F.I.F.O.** or **F.E.F.O.**). Receipt documents and/or product labelling must facilitate correct stock rotation.

Only persons authorised by the **pet food** manufacturer must have access to the storage facilities.

Outsourced activities (e.g. external warehousing) must be controlled, e.g. by means of auditing.

2.11. PRODUCT INFORMATION AND CONSUMER AWARENESS

2.11.1. General requirements

Information on content and intended use of pet food products must be communicated to customers and consumers (e.g. on a product label). Procedures must be in place detailing the correct labelling of products in accordance with applicable regulations.

Information for customers (e.g. industry or trade users) should be clearly distinguishable from consumer information, particularly on food labels.

Consumers should be made aware of food hygiene basic standards to enable them to understand the importance of product information, make informed choices appropriate to the individual, and prevent **contamination** and growth or survival of foodborne pathogens by storing, preparing and using it correctly.

2.11.2. Product information

Products should bear appropriate information to ensure that adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product in a safe and correct way.

Insufficient product information can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene **control measures** have been taken earlier in the food chain.

3. HACCP System

3.1. DEFINITION, SCOPE AND BOUNDARIES

3.1.1. Definition

HACCP means **hazard** analysis and **Critical Control Point** and is originated from the Codex Alimentarius.

HACCP is a management system in which **pet food safety** is addressed through the analysis and control of biological, chemical, and physical **hazards** from raw

material procurement and handling, to manufacturing and distribution of the finished product.

However, **HACCP** principles alone are not self-sufficient, and must be backed-up by a strong management system, **traceability** procedures and **prerequisite programs**.

3.1.2. Scope and boundaries

HACCP procedures are procedures based on the **hazard** analysis and **critical control points (HACCP)** principles i.e. an auto-control system which identifies, evaluates and controls **hazards** which are significant for **pet food safety**.

HACCP procedures should be science/risk-based and systematic, identifying specific **hazards**, and measures for control of those **hazards**, to ensure the safety of food. HACCP procedures are tools to identify and assess biological, chemical and physical **hazards** (see table of hazards n° 1, 2 and 3 further below in the Guide) and establish control systems that focus on prevention.

HACCP management is a continuous process which must be reviewed according to any change occurring in the sourcing, transport, storage or manufacturing process in order to ensure that new **hazards** have been introduced when such changes are made.

The regular act of reviewing all aspects of the **HACCP plan** is meant to:

- Reflect accurately the reality of the process on the factory floor;
- Ensure continuous identification of new pet food safety **hazards** and performance of **risk assessments** of all factory practices; and
- Use all **verification** data to identify trends and take appropriate actions.

A hazard analysis study (HACCP) shall be undertaken during the design/development phase of the product, packaging and process and should be reviewed upon any change in product, process, procedures or practices which may affect product safety. In principle any change should be assumed to have an impact and therefore should be **risk** assessed. In any event, a review of the HACCP plan should be carried out at least once a year.

For instance, the **HACCP** system may require partial or full review in the following cases:

- Changes in raw materials specifications, **suppliers** or origins of supplies;
- Changes in formulation of the **finished products**;
- Changes in technologies or processes;
- Changes in factory equipment or layout;
- Changes in cleaning or maintenance practices;
- Changes in packaging, transport or storage;
- Changes in personnel;
- Changes in product type (e.g. **wet or dry pet food**) or target species (e.g. dogs, cats, small animals);
- Changes in legislation/other requirements;
- Feedback/complaints from customers;
- New scientific evidence/literature on **hazards**;
- A breach to operating and/or **critical limits** as set in the **HACCP plan**.

3.2. THE HACCP SYSTEM: STEP BY STEP

The HACCP system is carried out in 12 steps which follow the seven principles described in the Codex Alimentarius based on the a priori implementation of Pre-requisite

programmes. The seven principles can be summarised as follows and are further detailed in the below sections of the Guide.

Codex Principle 1	Conduct a hazard analysis	Step 1: Assemble HACCP Team Step 2: Describe product Step 3: Identify intended use Step 4: Construct flow diagram Step 5: Confirm flow diagram on site Step 6: List all potential hazards Step 6: Conduct a hazard analysis Step 6: Consider control measures
Codex Principle 2	Determine the Critical Control Points (CCPs) and Operational Pre- Requisite Programmes (OPRPs)	Step 7: Use decision tree to determine CCPs and OPRP
Codex Principle 3	Establish critical limits	Step 8: Establish action and critical limits for each CCP and OPRP
Codex Principle 4	Establish CCP monitoring procedures	Step 9: Establish monitoring systems for each CCP and OPRP
Codex Principle 5	Establish corrective action plans	Step 10: Establish the corrective action to be taken when monitoring indicates that a particular CCP or OPRP is not under control
Codex Principle 6	Establish verification procedures	Step 11: Establish procedures for verification to confirm that the HACCP system is working effectively
Codex Principle 7	Establish documentation and record keeping systems	Step 12: Establish documentation concerning all procedures and records appropriate to these principles and their application

3.2.1. Principle 1: Conduct a Hazard analysis

The HACCP team must have the responsibility and authority to:

- Ensure that the feed safety management system is established, implemented, maintained and updated in accordance with the requirements in this Code and the regulatory requirements.
- Report directly to the organization's management on the effectiveness and suitability of the management system.
- Arrange relevant training and education of the HACCP-team members.

The HACCP team leader must be a management representative or have direct access to management. In any event, the Management should bear the responsibility of feed safety management system.

The management must provide adequate resources for the establishment, implementation, maintenance, updating and control of the feed safety management system. Adequate communication must be in place to inform the HACCP team (leader) of significant changes in products or processes.

a) Assemble the HACCP/pet food safety team

The pet food operation should assure that the appropriate product specific knowledge is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should

describe which segment of the pet food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

b) Describe product and identify intended use

A full description of the product should be developed which includes all relevant information on feed safety. As a guide this may include the following, although this is not an exhaustive list:

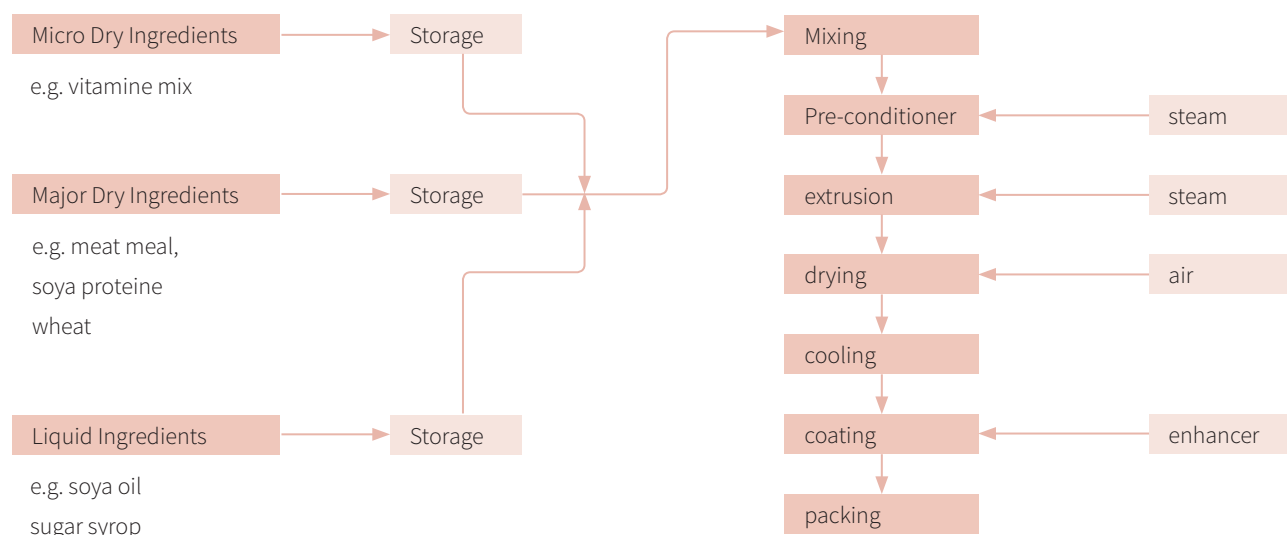
- Origin of all feed materials
- Physical or chemical properties that impact feed safety (e.g. pH, Aw)
- Treatment and processing (heating, freezing, salting)
- Packaging system (e.g. modified atm, vacuum)
- Storage and distribution conditions (chilled, ambient)
- Target shelf life under prescribed storage and usage conditions
- Instruction for use (e.g. storage, preparation)
- Consideration of potential misuse e.g. storage, preparation

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to consider.

c) Construct and confirm flow diagram

The flow diagram should be constructed by the HACCP team. The flow diagram should cover each product, product category and all steps in the operation.

Example of a flow diagram for a processing progress:



When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation:

- A map of the facility that includes the placement of production, equipment etc;
- Feed materials including introduction of utilities and other contact materials (e.g. water, packaging)
- Sequence and interaction of all process steps
- Outsourced processes and subcontracted work
- Process parameters
- Potential for process delay
- **Rework** and recycling low/high and clean/dirty area segregation
- **Finished products**, intermediate/semi processed products, by-products and waste.

The HACCP team should confirm the processing operation on site against the **flow diagram** during all stages and hours of the operation amending the **flow diagram** where appropriate.

d) List all potential hazards associated with each step, conduct a hazard analysis, consider any measures to control identified hazards

The HACCP team should list all of the **hazards** that may reasonably be expected to occur at each step from primary production, processing, manufacture and distribution until the point of consumption. A **hazard** is a biological, chemical or physical agent in, or condition of, pet food with the potential to cause an adverse health effect.

The HACCP team should next conduct a **hazard** analysis to identify for the HACCP plan which **hazards** are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe **pet food**.

In conducting the **hazard** analysis, the following aspects should be included, wherever possible:

- The likely occurrence of **hazards** and severity of their adverse health effects;
- The qualitative and/or quantitative evaluation of the presence of **hazards**;
- Severity or the effects on consumer safety;
- Vulnerability of those exposed;
- Survival or multiplication of micro-organisms of concern;
- Production or persistence in **pet food** of toxins, chemicals or physical agents and

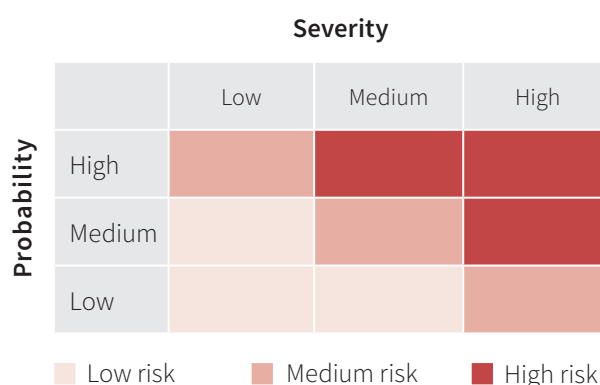
- Foreign bodies; and
- Conditions leading to the above.

At each stage of the operations diagram, the causes of the potential **hazards** are identified using the “5 Ms methods”. 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, protein crops
“Milieu” - Environment	Atmosphere, surrounding areas
Man	Hygiene
Method	Operating method
Machine	Installations, transport equipment

Example of **hazard assessment** with a severity-probability matrix:



The HACCP team must then consider what **control measures**, if any, exist which can be applied for each **hazard**. More than one **control measure** may be required to control a specific **hazard(s)** and more than one **hazard** may be controlled by a specific **control measure**. Justification for acceptable levels in the **finished product** for each **hazard** must be determined and documented. **Control measures** should be validated, i.e. to obtain evidence that **control**

measures are capable of being effective through the HACCP plan and the OPRPs, if properly implemented, by controlling the hazards to a specific outcome. Revalidation may be required in case of changes.

performed at the time a control measure or a feed safety control system is designed, or when changes indicate the need for revalidation (i.e. system failure, process changes, new scientific or regulatory information).

Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control. Validation involves measuring performance against a desired feed safety outcome or target, in respect of a required level of hazard control. Validation is

Validation of control measures is, whenever possible, performed before their full implementation.

Practical example of validation: control of metal fragments:

Validation – Control of metal fragments	
Step/phase	Actions
Pre-validation Tasks	<ul style="list-style-type: none"> a. Hazard: Metal fragments b. Food Safety Outcome: Less than 1 metal fragment over 2 mm in 100,000 kg of product c. Control Measure: Introduction of a sieve into a production line
Approach	Collection of data during normal operation
Parameters and decision criteria	Control measure will be considered validated if a metal detector indicates that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product. Operational data will be collected for one month and reviewed to determine the size of any metal pieces in products rejected by the metal detector.
Assemble relevant validation information	<ul style="list-style-type: none"> a. Determine the size of metal fragments in products rejected by the metal detector. b. Ensure that the metal detector is sensitive enough and calibrated to detect metal pieces of 2 mm or more in the specific product. c. Ensure that the sieve remains intact during normal operations.
Analyze results	Determine the rate at which the sieve allowed fragments of 2 mm or more in the final product.
Document and review the validation	<ul style="list-style-type: none"> a. Document all findings from the metal detector. b. Document the integrity of the sieve and the sensitivity and calibration of the metal detector.
Conclusion	<ul style="list-style-type: none"> a. Control measure can be implemented if data indicate that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product. b. Validation will likely provide information on monitoring needed to ensure that sieve remains intact. c. The metal detector can be used after the validation as an ongoing verification activity to ensure that the sieve is controlling the hazard as intended.

3.2.2. Principle 2: Determine Critical Control Points (CCPs)

There may be more than one step in the process at which control is applied to address the same **hazard**. The last step that will prevent or eliminate the **hazard** or reduce it to acceptable level will be defined as a **CCP**. The determination of a **CCP** or an **OPRP** in the **HACCP** system can be facilitated by the application of a decision tree which indicates a logic reasoning approach.

An example of decision tree guiding the operator to consider **CCPs** or **OPRPs** is provided in annex to this Guide. This decision tree may not be applicable to all situations; other approaches may be used. Training in the application of the decision is recommended.

Boundaries/distinction between **PRPs**, **OPRPs**, **CCPs**:

Type of control measure	PRP	OPRP	CCP
Scope	Measures related to creating the environment for safe food: measures impacting food suitability and safety	Measures related to the environment and/or product (or combination of measures) to prevent contamination , or to prevent, eliminate or reduce hazards to an acceptable limit in the end product. These measures are implemented after the implementation of PRPs .	
Relation to hazards	Not specific to any hazard	Specific to each hazard or group of hazards	
Determination	Development based on: <ul style="list-style-type: none"> • Experience, • Reference documents (guides, scientific publications...), • Hazard or hazard analysis 	Based on the hazard analysis taking PRPs into account. CCPs and OPRPs are product and/or process specific.	
Validation	Not necessarily carried out by operators. (i.e. cleaning products manufacturer has validated the efficiency of the product and determined product spectrum and instructions of use – Feed Business Operator has to follow instructions and keep technical specification of product)	Validation has to be carried out	
Criteria	/	Measurable or observable criteria	Measurable critical limit
Monitoring	Where relevant and feasible	Monitoring of the implementation of control measures : usually recorded	
Loss of control: corrections/corrective actions	Corrective actions and/or corrections on the implementation of PRPs where relevant	Corrective actions on the process Possible corrections on the product (case by case) Records kept	Pre-set corrections on the product Possible corrective actions on the process Records kept
Verification	Scheduled verification of implementation	Scheduled verification of implementation, verification of achievement of planned hazard control	

Typical example of CCP with document and record keeping:
metal detection

Step	Hazard	Category	CCP	Monitoring			
				What	How	When	Who
Filling	Metal Foreign Object	Physical	x	Metal detector prior to filler	- Detection of all test pieces - Ejection system is working properly (belts stop for belt detectors or ejection valve is switched on for pipe detectors)	Twice a shift	Trained operator

Critical limits	Corrective Action	Records	Verification
One of the test pieces is not detected Ejection system is not working Operator is not trained	Product put on hold from the last control	Factory documents (ref xxx)	Consumer complaints Product panels

3.2.3. Principle 3: Establish critical limits for each CCP or OPRP

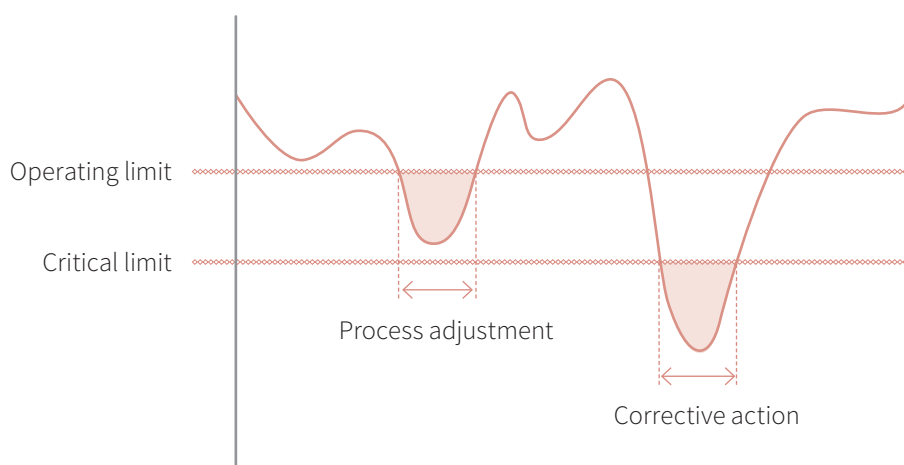
Critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters which can demonstrate that the critical point is under control. They should be based on substantiated evidence that the chosen values will result in process control.

Critical limits must be specified and validated if possible for each **Critical Control Point (CCP)** or **Operational Prerequisite Programme (OPRP)**. In some cases more than one **critical limit** will be elaborated at a particular step. Criteria often used include measurement of temperature, time, moisture level, pH, Aw, available chlorine and sensory

parameters such as visual appearance, smell and texture.

Critical limits must be measurable wherever possible (e.g. time, temp, pH) and the rationale for their establishment clearly documented. The **HACCP** team must take into account government regulations and guidelines and industry standards. Any **critical limits** based on subjective data (such as visual inspection) must be supported with written protocols and clear examples. **HACCP** team must validate each of the **CCP**. Documented evidence must show that the **control measures** selected are capable of consistently controlling the **hazard** to the level specified in **critical limit**.

Example of management of process monitoring



3.2.4. Principle 4: Establish a monitoring system for each CCP and OPRP

Monitoring is the scheduled measurement or observation of a **CCP** or **OPRP** relative to its **critical limits**. The **monitoring** procedures must be able to detect loss of control at the **CCP** or **OPRP**. Further, **monitoring** should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the **critical limits**. Where possible, process adjustments should be made when **monitoring** results indicate a trend towards loss of control at a **CCP** or **OPRP**. The adjustments should be taken before a deviation occurs. Data derived from **monitoring** must be evaluated by a designated person with knowledge and authority to carry out **corrective actions** when indicated. If **monitoring** is not continuous, then the amount or

frequency of **monitoring** must be sufficient to guarantee the **CCP** or **OPRP** is in control. Most **monitoring** procedures for **CCPs** and **OPRPs** will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing.

Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological status of the product. All records and documents associated with **monitoring CCPs** and **OPRPs** must be signed by the person(s) doing the **monitoring** and by a responsible reviewing official(s) of the company.

3.2.5. Principle 5: Establish corrective actions

Specific **corrective actions** must be developed for each **CCP** and each **OPRP** in the **HACCP** system in order to deal with deviations when they occur. The actions must ensure that the **CCP** or **OPRP** has been brought under control. Actions

taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the **HACCP** record keeping.

3.2.6. Principle 6: Establish verification procedures

Establish procedures for **verification**. **Verification** and auditing methods, procedures and test, include random sampling and analysis, can be used to determine if the **HACCP** system is working correctly. The frequency of **verification** should be sufficient to confirm that the **HACCP** system is working effectively.

Examples of **verification** activities include:

- Review of the **HACCP** system and its records, e.g. via **audit** and inspection;
- Review of the deviations and product dispositions;
- Review of complaints;
- Review of incidents with **product recall**.

3.2.7. Principle 7: Establish Documentation and Record keeping

Efficient and accurate record keeping is essential to the application of a **HACCP** system. **HACCP** procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Documentation examples are:

- **Hazard** analysis;
- **CCP**, **OPRP** determination; and
- **Critical limit** determination.

Record examples are:

- **CCP** and **OPRP monitoring** activities;

- Deviations and associated **corrective actions**;
- Modifications to **HACCP** system; and
- Confirmation that the **CCPs** are kept under control.

Where possible, **validation** activities should include actions to confirm the efficacy of all elements of the **HACCP** plan. If a **hazard** has been identified at a step where control is necessary for safety, and no **control measure** exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage to include a **control measure**.

3.3. LIST OF HAZARDS

Hazards are biological, physical or chemical agents in animal feed that are reasonably likely to cause illness or injury for **pets** in the absence of their control. Whether a particular **hazard** named in the list below will need to be addressed in a **HACCP plan**, will depend on an evaluation of the actual **risk** and severity of the **hazard** in **pet food**. **Hazards** may be introduced into the **pet food** or raw material for **pet food** any time during harvesting,

formulation and processing, packaging and labelling, transportation, storage, preparation and feeding.²⁹ For more details and information regarding the determination the significance of the **hazards**, the following websites can be used as an example:

www.efsa.europa.eu/en/scientific-work

www.who.int/topics/foodborne_diseases/en

3.3.1. Table 1: List of hazards - Dry pet Food

Nature of hazards	Hazards/Description	Dry pet food ≤14% moisture	Comments
Biological	Aeromonas is a Gram-negative, non-spore-forming, tentatively anaerobic bacterium. This bacterium can be found in fresh or brackish water.	Applicable	No spore forming. Risk for dry pet food is very low. Biological contamination might occur so that adequate rules for product and personnel flows must be in place.
Biological	Campylobacter is a Gram-negative bacteria, non-spore forming bacterium. Campylobacter species are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs and sheep. They live harmlessly in the gut but during slaughter and processing of farm animals, the contamination can spread from the gut to other parts of the animal.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. No risk when the aw-value is low. Biological contamination might occur so that adequate rules for product and personnel flows must be in place.
Biological	Clostridium perfringens is a Gram-positive, rod-shaped, anaerobic, spore-forming. C. perfringens is found frequently in the intestines of many animals and is present in soil and areas contaminated by human or animal feces.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. Biological contamination might occur so that adequate rules for product and personnel flows must be in place.
Biological	Clostridium botulinum is an anaerobic rod-shaped bacterium, i.e. it lives and grows in low oxygen conditions. The spore has a hard protective coating and is able to survive for years. C. botulinum is responsible for a disease called botulism. Clostridium botulinum is found in soil and untreated water throughout the world.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. Depending on the process C.b. remains in the product, because of anaerob conditions (folio). If C.b. has been in product, the toxin remains. Sterilisation process is meant to destroy this bacterium and spore, not the toxin. Biological contamination might occur so that adequate rules for product and personnel flows must be in place.
Biological	The Enterobacteriaceae are a large family of Gram-negative bacteria. They are not spore-forming. Many members of this family are a normal part of the gut flora found in the intestines of humans and other animals, while others are found in water or soil, or are parasites on a variety of different animals and plants.	Applicable	Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard. Adequate rules for product and personnel flows must be in place to avoid biological contamination.

Nature of hazards	Hazards/Description	Dry pet food ≤14% moisture	Comments
Biological	Listeria monocytogenes is a Gram-positive bacterium. Listeria is found in soil, plants and water. Animals, including cattle, sheep and goats, can also carry the bacteria. Cooking at temperatures higher than 65 °C kills the bacteria.	Applicable	Non-spore-forming and not thermo resistant which make it low risk for dry pet food. Adequate rules for product and personnel flows must be in place to avoid biological contamination.
Biological	Pathogenic E.coli: <i>Escherichia coli</i> is a gram-negative, tentatively anaerobic, rod-shaped bacterium of the genus <i>Escherichia</i> that is commonly found in the lower intestine of warm-blooded organisms (endotherms).	Applicable	Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard. Biological contamination might occur so that adequate rules for product and personnel flows must be in place.
Biological	Salmonella is a gram-negative bacteria of the Enterobacteriaceae family. Salmonella species are non-spore-forming.	Applicable	Indicator for microbiological infestation. Infestation could occur via packaging personnel after thermal treatment or via droppings of animals when buildings are not closed. Adequate rules for product and personnel flows must be in place to avoid biological contamination.
Biological	Moulds and yeasts are fungus that grow in the form of multicellular filaments called hyphae. In contrast, fungi that can adopt a single-celled growth habit are called yeasts.	Applicable	Storage conditions of dry materials (cereals, vegetables...). Heat treatment is required. Adequate rules for product and personnel flows must be in place to avoid biological contamination. Dry pet food can get mouldy depending on its residual moisture content and aw-value. Furthermore it's important to avoid condensation.
Biological	Staphylococcus aureus is a gram-positive coccal bacterium. Produces several enterotoxins generally highly resistant to enzymatic degradation and heat. Bacterium exists in soil.	Applicable	Spores are not thermo-resistant but the toxin is. Staphylococci are living in warm blood animals. It indicates bad cleaning conditions. Adequate rules for product and personnel flows must be in place to avoid biological contamination.
Biological	Pests are rodents or insects which may carry pathogenic organisms which are source of contamination.	Applicable	Clean facilities and proper pest control policy must be in place. May also occur via raw materials.
Chemical	Biocides (cleaning substances) are any substances or mixtures consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. This includes insecticides, insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibers and anti-fouling paints for the protection of ship hulls.	Applicable	May occur at level of incoming materials as well as during production process via residues of sanitizing operations. Control measures after cleaning must be in place.

Nature of hazards	Hazards/Description	Dry pet food ≤14% moisture	Comments
Chemical	Carry over of substances for non-target species is a transfer of any authorised substance or product from one production batch to the immediate subsequent batch destined to a different target species.	Applicable	May occur during manufacturing process when different products are produced simultaneously or one after the other.
Chemical	Dioxins and dioxin-like compounds (DLCs) are compounds that are highly toxic environmental persistent organic pollutants.	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk (e.g. package by recycled material). May also occur during production process (e.g. Crisis in Ireland back in 2008).
Chemical	Heavy metals are metals with a relatively high density, atomic weight or atomic number which presence may occur in pet food. Typical examples are lead, mercury and cadmium.	Applicable	Sources in the feed chains are pollution, soil, machines, water used for production...
Chemical	Mycotoxins are toxic secondary metabolites produced by organisms of the fungus kingdom. The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops. One mold species may produce many different mycotoxins, and several species may produce the same mycotoxin.	Applicable	Raw material contamination or during transport and storage. Higher risk depending on the geographical origin of incoming material and weather conditions. The occurrence of risk is linked to the quantity of cereals and vegetables used in the recipes.
Chemical	PCBs or polychlorinated biphenyls are organic chlorine compounds. PCBs cause cancer in animals and are probable human carcinogens. Because of PCBs' environmental toxicity and classification as a persistent organic pollutant, PCB production was banned by the United States Congress in 1979 and by the Stockholm Convention on Persistent Organic Pollutants in 2001.	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk. May also occur during production process, e.g.: - Use of unappropriated combustion for heat treatment (e.g. bread meal) - Residues of plastic used as folio, boxes etc.

Nature of hazards	Hazards/Description	Dry pet food ≤14% moisture	Comments
Chemical	Toxins Veterinary drugs are hormones, growth regulators, antibiotics... used for feed animal treatments.	Applicable	The origin of animal by-products needs to be taken into account to ensure that no residues are found in the incoming materials. Occurrence of toxins veterinary drugs may be the result of a cross-contamination at the level of a premix plant and ultimately impacting the safety of the pet food product.
Chemical	Melamine is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. Is widely used in plastics and adhesives. Several frauds during the past years to simulate a higher level of protein of some materials (the normal check of the protein level is done through a test measuring nitrogen content; the addition of melamine increases the nitrogen content of the material and therefore its apparent protein content).	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk . Occurrence also linked to residues of packaging (soft plastic).
Chemical	Peroxides/Free Fatty Acids (FFA) are the result of oxidation or hydrolysis of grade oils and fats. This may provoke vomiting of cats and dogs.	Applicable	Quality and storage conditions of raw materials (oils, fats, etc.) needs to be taken into account. Raw materials and finished products need to be stabilized.
Chemical	Biogenic amines (incl. Histamine) are basic nitrogenous compounds formed mainly by decarboxylation of amino acids or by amination. Quality of raw material may impact on the occurrence of the hazard. May also occur during the and transamination of aldehydes and ketones. High amount of biogenic amines may be an indication of material spoilage. Histamine is naturally high in some fish species (e.g. tuna, mackerel, sardine...) and may have undesirable or harmful effect on dogs and/or cats (e.g. allergies).	Applicable	Quality of raw material may impact on the occurrence of the hazard . May also occur during the production process (standing time, temperature), e.g. in fish meal.
Chemical	Pesticides prevent, destroy or control a harmful organism ('pest') or disease, or protect plants or plant products during production, storage and transport. The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematocides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides.	Applicable	May occur at level of incoming materials as well as during production process via residues of sanitizing operations. The sanitizing or pest control must be monitored by control measurements.

Nature of hazards	Hazards/Description	Dry pet food ≤14% moisture	Comments
Chemical	Lubricants: US FDA defines 3 types of lubricants: H1: lubricants that could have incidental food contact H2: lubricants with no possibility of contacting food H3: soluble oils	Applicable	Food lubricants are mostly used in pet food production. In case it is not, contamination may occur in finished pet food .
Physical	Glass: The presence of glass may origin from raw materials, factories environment (e.g. lab equipment, lightings...), primary packs or manpower (e.g. glasses, watches...)	Applicable	Raw materials contamination PRPs are key to prevent occurrence of glass in pet food .
Physical	Hard plastic: The presence of hard plastic may origin from raw materials (e.g. handling bins, weasand clips...), factories equipment (e.g. belts scrapers, elevators, protections...) or manpower (pens, identification badges...)	Applicable	Raw materials contamination PRPs are key to prevent occurrence of hard plastic in pet food .
Physical	Metal: The presence of metal may origin from raw materials, factories equipment, engineering works (e.g. welding, screws and bolts...) or manpower. PRPs and CCPs are key to prevent occurrence of glass in pet food.	Applicable	Raw materials contamination PRPs and CCPs are key to prevent occurrence of metal in pet food .
Physical	Wood: The presence of wood may origin from raw materials, factories or engineering works.	Applicable	Raw materials contamination PRPs are key to prevent occurrence of wood in pet food .
Physical	Soft plastic & non-woven fabric: The presence of soft plastic & non-woven fabric may origin from raw materials (protection of frozen meat pallets, bags of dry materials, etc.).	Applicable	Raw materials contamination PRPs and CCPs are key to prevent occurrence of soft plastic & non-woven fabric in pet food .
Physical	Bones: The presence of bones origins from raw materials (processed animal proteins or cereals harvested in land with bones residues).	Not applicable	/
Physical	Stones: The presence of stones origins from raw materials such as vegetables, animal stomachs or from factories (e.g. floors).	Applicable	Raw materials contamination PRPs are key to prevent occurrence of stones in pet food .

Nature of hazards	Hazards/Description	Dry pet food ≤14% moisture	Comments
Physical	Pests: The presence of pests originates from either raw materials or factories environment.	Applicable	Raw materials contamination PRPs are key to prevent occurrence of pests in pet food.
Physical	Workers' accessories: Workers' accessories such as jewels, ties, scarfs, glasses, watches may end up in pet food. PRPs are key to prevent occurrence of foreign materials in finished products.	Applicable	PRPs are key to prevent occurrence of foreign materials in finished products.
Physical	Mud, soil: The presence of mud and soil may originate from either raw materials or factories environment.	Applicable	Raw materials contamination PRPs are key to prevent occurrence of soil in pet food. Some biological hazards can be an indicator for soil contamination, e.g. truck wheels during raw materials unloading.
Physical	Rubber: The presence of rubber may originate from either raw materials or factories environment.	Applicable	Raw materials contamination PRPs are key to prevent occurrence of rubber in pet food, e.g. parts of packaging lines.

3.3.2. Table 2: List of hazards - Semi-moist pet Food

Nature of hazards	Hazards/Description	Semi-moist pet food 14-60% moisture	Comments
Biological	Aeromonas: Aeromonas is a Gram-negative, non-spore-forming, tentatively anaerobic bacterium. This bacterium can be found in fresh or brackish water.	Not applicable	No spore forming so no risk for semi-moist pet food.
Biological	Campylobacter is a Gram-negative bacteria, non-spore forming bacterium. Campylobacter species are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs and sheep. They live harmlessly in the gut but during slaughter and processing of farm animals, the contamination can spread from the gut to other parts of the animal.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. No risk when the aw-value is low.

Nature of hazards	Hazards/Description	Semi-moist pet food 14-60% moisture	Comments
Biological	<i>Clostridium perfringens</i> is a Gram-positive, rod-shaped, anaerobic, spore-forming. <i>C. perfringens</i> is found frequently in the intestines of many animals and is present in soil and areas contaminated by human or animal feces.	Applicable	Raw material contamination . Risk of occurrence may increase with standing time and temperature within the factory.
Biological	<i>Clostridium botulinum</i> is an anaerobic rod-shaped bacterium, i.e. it lives and grows in low oxygen conditions. The spore has a hard protective coating and is able to survive for years. <i>C. botulinum</i> is responsible for a disease called botulism. <i>Clostridium botulinum</i> is found in soil and untreated water throughout the world.	Applicable	Raw material contamination . Risk of occurrence may increase with standing time and temperature within the factory. Depending on the process, <i>Clostridium botulinum</i> may remain in the product, because of anaerobic conditions (folio). If <i>Clostridium botulinum</i> was in the product, the toxin remains. Sterilisation process is meant to destroy this bacterium and spore, not the toxin.
Biological	The <i>Enterobacteriaceae</i> are a large family of Gram-negative bacteria . They are not spore-forming. Many members of this family are a normal part of the gut flora found in the intestines of humans and other animals, while others are found in water or soil, or are parasites on a variety of different animals and plants.	Applicable	Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard .
Biological	<i>Listeria monocytogenes</i> is a Gram-positive bacterium. <i>Listeria</i> is found in soil, plants and water. Animals, including cattle, sheep and goats, can also carry the bacteria. Cooking at temperatures higher than 65 °C kills the bacteria.	Not applicable	Non-spore-forming and not thermo resistant which make it insignificant for semi-moist pet food .
Biological	<i>Pathogenic E.coli: Escherichia coli</i> is a gram-negative , tentatively anaerobic, rod-shaped bacterium of the genus <i>Escherichia</i> that is commonly found in the lower intestine of warm-blooded organisms (endotherms).	Applicable	Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard .
Biological	<i>Salmonella</i> is a gram-negative bacteria of the <i>Enterobacteriaceae</i> family. <i>Salmonella</i> species are non-spore-forming.	Applicable	Non-spore-forming and not thermo resistant which make it insignificant for wet pet food . <i>Salmonella</i> presence may be an indicator of occurrence of other microbiological risks . <i>Salmonella</i> occurrence may happen after thermal treatment via packaging or personnel as well via droppings of animals in case buildings are not closed.

Nature of hazards	Hazards/Description	Semi-moist pet food 14-60% moisture	Comments
Biological	Moulds and yeasts are fungus that grow in the form of multicellular filaments called hyphae. In contrast, fungi that can adopt a single-celled growth habit are called yeasts.	Applicable	Storage conditions of dry materials (cereals, vegetables...). Heat treatment is required. Semi-moist pet food must be protected under anaerobic condition by nitrogen or similar.
Biological	Staphylococcus aureus is a gram-positive coccal bacterium. Produces several enterotoxins generally highly resistant to enzymatic degradation and heat. Bacterium exists in soil.	Applicable	<i>Staphylococci</i> are living in warm blood animals. It indicates bad cleaning conditions. Adequate rules for product and personnel flows must be in place to avoid biological contamination .
Biological	Pests are rodents or insects which may carry pathogenic organisms which are source of contamination .	Applicable	Clean facilities and proper pest control policy must be in place. May also occur via raw materials.
Chemical	Biocides (cleaning substances) are any substances or mixtures consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. This includes insecticides, insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibers and anti-fouling paints for the protection of ship hulls.	Applicable	May occur at level of incoming materials as well as during production process via residues of sanitizing operations. Control measures after cleaning must be in place.
Chemical	Carry over of substances for non-target species is a transfer of any authorised substance or product from one production batch to the immediate subsequent batch destined to a different target species.	Applicable	May occur during manufacturing process when different products are produced simultaneously or one after the other.
Chemical	Dioxins and dioxin-like compounds (DLCs) are compounds that are highly toxic environmental persistent organic pollutants.	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk (e.g. package by recycled material). May also occur during production process (e.g. Crisis in Ireland back in 2008).
Chemical	Heavy metals are metals with a relatively high density, atomic weight or atomic number which presence may occur in pet food . Typical examples are lead, mercury and cadmium.	Applicable	Raw material contamination especially fish.

Nature of hazards	Hazards/Description	Semi-moist pet food 14-60% moisture	Comments
Chemical	Mycotoxins are toxic secondary metabolites produced by organisms of the fungus kingdom. The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops. One mold species may produce many different mycotoxins, and several species may produce the same mycotoxin.	Applicable	Raw material contamination or during transport and storage. Higher risk of contamination depending on the geographical origin of the incoming materials (weather conditions). The occurrence of the risk is linked to the quantity of cereals and vegetables used in the recipes. It is not as sensitive in semi-moist pet food as in dry pet food .
Chemical	PCBs or polychlorinated biphenyls are organic chlorine compounds. PCBs cause cancer in animals and are probable human carcinogens. Because of PCBs' environmental toxicity and classification as a persistent organic pollutant, PCB production was banned by the United States Congress in 1979 and by the Stockholm Convention on Persistent Organic Pollutants in 2001.	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk . May also occur during production process, e.g.: <ul style="list-style-type: none"> - Use of unappropriated combustion for heat treatment (e.g. bread meal) - Residues of plastic used as folio, boxes etc.
Chemical	Toxins Veterinary drugs are hormones, growth regulators, antibiotics... used for feed animal treatments.	Applicable	The origin of animal by-products needs to be taken into account to ensure that no residues are found in the incoming materials. Occurrence of toxins veterinary drugs may be the result of a cross-contamination at the level of a premix plant and ultimately impacting the safety of the pet food product.
Chemical	Melamine is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. Is widely used in plastics and adhesives. Several frauds during the past years to simulate a higher level of protein of some materials (the normal check of the protein level is done through a test measuring nitrogen content; the addition of melamine increases the nitrogen content of the material and therefore its apparent protein content).	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk . Occurrence also linked to residues of packaging (soft plastic).
Chemical	Peroxides/Free Fatty Acids (FFA) are the result of oxidation or hydrolysis of grade oils and fats. This may provoke vomiting of cats and dogs.	Applicable	Depends on the process, semi-moist pet food must be protected under anaerobic condition by nitrogen or similar. This process must be controlled.

Nature of hazards	Hazards/Description	Semi-moist pet food 14-60% moisture	Comments
Chemical	Biogenic amines (incl. Histamine) are basic nitrogenous compounds formed mainly by decarboxylation of amino acids or by amination. Quality of raw material may impact on the occurrence of the hazard. May also occur during the and transamination of aldehydes and ketones. High amount of biogenic amines may be an indication of material spoilage. Histamine is naturally high in some fish species (e.g. tuna,mackerel, sardine...) and may have undesirable or harmful effect on dogs and/or cats (e.g.allergies).	Applicable	Quality of raw material may impact on the occurrence of the hazard . May also occur during the production process (standing time, temperature).
Chemical	Pesticides prevent, destroy, or control a harmful organism ('pest') or disease, or protect plants or plant products during production, storage and transport. The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematocides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides.	Applicable	May occur at level of incoming materials as well as during production process via residues of sanitizing operations. The sanitizing or pest control must be monitored by control measurements.
Chemical	Lubricants: US FDA defines 3 types of lubricants: - H1: lubricants that could have incidental food contact - H2: lubricants with no possibility of contacting food - H3: soluble oils	Applicable	Food lubricants are mostly used in pet food production. In case it is not, contamination may occur in finished pet food .
Physical	Glass: The presence of glass may origin from raw materials, factories environment (e.g. lab equipment, lightings...), primary packs or manpower (e.g. glasses, watches...).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of glass in pet food .
Physical	Hard plastic: The presence of hard plastic may origin from raw materials (e.g. handling bins, weasand clips...), factories equipment (e.g. belts scrapers, elevators, protections...) or manpower (pens, identification badges...).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of hard plastic in pet food .

Nature of hazards	Hazards/Description	Semi-moist pet food 14-60% moisture	Comments
Physical	Metal: The presence of metal may origin from raw materials, factories equipment, engineering works (e.g. welding, screws and bolts...).	Applicable	Raw materials contamination . PRPs and CCPs are key to prevent occurrence of metal in pet food .
Physical	Wood: The presence of wood may origin from raw materials, factories or engineering works.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of wood in pet food .
Physical	Soft plastic & non-woven fabric: The presence of soft plastic & non-woven fabric may origin from raw materials (protection of frozen meat pallets, bags of dry materials, etc.).	Applicable	Raw materials contamination . PRPs and CCPs are key to prevent occurrence of soft plastic in pet food .
Physical	Bones: The presence of bones origins from raw materials (processed animal proteins or cereals harvested in land with bones residues).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of bones in pet food .
Physical	Stones: The presence of stones origins from raw materials such as vegetables, animal stomachs or from factories (e.g. floors).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of stones in pet food .
Physical	Pests: The presence of pests origins from either raw materials or factories environment.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of pests in pet food .
Physical	Workers' accessories: Workers' accessories such as jewels, ties, scarfs, glasses, watches may end up in pet food. PRPs are key to prevent occurrence of foreign materials in finished products.	Applicable	PRPs are key to prevent occurrence of foreign materials in finished products .
Physical	Mud, soil: The presence of mud and soil may origin from either raw materials or factories environment.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of soil in pet food. Some biological hazards can be an indicator for soil contamination .
Physical	Rubber: The presence of rubber may origin from either raw materials or factories environment.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of rubber in pet food .

3.3.3. Table 3: List of hazards - Wet pet Food

Nature of hazards	Hazards/Description	Wet pet food ≤60% moisture	Comments
Biological	Aeromonas is a Gram-negative, non-spore-forming, tentatively anaerobic bacterium. This bacterium can be found in fresh or brackish water.	Not applicable	No spore forming so no risk for wet pet food.
Biological	Campylobacter is a Gram-negative bacteria, non-spore forming bacterium. Campylobacter species are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs and sheep. They live harmlessly in the gut but during slaughter and processing of farm animals, the contamination can spread from the gut to other parts of the animal.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory.
Biological	Clostridium perfringens is a Gram-positive, rod-shaped, anaerobic, spore-forming. C. perfringens is found frequently in the intestines of many animals and is present in soil and areas contaminated by human or animal feces.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory.
Biological	Clostridium botulinum is an anaerobic rod-shaped bacterium, i.e. it lives and grows in low oxygen conditions. The spore has a hard protective coating and is able to survive for years. C. botulinum is responsible for a disease called botulism. Clostridium botulinum is found in soil and untreated water throughout the world.	Applicable	Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. Sterilisation process is meant to destroy this bacterium and spore.
Biological	The Enterobacteriaceae are a large family of Gram-negative bacteria. They are not spore-forming. Many members of this family are a normal part of the gut flora found in the intestines of humans and other animals, while others are found in water or soil, or are parasites on a variety of different animals and plants.	Applicable	Applicable for wet pet food only to determine hygiene levels.
Biological	Listeria monocytogenes is a Gram-positive bacterium. Listeria is found in soil, plants and water. Animals, including cattle, sheep and goats, can also carry the bacteria. Cooking at temperatures higher than 65 °C kills the bacteria.	Not applicable	Non-spore-forming and not thermo resistant which make it insignificant for wet pet food.

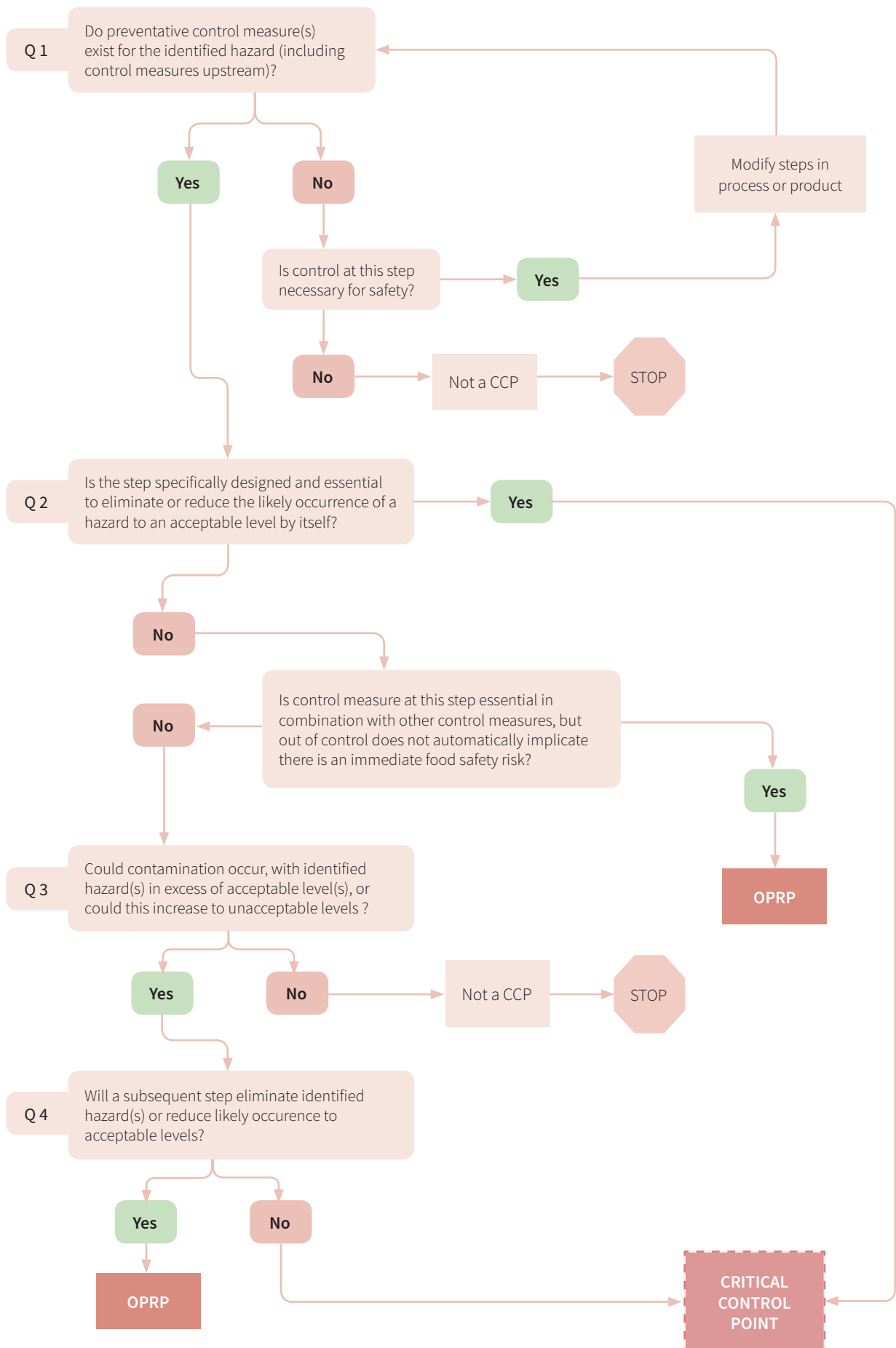
Nature of hazards	Hazards/Description	Wet pet food ≤60% moisture	Comments
Biological	Pathogenic E.coli: <i>Escherichia coli</i> is a gram-negative , tentatively anaerobic, rod-shaped bacterium of the genus <i>Escherichia</i> that is commonly found in the lower intestine of warm-blooded organisms (endotherms).	Applicable	Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard .
Biological	Salmonella is a gram-negative bacteria of the Enterobacteriaceae family. Salmonella species are non-spore-forming.	Not applicable	Non-spore-forming and not thermo resistant which make it insignificant for wet pet food .
Biological	Moulds and yeasts are fungi that grow in the form of multicellular filaments called hyphae. In contrast, fungi that can adopt a single-celled growth habit are called yeasts.	Applicable	Storage conditions of dry materials (cereals, vegetables...).
Biological	Staphylococcus aureus is a gram-positive coccal bacterium. Produces several enterotoxins generally highly resistant to enzymatic degradation and heat.	Applicable	Spores are not thermo-resistant but the toxin is. Staphylococci are living in warm blood animals. It indicates bad cleaning conditions. Adequate rules for product and personnel flows must be in place to avoid biological contamination .
Biological	Pests are rodents or insects may carry pathogenic organisms which are source of contamination .	Applicable	Clean facilities and proper pest control policy must be in place. May also occur via raw materials.
Chemical	Biocides (cleaning substances) are any substances or mixtures consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. This includes insecticides, insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibers and anti-fouling paints for the protection of ship hulls.	Applicable	May occur at level of incoming materials as well as during production process via residues of sanitizing operations.
Chemical	Carry over of substances for non-target species is a transfer of any authorised substance or product from one production batch to the immediate subsequent batch destined to a different target species.	Applicable	May occur during manufacturing process when different products are produced simultaneously or one after the other.

Nature of hazards	Hazards/Description	Wet pet food ≤60% moisture	Comments
Chemical	Dioxins and dioxin-like compounds (DLCs) are compounds that are highly toxic environmental persistent organic pollutants.	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk . (e.g. package by recycled material) May also occur during production process (e.g. Crisis in Ireland back in 2008).
Chemical	Heavy metals are metals with a relatively high density, atomic weight or atomic number which presence may occur in pet food . Typical examples are lead, mercury and cadmium.	Applicable	Raw material contamination as well as during the production process (leakage or deficient machinery).
Chemical	Mycotoxins are toxic secondary metabolites produced by organisms of the fungus kingdom. The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops. One mold species may produce many different mycotoxins, and several species may produce the same mycotoxin.	Applicable	Raw material contamination or during transport and storage. Higher risk of contamination depending on the geographical origin of incoming material and weather conditions. The occurrence of risk is linked to the quantity of cereals and vegetables used in the recipes. It is not as sensitive in wet pet food as in dry pet food .
Chemical	PCBs or polychlorinated biphenyls are organic chlorine compounds. PCBs cause cancer in animals and are probable human carcinogens. Because of PCBs' environmental toxicity and classification as a persistent organic pollutant, PCB production was banned by the United States Congress in 1979 and by the Stockholm Convention on Persistent Organic Pollutants in 2001.	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk . May also occur during production process, e.g.: - Use of unappropriated combustion for heat treatment (e.g. bread meal) - Residues of plastic used as folio, boxes etc.
Chemical	Toxins Veterinary drugs are hormones, growth regulators, antibiotics... used for feed animal treatments.	Applicable	The origin of animal by-products needs to be taken into account to ensure that no residues are found in the incoming materials. Occurrence of toxins veterinary drugs may be the result of a cross- contamination at the level of a premix plant and ultimately impacting the safety of the pet food product.
Chemical	Melamine is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. Is widely used in plastics and adhesives. Several frauds during the past years to simulate a higher level of protein of some materials (the normal check of the protein level is done through a test measuring nitrogen content; the addition of melamine increases the nitrogen content of the material and therefore its apparent protein content).	Applicable	The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk . Occurrence also linked to residues of packaging (soft plastic).

Nature of hazards	Hazards/Description	Wet pet food ≤60% moisture	Comments
Chemical	Peroxides/Free Fatty Acids (FFA) are the result of oxidation or hydrolysis of grade oils and fats. This may provoke vomiting of cats and dogs.	Not applicable	Relevant only to dry pet food .
Chemical	Biogenic amines (incl. Histamine) are basic nitrogenous compounds formed mainly by decarboxylation of amino acids or by amination. Quality of raw material may impact on the occurrence of the hazard. May also occur during the and transamination of aldehydes and ketones. High amount of biogenic amines may be an indication of material spoilage. Histamine is naturally high in some fish species (e.g. tuna, mackerel, sardine...) and may have undesirable or harmful effect on dogs and/or cats (e.g. allergies).	Applicable	Quality of raw material may impact on the occurrence of the hazard . May also occur during the production process (standing time, temperature).
Chemical	Pesticides prevent, destroy, or control a harmful organism ('pest') or disease, or protect plants or plant products during production, storage and transport. The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematocides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides.	Applicable	May occur at level of incoming materials as well as during production process via residues of sanitizing operations.
Chemical	Lubricants: US FDA defines 3 types of lubricants: - H1: lubricants that could have incidental food contact - H2: lubricants with no possibility of contacting food - H3: soluble oils	Applicable	Food lubricants are mostly used in pet food production. In case it is not, contamination may occur in finished pet food .
Physical	Glass: The presence of glass may origin from raw materials, factories environment (e.g. lab equipment, lightings...), primary packs or manpower (e.g. glasses, watches...).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of glass in pet food .
Physical	Hard plastic: The presence of hard plastic may origin from raw materials (e.g. handling bins, weasand clips...), factories equipment (e.g. belts scrapers, elevators, protections...) or manpower (pens, identification badges...).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of hard plastic in pet food .

Nature of hazards	Hazards/Description	Wet pet food ≤60% moisture	Comments
Physical	Metal: The presence of metal may origin from raw materials, factories equipment, engineering works (e.g. welding, screws and bolts...) or manpower. PRPs and CCPs are key to prevent occurrence of glass in pet food .	Applicable	Raw materials contamination . PRPs and CCPs are key to prevent occurrence of metal in pet food .
Physical	Wood: The presence of wood may origin from raw materials, factories or engineering works.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of wood in pet food .
Physical	Soft plastic & non-woven fabric: The presence of soft plastic & non-woven fabric may origin from raw materials (protection of frozen meat pallets, bags of dry materials, etc.).	Applicable	Raw materials contamination . PRPs and CCPs are key to prevent occurrence of soft plastic in pet food .
Physical	Bones: The presence of bones origins from raw materials (processed animal proteins or cereals harvested in land with bones residues).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of bones in pet food .
Physical	Stones: The presence of stones origins from raw materials such as vegetables, animal stomachs or from factories (e.g. floors).	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of stones in pet food .
Physical	Pests: The presence of pests origins from either raw materials or factories environment.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of pests in pet food .
Physical	Workers' accessories: Workers' accessories such as jewels, ties, scarfs, glasses, watches may end up in pet food .	Applicable	PRPs are key to prevent occurrence of foreign materials in finished products .
Physical	Mud, soil: The presence of mud and soil may origin from either raw materials or factories environment.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of soil in pet food .
Physical	Rubber: The presence of rubber may origin from either raw materials or factories environment.	Applicable	Raw materials contamination . PRPs are key to prevent occurrence of rubber in pet food .

Example of a decision-tree to identify CCPs and OPRPs



Annex 1. European pet food legislation

The list below of Community legislation is a selection of the main legislation and does not include all the legislation applicable to the **pet food** sector.

Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making up by weight or by volume of certain pre-packaged products

The pre-packages may bear the so called “e mark” constituting a guarantee that they meet the weight and measures requirements of this Directive, including tolerances for packaging up to 10kg (annex 1).

- It includes reference to method for statistical checking of **batches** of pre-packages in order to fulfill criteria for “e mark”.
- “e mark” shall be used as described in section 3 of Annex II to Directive 71/316/EEC.

Directive 94/62/EC on packaging and packaging waste.

- Prevention of environmental impact of packaging and packaging waste.
- Reduction of packaging waste.
- Maximum heavy metal concentrations in packaging materials.

Regulation (EC) No 999/2001 laying down the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE Regulation)

Rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals.

- Determination of BSE status – Classification of countries or regions into 3 categories.
- TSE **Monitoring** Programme.
- Animal feeding.
- Specified **Risk** Materials (SRMs).
- Placing on the market and export of products of animal origin including pet food.
- Import of products of animal origin including feed materials and pet food.

Directive 2002/32/EC on undesirable substances in animal feed

- Feed materials may only be put into circulation in the EC if they are sound genuine and of merchantable quality.

- List of undesirable substances and the tolerated maximum levels in feed materials and feedingstuffs.
- Dilution and mixing with other consignments of feed materials or **feedingstuffs** is banned.

Directive 2002/72/EC on plastic materials and articles intended to come in contact with foodstuffs.

- Authorised materials to be used in the manufacture of packaging materials.
- Migration limits from packaging material to food materials.

Regulation (EC) No 178/2002 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

- The Regulation applies to all stages of the production, processing and distribution of food and feed.
- It applies to feed produced for, or fed to, food producing animals, not directly to **pet food**. The Regulation’s principles on safety, **traceability**, self-responsibilities and definitions must be observed by **pet food** manufacturers.
- Via Regulation 1831/2003/EC on Feed Additives, the Rapid Alert System for Food and Feed (**RASFF**) applies to pet food.
- Basic principles of the Regulation should be followed by the pet food industry, such as:
 - Feed safety requirements - Feed must be safe.
 - **Traceability** principles (full **traceability** of feed materials and **finished products**).

Regulations (EC) No 1069/2009 and (EU) No 142/2011 laying down health rules as regards animal by-products and derived products not intended for human consumption (Animal by-products Regulation) and its implementing Regulation

- Animal and public health rules for the collection, transport, storage handling, processing and use or disposal of **animal by-products**, to prevent these products from presenting a **risk** to animal or public health.
- Approval of **pet food** plants including the requirements, which must be fulfilled by the plants.
- Specific health requirements for feed materials, processed animal proteins and **pet food** with regards

to feed material origin (Category 3), heat treatment, prevention of re- **contamination**, packaging and microbiological testing.

- Health requirements and health certificates for import of **animal by-products** including feed materials, processed animal proteins and **pet food** from 3rd countries.

Regulation (EC) No 1829/2003 on **genetically modified food and feed**

- Lays down Community procedures for the authorisation and supervision of **genetically modified food and feed** (including **pet food**).
- Lays down provisions for the labelling of **genetically modified food and feed**.
- Covers all GMO derivatives, including those which have no trace of DNA or genetically modified proteins.
- Applies to three types of products: **GMOs** for food and feed use; food and feed containing **GMOs**; food and feed produced from or containing feed materials **produced from GMOs**.
- From its scope excludes products obtained using a genetically modified processing aid.
- Provides that the labeling requirements do not apply to feed containing material which contains, consist of or is **produced from GMOs** in a proportion no higher than 0.9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.
- Paragraph 3 provides that in order to establish that the presence of this material is adventitious and technically unavoidable; operators must be in position to supply evidence to satisfy the competent compnationalm that they have taken appropriate steps to avoid the presence of such material.

Regulation (EC) No 1830/2003 on the **traceability** and labelling of **genetically modified organisms** and the **traceability** of food and feed products produced from **genetically modified organisms**

- Provides a framework for the traceability of feed and food produced from **GMOs**.
- Facilitates accurate labelling of feed products and to monitor the implementation of the appropriate **risk management**.

Regulation (EC) No 1831/2003 concerning **additives** in animal nutrition

- List of authorized **additives** for **pet food**.
- Maximum content and other provisions in the use of authorised **additives**.

Directive 2004/10/EC on the principles of good laboratory practice and the **verification** of their applications for tests on chemical substances

- Laboratories carrying out tests on chemical products in accordance with Directive
- 67/548/EEC shall comply with the OECD Principles of Good Laboratory Practice as laid down in Annex I.
- Member States shall make inspections and study checks in accordance with the GLP principles of OECD as laid down in Annex I.
- OECD standards, described in Section I, apply to the non-clinical safety testing of test items contained e.g. in veterinary drugs, food and feed **additives** and industrial chemicals.
- These principles of GLP apply to all non-clinical health and environmental safety studies required by regulation for the purpose of registering food and feed **additives** and similar products, and for the regulation of industrial chemicals, unless exempted by national legislation.

Regulation (EC) No 852/2004 on the hygiene of foodstuffs

- This regulation does not apply to **pet food**, as **pet food** is in the scope of Regulation (EC) No 183/2005 (feed hygiene).
- It is included here for definitions in the glossary.

Regulation (EC) No 183/2005 laying down requirements for feed hygiene

- Provides the primary responsibility of the feed business operator for feed safety.
- Registration of all establishments manufacturing **pet food**.
- Approval of establishments (only feed business operators producing certain **additives**).
- Minimum manufacturing conditions requirements with regards to facilities & equipment, personnel, production, **quality control**, storage, and register, which must be fulfilled by the **pet food** manufacturer.

- HACCP implementation is mandatory; permanent, written procedures shall be based on HACCP principles as mentioned in Article 6.
- Conditions and arrangements ensuring full traceability of feed materials and compound feed.
- Industry Guides are voluntary, they shall take into account the relevant codes of practice of the Codex Alimentarius; they are finally assessed by the Community and periodically reviewed; published in C series OF Official Journal of European Union;
- Provides that the Rapid Alert System applies to feed animals not kept for food production including pet food.
- Help to prepare the dossier for the authorization of additives.
- The following documents mention detailed requirements:
 - “Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC”.
 - “Guidance for the preparation of dossiers for the additives already authorised for use in food”.
 - Guidances for the preparation of dossiers for the technological, sensory, nutritional and zootechnical additives.

Commission Recommendation (EU) 2016/1319 of 29 July 2016 amending Recommendation 2006/576/EC as regards deoxynivalenol, zearalenone and ochratoxin A in pet food

- Establishes guidance values for deoxynivalenol, zearalenone, ochratoxin A, fumonisins B1+B2 and T-2 and HT-2 toxin in feed materials and pet food.
- Pet food manufacturers should use these guidance levels, which are aligned with the well-established pet food industry recommendations, in their HACCP system to determine the critical limits, which separate acceptability from unacceptability.

Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation No 1831/2003 as regards the preparation and presentation of the applications and the assessment and the authorization of feed additives

- Provides very detailed information on how to prepare the application for the authorization of feed additives inter alia; the content and format of Application Form, Public Summary and Scientific Summary of the dossier.
- Specifies requirements for studies on safety, efficacy, identity, characterization, conditions of use of the additive and post market monitoring plan.
- Describes preparatory requirements for various dossiers like for additives used in pet food manufacturing and additives already authorized under Directive 70/524/EEC.

The EFSA Guidances, prepared by the Panel on Additives and Products or Substances used in Animal Feed, 2008

- It is important to mention that the EFSA guidance does not substitute for the obligation of an applicant to comply with the requirements of Regulation No 1831/2003.

Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed.

- Lays down the methods of sampling and analysis for the official control of feed.
- Specifies method for sampling to determine of constituents, additives and undesirable substances in Annex I.
- Includes provisions relating to preparation of samples, reagents and apparatus used in methods of analysis in Annex II.
- Provides information on analytical methods and expression of results in Annex III.
- Describes quality assurance requirements, requirements for laboratories and methods of analysis to control undesirable substances including the determination of total gossypol, level of dioxins (PCDD/PCDF) and dioxin-like PCBs in Annex V.
- Provides information on interpreting results for PCDD and PCBs: The batch is accepted if the analytical results of a single analysis do not exceed the respective maximum level as laid down in Directive 2002/32/EC taking into account the measurement uncertainty.
- The lot is non-compliant with maximum level as laid down in Directive 2002/32/EC if the upperbound analytical result confirmed by duplicate analysis exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.
- Lays down the methods of analysis to control illegal presence of no longer authorised additives in feed in Annex VIII.

Regulation (EC) No 767/2009 as amended by Regulation (EC) 2017/2279 on the marketing and use of feed

- Replaces amongst others directive 79/373/EEC and directive 96/25/EC.
- **Pet food** may only be placed on the market if safe.
- Lays down the rules for labelling and also the off-pack communication of **pet food**.
- Regulates claims.
- Catalogue of Feed Materials.

Note: The current version of the EU Catalogue of feed materials (Regulation 68/2013 as amended by Regulation 2017/1017) lists feed materials permitted in animal feed in a voluntary/non-conclusive way; feed materials not listed may be listed in the EU register of feed materials. It is important to stress out that feed materials mentioned in the register are not evaluated and the use of these feed materials is on the users' sole risk.

- Feed materials must not represent any danger to animal or human health or to the environment.
- Feed may only be put into circulation if they are of sound, genuine and merchantable quality.
- Labelling requirements for feed materials.
- A non-exclusive list of feed materials with specific names, description and compulsory declarations.

Directive 82/475 on the categories of ingredients which may be used for the purposes of labelling compound **feedingstuffs for pet animals**

Lists and defines the 19 categories of feed materials that may be used in **pet food** and labelled as such on finished **pet food** products.

Most directives and regulations including later amendments are compiled in the European **pet food** legislation compendium issued by FEDIAF. All regulations, directives and decisions are available from the FEDIAF Secretariat. For the current implementation of the directives and regulations above, please refer to national legislation within the Member State.

European Register of feed **additives**

- Listing all feed **additives** authorised in animal feed
- Available online and updated on a regular basis
- http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

Note: the current version of the register has no legal value, but should be consulted for checking if **additives are approved by referring to the authorising legal act.**

Annex 2. Practical examples of CCPs and OPRPs

CCP is a step at which it is essential that a specific **control measure** is applied to prevent or eliminate a **(pet) food safety hazard** or reduce the **risk** to an acceptable level.

OPRP is an **Operational Prerequisite Programme** identified by a **hazard** analysis as essential in order to control the likelihood of either the **pet food** product or the process environment being exposed to safety **hazards**, that either will be contaminated, or that the **hazards** will proliferate. It will not eliminate the **hazard** on its own.

The following examples of **CCP** and **OPRP** are not obligatory as the determination whether it is **CCP** or **OPRP** must come as the output of **HACCP** study performed for each production line and product etc.

Manufacturers should use this for guidance only – The examples do not replace a site, process and product specific HACCP study for each pet food manufacturing unit.

Table 1: Specific examples of CCPs and OPRPs for wet pet food, e.g. cans, trays, pouches

The following is an example of an **HACCP** outcome when applied to **wet pet food** e.g: cans, trays, **pouches**.

Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport/storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Feed materials conform spec	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Processing	Microbial growth due to incorrect processing	Monitoring time and temperature inspection, shelf-life control
Metal detection	Metal contamination (e.g. fish hooks)	Permanent magnets, electric metal detection device
Filling	Microbial growth due to under-sterilisation (caused by overfilling of chunks)	100% inspection by headspace control/ weight control
Gravy addition	Microbial growth due to under-sterilisation (caused by overfilling of chunks)	100% inspection by headspace control/ weight control
Seaming/Sealing	Growth micro-organisms (e.g. product inclusion in seal, damaged flanges)	Seam/seal control
Sterilisation	Microbial growth due to under-sterilisation (e.g. due to low initial temperature, low sterilisation time or low sterilisation temperature) which leads to a F0 less than 3	Calibration and monitoring
Cooling	Microbiological occurrence during cooling (e.g. due to lack of Chlorine)	Calibration and monitoring (of dosing equipment and water quality)
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

Table 2: Specific examples of CCPs and OPRPs for semi-moist pet food

Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport/storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Feed materials conform specification	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Addition of preservatives	Microbiological growth	Monitoring/inspection
Processing	Microbial or mould growth (e.g. due to high Aw)	Aw monitoring/inspection, shelf-life control
Filling	Microbial growth due to condensation (caused by too high filling temperature) and risk of moulding	Monitoring/inspection filling temperature and external temperature
Metal detection	Metal contamination	Electric metal detection device
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

Table 3: Specific examples of CCPs and OPRPs for dry pet food

Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport/storage	Contamination or deterioration (e.g. humidity)	Assurance and inspection programme
Feed materials conform spec.	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Heating	Bacterial growth caused by lethality too low, e.g. low time/temperature (less than 90°C) of product during extrusion/pressing/baking)	Control of temp/time and monitoring/inspection, shelf-life control
Processing	Microbial or mould growth (e.g. due to high Aw)	Aw, moisture, monitoring/inspection, shelf life control
Filling	Microbial growth due to condensation (caused by too high filling temperature)	Monitoring/inspection filling temperature and external temperature
Metal detection	Metal contamination	Permanent magnets, electric metal detection device
Storage of product	Microbial or mould growth	Aw/Warehouse assurance program
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

Table 4: Specific examples of CCPs and OPRPs for Chews

Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport/storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Feed materials conform spec.	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Processing	Growth of spoilage bacteria in process (e.g. occurrence of Salmonella due to poor processing conditions; Aw, time and temperature, cross-contamination)	Monitoring/inspection, shelf-life control
Bag Filling	Condensation (due to high filling temperature)	Monitoring/inspection filling temperature and external temperature
Metal detection	Metal contamination	Permanent magnets, electric metal detection device
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

Table 5: Specific examples of CCPs and OPRPs for small pets

Manufacturers of pet food destined for small pets (birds, small mammals, fish, etc.) must put in place HACCP according to the production’s specific CCPs, hazards and appropriate control measures.

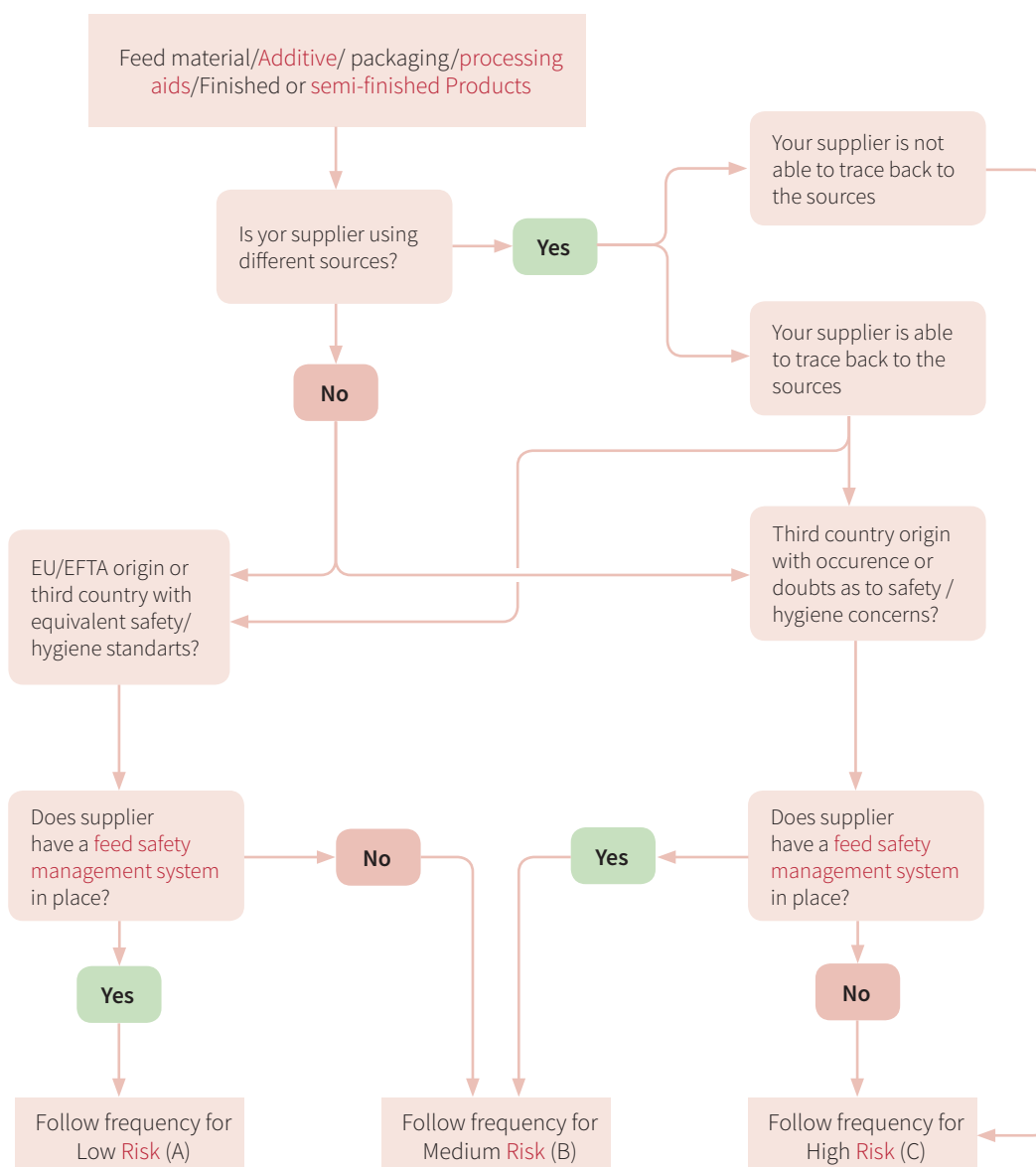
Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport/storage	Contamination or deterioration (e.g. humidity)	Assurance and inspection programme
Feed materials conform spec.	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Cooling of feed materials	Contamination or deterioration, growth of micro-organism	Transport assurance, temperature monitoring, shelf life control
Heating	Bacterial growth caused by lethality too low, e.g. low time/temperature (less than 90°C) of product during extrusion/pressing/baking)	Control of temp/time and monitoring/inspection, shelf-life control
Mixing	Homogeneous basic products	Manufacturer’s declaration, personnel training, visual control
Processing	Microbial or mould growth	Aw, moisture monitoring/inspection, shelf life control, personnel hygiene
Metal detection	Metal contamination	Permanent magnets, electric metal detection device
Storage of product	Microbial or mould growth	Aw/Warehouse assurance program
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control, personnel training

Annex 3. Assessment of suppliers for the purpose of controlling undesirable substances and contaminants

This annex is describing an example on a way for management of vendors and their supplies. The proposed decision tree in section 1 shows how to determine the level of control needed and the level of frequency of checks to be done. The frequency must be established by the manufacturer on a case by case basis depending on

the nature of the supply and the potential risk involved. The pet food operator needs to be able to show the feed safety risk is under control. Section 2 is an example of undesirable substances that need to be controlled. The list is not exhaustive and needs to be adapted according to the latest situation.

Section 1: Decision tree on undesirable substances/contaminants monitoring system to determine monitoring frequencies (likelihood of occurrence to be used to determine frequency of testing)



Section 2: Monitoring of undesirable substances according to legislation and FEDIAF guidance

What follows is a compendium of the **undesirable substances** and their probable origins/source materials as identified by current regulations as well as upon FEDIAF experience on the subject.

The relevant inspection plan – and the corresponding number of **samples** to be analysed – must be tailor-made to each **pet food** manufacturer, even production site, upon:

- The outcome from the application of the Decision Tree for **monitoring** of **undesirable substances** as provided

for in Annex III, Section 1, its implemented vendor assurance systems (including the existence of specific quality agreements with **suppliers**);

- The characteristics of products.

As a principle, materials outsourced from a **supplier** identified as having a level of **risk A** from the aforementioned Decision Tree must have a lighter inspection plan than ones rated as B, and the latter must be lighter than a **supplier** with a **risk** rated C.

Undesirable Substance	Potential source material	Reference
Ergot	Feedingstuffs containing ungrounded cereals	Directive 2002/32/EC on undesirable substances in animal feed.
As, Pb, Hg	Feed materials Complete/complementary pet food	
Cd	Feed materials of vegetable origin Mineral feedingstuffs	
Fluorine	Feed materials Complete pet food	
Nitrites	Fish meal	
Aldrin	All feedingstuffs	
Dieldrin	All feedingstuffs	
Camphechlor	All feedingstuffs	
Chlordane	All feedingstuffs	
DDT	All feedingstuffs	
Endosulphan	All feedingstuffs	
Endrin	All feedingstuffs	
Heptachlor	All feedingstuffs	
Hexachlorobenzene	All feedingstuffs	
Hexachlorocyclo hexane	All feedingstuffs	
Dioxin & Dioxin like PCB's	Feed materials Complete/complementary pet food	
Coccidiostats residues	Feed materials Complete/complimentary pet food	
Theobromine	Complete pet food	

Undesirable Substance	Potential source material	Reference
Aflatoxin B1	Feed materials, specially cereals and seeds Complete/complementary pet food	Directive 2002/32/EC on undesirable substances in animal feed
DON (Deoxynivalenol)	Cereals Complete/complementary pet food	Commission Recommendation 2006/576/EC on the presence of mycotoxins in products intended for animal feeding
Fumonisin	Maize and maize by-products Complete/complementary pet food	FEDIAF recommendations on the mycotoxin levels for finished pet food
Zearalenon	Cereals Seeds (as feed material) for birds and small animals Complete/complementary pet food	FEDIAF recommendations on the mycotoxin levels for finished pet food
Ochratoxin A	Cereals Liver Kidney Seeds (as feed material) for birds and small animals Complete/complementary pet food	FEDIAF recommendations on the mycotoxin levels for finished pet food
T2/HT2/Nivalenol	Cereals as feed materials Complete/complementary pet food	FEDIAF recommendations on the mycotoxin levels for finished pet food
Pesticide residues (other than already mentioned)	Cereals Fish & animal meals Vitamin Premixture Complete/complementary pet food	
Di-ethylene glycol	Glycerol	
PCP (pentachlorophenol)	Guar gum	
Histamine	Fish & animal meals	
Antibiotics	Fish & animal meals Shrimps (frozen)	
Nitrofurans Metabolites	Fish, seafood & animal meals	
Nitrosamines	Fish & animal meals	
Melamine	Protein sources Metal cans	
PAH profile or benzopyrenes	Cereals (as feed material) Fish & animal meals Additives	
Bisphenol A, F & Noge	Packaging, cans (coating)	
Phthalates	Packaging	
SEM (semicarbazide)	Packaging, can sealing	
Furans	Wet pet food	

Footnotes

1. Article 21 and 22 of [Regulation \(EC\) No 183/2005](#)
2. FEDIAF represents the pet food industry in 21 European countries via 16 national or regional pet food industry associations before EU institutions and other international bodies, which corresponds to more than 150 companies and 650 manufacturing plants across Europe.
3. Article 4§1 of [Regulation \(EC\) No 183/2005](#)
4. Annex II “PERSONNEL” of [Regulation \(EC\) No 183/2005](#)
5. Article 3(15) and 18 of [Regulation \(EC\) No 178/2002](#) and [Commission Guidance](#) on the implementation of articles of General Food Law
6. Article 9 & 10 of [Regulation \(EC\) No 183/2005](#)
7. Article 8 of [Regulation \(EC\) No 767/2009](#)
8. Article 23 of [Regulation \(EC\) No 1069/2009](#)
9. Article 9§2 of [Regulation \(EC\) No 183/2005](#)
10. Annex II “QUALITY CONTROL” of [Regulation \(EC\) No 183/2005](#)
11. Annex II “RECORD KEEPING” of [Regulation \(EC\) No 183/2005](#)
12. Annex IV, Chapter 2, Section 4 § 3 of [Regulation \(EU\) No 142/2011](#)
13. Article 4 & 5 of [Regulation \(EC\) No 1830/2003](#)
14. Annex II “COMPLAINTS AND PRODUCT RECALL” of [Regulation \(EC\) No 183/2005](#)
15. Article 19 of [Regulation \(EC\) No 178/2002](#)
16. Annex II “FACILITIES AND EQUIPMENT” of [Regulation \(EC\) No 183/2005](#)
17. Annex II “FACILITIES AND EQUIPMENT” §4 of [Regulation \(EC\) No 183/2005](#)
18. Article 12 & 13 of [Regulation \(EC\) 1069/2009](#)
19. Annex II “FACILITIES AND EQUIPMENT” §5 of [Regulation \(EC\) No 183/2005](#)
20. Annex II “FACILITIES AND EQUIPMENT” §3 of [Regulation \(EC\) No 183/2005](#)
21. Annex II “FACILITIES AND EQUIPMENT” §3a of [Regulation \(EC\) No 183/2005](#) and Article 25 §1 d) of [Regulation \(EC\) 1069/2009](#)
22. [Codex Alimentarius](#) General Guidelines on Sampling CAC/GL 50-2004
23. [Regulation \(EC\) No 183/2005](#) Annex II (Storage and Transport), [Regulation \(EU\) No 142/2011](#) (IX) Annex VIII: Chapter I 1 IV, [Regulation \(EC\) No 767/2009](#), EN-ISO 22000 :2005, par. 7.3.3 (Product characteristics)
24. Annex VIII, Chapter 1, Section 1, point 1 of [Regulation \(EC\) No 142/2011](#)
25. Annex VIII, Chapter 1, Section 2, point 2a of [Regulation \(EC\) No 142/2011](#)
26. Annex VIII, Chapter 2, point 2b of [Regulation \(EC\) No 142/2011](#)
27. Annex VIII, Chapter 1, Section 1, point 2 of [Regulation \(EC\) No 142/2011](#)
28. [Regulation \(EU\) No 142/2011](#), [Regulation \(EC\) No 999/2001](#), [Regulation \(EC\) No 183/2005](#) Annex II (Storage and Transport) , [Directive 2002/32/EC](#)
29. The information contained in the present section and tables is for general information purposes only. The information is provided by FEDIAF and while we endeavour to keep the information up to date and correct, we make no representations or warranties of any kind about the completeness, accuracy, reliability, suitability or availability with respect to the information provided. The **Pet Food Safety Management System** you implement within your factory/plant shall be based on your own **hazard** analysis is therefore strictly at your own **risk**.



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