



F.E.D.I.A.F.

GUIDE TO GOOD PRACTICE FOR THE MANUFACTURE OF SAFE PET FOODS

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FEDIAF Guide to Good Practice for the Manufacture of Safe Pet Foods

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The glossary contains definitions of key words used in this Guide followed by the source of the definition. The sources of the definitions employed are, by order of importance: (i) EU legislation; (ii) Codex Alimentarius; (iii) ISO; and (iv) other. Whenever appropriate, definitions are adapted to **pet** food.

Glossary

Additives	Means 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): <ul style="list-style-type: none"> - 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 1831/2003/EC on feed additives (art. 2(2)(a))
Animal by-products (for pet food production)	Entire bodies or parts of animals or products of animal origin referred to in Article 6 (1) (a to j) of Regulation 1774/2002/EC not intended for human consumption, including ova, embryos and semen.	Regulation 1774/2002/EC on animal by-products (art. 2(1)(a))
Batch	A unit of production produced in a single plant using uniform production parameters – or a number of such units, when stored together – and that can be identified for the purposes of recall and re-treatment or disposal should tests show that to be necessary.	Regulation 1774/2002/EC on animal by-products (Annex I, 2)
Canned pet food	Heat-processed pet food contained within a hermetically sealed container.	Regulation 1774/2002/EC on animal by-products (Annex I, 7)
Competent authority	Means 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 882/2004/EC on official controls (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 999/2001/EC on TSE (art. 3(1)(e))
		Regulation 1774/2002/EC on animal by-products (art. 2(1)(i))
	Means the authority of a Member State or of a third country designated to carry out official controls.	Regulation 1831/2003/EC on feed hygiene (art. 3(e))
Control measure	Action or activity that can be used to prevent or eliminate a (pet) food safety hazard or reduce it to an acceptable level.	Codex (HACCP guidelines)
Corrective action	Action to eliminate the cause of a detected nonconformity or other undesirable situation.	EN ISO 9000:2000
Critical Control Point (CCP)	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.	Codex and ISO 22000:2005(E)
Critical Limit	Criterion which separates acceptability from unacceptability.	Codex and ISO 22000:2005(E)

Cross-contamination	The passing of microorganisms, chemicals or other harmful substances indirectly from one material to another through improper or unsterile equipment, procedures, or products.	-
Dog chews	Untanned products for pet animals to chew, produced from hides and skins of ungulates or other animal material.	Regulation 1774/2002/EC on animal by-products (Annex I, 22)
Dry pet food	Pet food with a moisture content of less than 14 %.	-
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
Feed hygiene	Measures and conditions necessary to control pet food safety hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use.	Regulation 183/2005/EC on feed hygiene (art. 3(a))
Feed materials	Various 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, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures.	Directive 79/373/EC on the circulation of compound feedingstuffs (art. 2(k))
		Directive 2002/32/EC on undesirable substances (art. 2(b))
		Directive 96/25/EC on the circulation of feed materials (art. 2(a))
	Means those feed materials, as defined in Directive 96/25/EC, that are of animal origin including processed animal proteins, blood products, rendered fats, fish oil, fat derivatives, gelatin and hydrolysed proteins, dicalcium phosphate, milk, milk-based products and colostrum.	Regulation 1774/2002/EC on animal by-products (Annex I, 23)
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 79/373/EC on the circulation of compound feedingstuffs (art. 2(a))
		Directive 2002/32/EC on undesirable substances (art. 2(a))
		Directive 93/74/EC on PARNUTS (art. 2(a))
Finished 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)
Food safety management system	A systematic approach to define standards and procedures to ensure all aspects of food safety (risk assessment, risk management and communication) are defined so as to assure that all products will not cause harm to the consumer when prepared and/or eaten according to the intended use.	-

HACCP (Hazard Analysis and Critical Control Point)	A system which identifies, evaluates, and controls hazards which are significant for food safety.	Codex Alimentarius Recommended international code of practice general principles of food hygiene <i>CAC/RCP 1-1969, Rev. 4-2003</i>
HACCP plan	Plan to manage the CCPs identified to eliminate, prevent or reduce specified feed safety hazards from the product, as determined during hazard analysis.	-
HACCP review	The regular act of reviewing all aspects of the HACCP plan to ensure: (i) it accurately reflects the reality of the process on the factory floor; (ii) continuous identification of new food safety hazards and performance of risk assessments of all factory practices; and (iii) that all verification data trends are consulted and acted on appropriately. The frequency should be set at least once annually and in response to any change in product, process, procedures or practices which may affect food safety. In principle any change should be assumed to have an impact and therefore should be risk assessed. The review is to be performed by a multidisciplinary team.	-
Hazard	A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.	Regulation 178/2002/EC on general food law (art. 3(14))
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 1774/2002/EC on animal by-products (Annex I, 28)
Moist/wet pet food	Pet food with a moisture content of 60 % or more.	-
Monitoring	Act of conducting a planned series of observations or measurements of control parameters to assess whether control measures are effective.	EN ISO 22000:2005(E)
Pet	Animals belonging to species normally nourished and kept, but not consumed by man, except animals bred for fur.	Directive 79/373/EC on the circulation of compound feedingstuffs (art. 2(i))
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.	-

Pet food chain	Sequence of the stages and operations involved in the processing, distribution, and handling of a pet food and its ingredients, from production to consumption.	-
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)
Pouch	A sealed plastic, foil or composite hermetically sealed container used in packaging pet food.	-
Premixtures	Means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals.	Regulation 1831/2003/EC on feed additives (art. 2(2)(e))
Prerequisite Programme (PRP)	“(Pet) 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.	EN ISO 22000:2005(E)
Preventive action	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.	EN ISO 9000:2000
Quality control	A system based upon sampling and testing, with the intention of ensuring compliance with specification and identifying non-conforming products.	EN ISO 9000:2000
Quality control plan	A description established by the control management containing general information on the structure and organisation of its control systems.	-
Quality policy	Overall intentions and direction of an organisation related to pet food quality and safety as formally expressed by the top management.	EN ISO 9000:2000
Quantity control	Part of quality management focused on fulfilling quality requirements.	EN ISO 9000:2000
Raw pet food	Means pet food which has not undergone any preserving process other than chilling, freezing or quick freezing to ensure preservation.	Regulation 1774/2003/EC on animal by-products (Annex I, 48)
Risk	Means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.	Regulation 178/2002/EC on general food law (art. 3(9))
Risk analysis	Means a process consisting of three interconnected components: risk assessment, risk management and risk communication.	Regulation 178/2002/EC on general food law (art. 3(10))
Risk assessment	Means a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.	Regulation 178/2002/EC on general food law (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	Means 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	Regulation 178/2002/EC on general food law (art. 3(13))

	decisions.	
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	Means 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 178/2002/EC on general food law (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
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 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 of 14 % or more and less than 60 %.	-
Shelf-life	The period during which the product maintains its microbiological safety 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.	Codex Alimentarius Hygienic practices for refrigerated foods with extended shelf-life CAC/RCP 46- (1999)
Traceability	Means 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 178/2002/EC on general food law (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 1830/2003 on the traceability and labelling of GMOs
Tray	A shallow hermetically sealed container designed for containing pet food.	-
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 on undesirable substances (art. 2(l))
Updating	Immediate and/or planned activity to ensure application of the most recent information.	EN ISO 22000:2005(E)
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.	EN ISO 9000:2000
	For example, obtaining evidence (in advance of implementation) that the identified control measures of the HACCP plan are effective. This should be reviewed by an independent team of appropriately qualified personnel.	

Verification	Confirmation, through the provision of objective evidence, that the requirements have been fulfilled. 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 9000:2000
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INTRODUCTION

FEDIAF represents the national Pet food industry associations in the EU and from, Norway, and Switzerland, representing in the region of 450 companies across Europe.

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 RAW MATERIALS TO THE FINISHED PRODUCT.

The “FEDIAF Guide to Good Practice for the Manufacture of Safe Pet Foods” provides a framework/tool for pet food manufacturers to fulfil their legal requirement for developing their individual company procedures to ensure the production of safe pet food. The scope covers the production, storage and distribution of canned pet food (e.g. trays, pouches), other than canned pet food (e.g. dry, semi-moist), dog chews and raw pet food manufactured in Europe as well as 3rd country imports into the EU.

The Guide is based on full self-responsibility of the individual Pet food manufacturer using the following principles:

- *current best practice in the food and Pet food industry,*
- *existing European legislation* including the new Regulation of the European Parliament and the Council laying down requirements for feed hygiene (183/2005/EC) affecting pet food,
- *requirements of Hazard Analysis Critical Control Points (HACCP) as mentioned within CODEX Alimentarius (II),*
- *EN ISO 9000:2000 (I)*
- *Requirements of standards developed by other stakeholders e.g. related business sectors, retailers.*

Guiding principles of the document include :

- *to set the objectives of safe pet food products without describing the specific means thereby leaving companies room for flexibility on how best to achieve these safety objectives*
- *to focus on pet food safety aspects, not on compositional standards*
- *to include the traceability aspect of the entire supply chain, both upstream and downstream*
- *to strike a balance between generic rules and pet food specific rules*

The main aim of this document is to ensure that pet food is fit and safe for the purpose of feeding pets, whilst at the same time meeting the relevant requirements of European Legislation. In addition, when using this document, companies must also refer to the requirements of national legislation.

This document is reviewed and updated at least once a year at the FEDIAF’s Annual General Meeting but it may also be reviewed and updated more often whenever there

are new relevant technological, scientific or legislative developments for the production of pet food. The European Commission on its own initiative or at the request of the Member States, within the framework of the SCFCAH (Standing Committee on the Food Chain and Animal Health), may also request FEDIAF to review and update the Guide. FEDIAF is responsible to inform the European Commission and the pet food industry whenever the Guide is updated.

Acknowledgements

FEDIAF is grateful for the comments and support received from interested parties during the drafting and the consultation periods:

The British Retail Consortium's "Technical Standard and Protocol for Companies Supplying Retailer Branded Food Products" was used as a background document for which FEDIAF used partially the BRC structure and vocabulary.

In addition, a range of interested third parties were consulted, covering National Authorities, Consumer Organizations, Veterinary Organizations and others. Details and specific endorsements can be obtained through FEDIAF Secretariat.

1 PERSONNEL

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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1.1 Training

The Pet food Manufacturer shall ensure that all employees are adequately trained, instructed and supervised, commensurate with their activity.

<ul style="list-style-type: none"> a) 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. b) All personnel, including temporary personnel and contractors, shall be in sufficient number, possess the skills and qualifications necessary for the manufacturing process and be appropriately trained prior to commencing work. They shall be adequately supervised throughout the working period. c) The staff must be adequately trained for quality management. The person responsible for supervising quality control must furthermore be in a position to carry out his/her tasks independently and to take the appropriate decisions. d) The Pet food manufacturer shall have full training programmes and records. 	<p>- Regulation 183/2005/EC Annex II, (Personnel) (IX)</p>
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1.2 Personal Hygiene – Raw material handling, preparation, processing, packing and storage areas

The Pet food Manufacturer's personal hygiene standards shall be documented and adopted by all personnel, including contractors and visitors to the factory. These standards shall be designed with due regard to the risk of product contamination.

<ul style="list-style-type: none"> a) Jewellery and watches should not be worn unless in exceptional circumstances when there is no risk of product contamination and with the exception of a plain wedding ring and sleeper earrings. b) All cuts and grazes on exposed skin shall be covered (e.g. by a detectable blue metal strip plaster, that is Pet food manufacturer-issued). c) Smoking, eating and drinking shall only be permitted in designated areas. d) Hand cleaning shall be performed in an appropriate manner and frequency. e) Medical screening procedures should be implemented, where appropriate, in particular for staff working in areas where product safety could be compromised. f) Personnel 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 handling area where 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. 	<p>- Current best available practices</p>
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1.3 Protective Clothing – Pet food handlers and others working in, or visiting pet food handling areas

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

<ul style="list-style-type: none">a) Where appropriate, all hair shall be fully covered to prevent product contamination.b) Suitable safety footwear shall be worn within the factory environment.c) All protective clothing shall be laundered effectively on a regular basis.d) Gloves, if worn, should be subject to adequate control to avoid product contamination.	
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2 QUALITY MANAGEMENT SYSTEM – THE REQUIREMENTS OF THE QUALITY MANAGEMENT SYSTEMS ARE BASED ON THE INTERNATIONALLY RECOGNISED STANDARDS, E.G. ISO 9000:2000 SERIES (REF. I)

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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2.1 Quality Policy and Quality Objectives

The Pet food Manufacturer shall have a clearly defined and documented quality policy statement and quality objectives, e.g. ISO 9000:2000 (I)

<ul style="list-style-type: none"> a) The policy shall state the Pet food manufacturer's intentions to meet its obligations to produce safe and legal products, and its responsibility to its customers. The policy must also include the commitment of continuously improving the effectiveness of the quality management system. b) Quality objectives must be established, implemented and reviewed. Targets need to be defined and quality indicators must be monitored in order to follow quality performance and trends. A regular evaluation of the data is a very important tool for the continuous improvement of the products and services which are delivered to the customer. c) The Pet food manufacturer's Directors and Senior Management shall demonstrate commitment to the implementation of the Pet food manufacturer Quality Policy. d) The policy and the objectives, as well as the actual quality performance/trends shall be communicated throughout the Pet food company, and regularly reviewed. 	<ul style="list-style-type: none"> - All relevant legislation in force (EU and National) - ISO 9000:2000 (I)
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2.2 Quality Manual

The Pet food Manufacturer shall have a Quality Manual which states the Pet food manufacturer's commitment to quality and which covers the requirements of this Guide to Good Practice.

<ul style="list-style-type: none"> a) The Quality Manual should contain an outline of working methods and practices that meet the requirements of this document. b) The requirements specified within the Quality Manual shall be fully implemented. 	<ul style="list-style-type: none"> - ISO 9000:2000 (I) - Regulation 183/2005/EC Annex II (IX)
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2.3 Organisational Structure, Responsibility and Management Authority

The Pet food Manufacturer shall have an organisational structure, clearly defined and documented, reflecting the effectiveness of all the required tasks and detailing personal responsibility and reporting relationships of the staff involved in the production process; in particular those activities affecting product safety, legality and quality.

<p>a) The Pet food manufacturer's Directors shall be responsible for Pet food manufacturer policy and objectives, and shall provide adequate resources and investment to ensure product safety, legality and quality. A qualified person responsible for quality and pet food safety should be designated.</p> <p>b) The Pet food manufacturer's Directors shall ensure that all employees are aware of their responsibilities and mechanisms are in place either to monitor the effectiveness of their operation and/or to trigger corrective actions.</p> <p>c) The Pet food manufacturer shall ensure that levels of responsibility and accountability are clearly defined for key staff involved with the production process, product safety, legality and quality systems. To this end, job descriptions and an organisation chart setting out qualifications and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. A qualified person responsible for production must be designated. There shall be appropriate arrangements in place to cover for the absence of key staff.</p> <p>d) The Pet food manufacturer shall have a system in place to ensure that it is kept informed of all relevant legislation, food safety issues as well as, legislative, scientific and technical developments.</p> <p>e) The Pet food manufacturer shall ensure that adequate resources are available for training all employees, in particular new employees.</p>	<ul style="list-style-type: none"> - Regulation 1831/2003/EC(VII) - Directive 79/373/EEC (VI) - Directive 82/471/EEC (XV) - ISO 9000:2000 (I) - Regulation 183/2005/EC Annex II (Personnel and Quality Control) (IX)
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2.4 Management review

The Management shall review the quality management system on a regular basis.

<p>a) Senior management shall review the organisation's quality management system, at planned intervals, to ensure its continuing adequacy and effectiveness. This review shall include an assessment of any opportunity for improvement, as well as an assessment of the need to change the quality management system, including the quality policy and quality objectives.</p>	<ul style="list-style-type: none"> - ISO 9000:2000 (I) - Regulation 183/2005/EC Annex II (IX)
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2.5 Procedures

The Pet food Manufacturer shall have, and operate in accordance with written detailed procedures, instructions, and reference documents to cover all relevant aspects of product safety, legality and quality.

<p>a) Documents shall be clearly legible, unambiguous and sufficiently detailed to enable effective use by appropriate personnel, and shall be readily accessible at all times.</p>	<ul style="list-style-type: none"> - ISO 9000:2000 (I) - Regulation 183/2005/EC Annex II (IX)
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2.6 Documentation Control

The Pet food Manufacturer shall ensure that all documents, records and data critical to the management of product safety, legality and quality, are in place and effectively controlled.

<p>a) The Pet food Manufacturer shall keep in a register, relevant data comprising details of purchase, transport, production and sales for effective tracing from receipt to delivery.</p> <p>b) The documentation relating to the manufacturing process must be designed to define and control the critical points in the manufacturing process and to establish and implement a quality control plan.</p> <p>c) The commercial documents and health certificates must be kept for a period of at least 2 years for presentation to the competent authority.</p> <p>d) All documents in use shall be properly authorised and be the versions as issued by the Pet food manufacturer.</p>	<p>- Regulation 183/2005/EC Annex II (IX)</p> <p>- ISO 9000:2000 (I)</p> <p>- Regulation 1774/2002/EC (art. 9 and Annex II chapter V) (XII)</p>
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2.7 Quality Records

The Pet food Manufacturer shall maintain records to demonstrate the effective control of product safety, legality and quality. These records should include product samples as appropriate.

<p>a) The Pet food manufacturer must have access to a laboratory with adequate staff and equipment.</p> <p>b) A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications.</p> <p>c) The Pet food manufacturer shall operate procedures for collation, review, maintenance, storage and retrieval of all records appertaining to product safety, legality and quality.</p> <p>d) The records shall be retained in good condition, for an appropriate defined period, but not less than two years in case of pet food containing animal by-products so that they can be reviewed.</p> <p>e) Samples of the finished products must be kept for a period appropriate to the use for which the feed is placed on the market, i.e. equivalent to the time the pet food is normally sold and consumed. As an indicative period, 6 months after production is considered appropriate.</p>	<p>- ISO 9000:2000 (I)</p> <p>- Regulation 183/2005/EC Annex II (Quality Control) (IX)</p> <p>- Regulation 1774/2002/EC (XII)</p>
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2.8 Information of Competent Authority in Case of Serious Animal or Public Health Hazards

The Pet food Manufacturer shall have in place a procedure to inform, as appropriate, competent authorities in case of hazards related to the product

<p>a) The Pet Food manufacturer processing animal by-products shall inform the competent authority, should the laboratory examination of samples or any other information available reveal the existence of a serious animal health or public health hazard.</p>	<p>Regulation 1774/2002/EC (art. 18 (2) (a) (v)) (XII)</p>
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2.9 Specifications and customer requirements/contract review

The Pet food Manufacturer shall ensure that appropriate specifications exist for:

- ◆ *Raw materials*
- ◆ *Packaging materials*
- ◆ *Processing*
- ◆ *Finished products*
- ◆ *Intermediate/semi-processed products (where appropriate)*
- ◆ *Transport & Warehouse*

- | | |
|--|---|
| <ul style="list-style-type: none"> a) Specifications shall be adequate, accurate, and shall ensure compliance with relevant safety and legislative requirements. b) Specifications shall be formally agreed with relevant parties. | <ul style="list-style-type: none"> - All relevant legislation in force (EU and National) - Regulation 1774/2002/EC (XII) - ISO 9000:2000 (I) |
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2.10 Customer satisfaction

The Pet food Manufacturer shall monitor information relating to customer perception, such as whether the customer requirements have been met or not.

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| <ul style="list-style-type: none"> a) A method for obtaining information on customer satisfaction and how to use the information must be determined. b) Key performance indicators (KPI) on customer satisfaction is an important tool for a continuous improvement of the product and service delivered. The KPIs should be developed in agreement with the customer, whenever possible. | <ul style="list-style-type: none"> ISO 9000:2000 (I) |
|---|---|

2.11 Internal Audit

The Pet food Manufacturer shall audit those systems and procedures, which are critical to product safety, legality and quality, to ensure they are in place, appropriate and complied with.

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| <ul style="list-style-type: none"> a) Internal audits shall be carried out by competent auditors, who shall be independent of the area of operation being assessed. b) Documentary results of the internal audit shall be brought to the attention of the personnel responsible for the activity audited. Corrective actions and time-scales for their implementation shall be agreed. | <ul style="list-style-type: none"> - Codex Alimentarius, 1997 (II) - ISO 9000:2000 (I) |
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2.12 Corrective and Preventive Actions

The Pet food Manufacturer shall, when necessary, put in place investigation processes to assess the cause of significant non-conformity with standards, specifications and procedures, which are relevant to product safety (according to HACCP principles and procedures), legality and quality.

<ul style="list-style-type: none"> a) Causes of problems, when clearly identified, should be used to re-engineer processes and/or procedures to avoid recurrence of the non-conformity. This information should also, whenever possible, be used to predict potential problems and to amend working practices to ensure that problems do not occur. b) Corrective actions shall be undertaken in a timely manner to prevent a re-occurrence of the non-conformity. c) Corrective actions shall be accurately documented, assigning responsibility and accountability. d) HACCP is the recommended tool when taking preventive actions. A careful and detailed assessment of hazards from the product development stage up to consumption must be performed for all products. e) Changes in existing or new production lines, equipment or products, must be based on HACCP study/review. 	<ul style="list-style-type: none"> - ISO 9000:2000 (I) - Codex Alimentarius, 1997 (II) - Regulation 183/2005/EC (IX)
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2.13 Complaint Handling

The Pet food Manufacturer shall have a system in place for the registration and management of product complaints.

<ul style="list-style-type: none"> a) The Pet food manufacturer shall implement a system for registering and processing complaints and a system for the prompt recall of products in the distribution network. Recalled products can be put back into circulation only after undergoing a quality-control reassessment. b) Appropriate actions to the seriousness and frequency of the problems identified, shall be carried out promptly and effectively. c) Complaint records and data shall, where appropriate, be used to improve the product safety, legality and quality, and seek to avoid a reoccurrence. d) Pet Food safety complaints must be evaluated in the light of the current HACCP plan and the defined Critical Control Points. The evaluation may lead to a review of the HACCP plan or the CCPs. 	<ul style="list-style-type: none"> - ISO 9000:2000 (I) - Regulation 183/2005/EC Annex II (Complaints and product recall) (IX)
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2.14 Continuous improvement

The Pet food Manufacturer shall continuously improve the quality management system.

<ul style="list-style-type: none"> a) The Pet food Manufacturer shall continuously improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. 	<ul style="list-style-type: none"> - ISO 9000:2000 (I)
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3 HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINTS)

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
<p><i>The basis of the Pet food manufacturer's food safety system shall be a HACCP Plan which shall be systematic, comprehensive and thorough and shall be based on the Codex Alimentarius HACCP principles (Ref. II)</i></p>	
<p>a) The Pet food manufacturer shall use the Codex HACCP principles to :</p> <ul style="list-style-type: none"> • Conduct a hazard analysis, • Determine the Critical Control Points (CCP), • Establish the Critical Limits, • Establish a system to monitor control of the CCP, • Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control, • Establish procedures of verification to confirm that a HACCP System is working effectively, • Establish documentation concerning all procedures and records appropriate to these principles and their applications <p>b) The HACCP study shall be based on an assessment of risk, and shall identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the correct production of pet food. In conducting the hazard analysis, wherever possible, the following should be included.</p> <ul style="list-style-type: none"> • The likely occurrence of hazards and severity of their adverse health effects. • The qualitative and/or quantitative evaluation of the presence of hazards. • Survival and multiplication of micro-organisms of concern. • Production and persistence in pet foods of toxins, chemical or physical agents • Conditions leading to the above. <p>c) HACCP shall have Senior Management commitment and shall be implemented through the Pet food manufacturer's quality management system.</p> <p>d) The HACCP team leader or nominated team representative shall be able to demonstrate competence in the understanding of HACCP principles and their application.</p> <p>e) Key personnel identified as HACCP Team members shall have adequate training and experience.</p> <p>f) The HACCP System shall be specific to the application, practical to implement and effective in controlling the associated hazards of the operation.</p> <p>g) All existing and new products shall be covered by the HACCP System, which shall be reviewed on a regular basis (at least once a year) and shall be validated.</p> <p>h) Critical Control Points, identified in relation to the operation, shall be controlled and monitored within predetermined Critical Limits. Records of conformance and effective corrective action resulting from non-conformance shall be maintained.</p> <p>i) The food safety management system shall consist of both a validated and verified prerequisite programme and a HACCP system, and through these, the Pet food manufacturer shall be able to demonstrate effective food safety control of all operations undertaken.</p> <p>j) The HACCP study shall be carried out by a multi-disciplinary team.</p>	<ul style="list-style-type: none"> - Codex Alimentarius, 1997 (II) HACCP handbook for SMEs (III/5087/96) (III) - Regulation 1774/2002 (XII) - Regulation 183/2005/EC, Article 6 (IX)

4 TRACEABILITY

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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4.1 Registration and Approval

Registration and/or approval of the Pet food Manufacturer by the competent authority is compulsory.

<p>a) The Pet food manufacturer shall notify the appropriate competent authority of any establishment under their control involved in any stages of production, processing, storage or distribution of pet food in the form required by the competent authority with a view to registration and/or approval.</p> <p>b) The Pet food manufacturer shall provide the competent authority with up-to-date information on any establishments under their control including notifying the competent authority of any significant change in activities and any closure of an existing establishment.</p>	<p>- Regulation 183/2005/EC Article 9 (IX) - Regulation 1774/2002 (XII)</p>
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4.2 Traceability - Key requirements

Traceability shall apply and be the responsibility of each operator of the entire Pet food chain ("from farm to feeding bowl").

The Pet food Manufacturer shall adequately identify all materials used in the pet food production (raw materials, additives, packaging, packaging materials), including the finished product, and be able to trace what occurred in all phases of production, and up to the distribution to the customer.

<p>a) The Pet food manufacturer must work with a system of documentation designed to ensure an adequate level of traceability. Traceability is the capability to be able to identify any person from whom they have been supplied with feed materials, additives, packaging material or any substance intended to be, or expected to be, used for the production of pet food. The Pet food manufacturer must record and keep the following information for at least two years, or five years if the product contains GMOs, in order to ensure product traceability:</p> <ul style="list-style-type: none"> • The name and address of the suppliers (e.g. raw materials, , additives/premixtures, packaging) and the sources of these raw materials/packaging, including the batch number, quantity and delivery date. • The approval or registration number of the suppliers of raw materials 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. <p>b) Where rework or any reworking operation is performed, traceability shall be maintained.</p>	<p>- Regulation 183/2005/EC Annex II (Quality Control, Record-keeping 1, 2 (b) (iv)) (IX) - Regulation 1774/2002/EC (XII)</p>
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4.3 Product Identification and Labelling of Traceability Tools

The Pet food Manufacturer shall identify each individual sales unit.

<p>a) The Pet food manufacturer shall establish and maintain documented procedures for identifying materials from reception through production to finished products. Finished products should be labelled to ensure traceability to batch.</p>	<p>- Directive 79/373/EEC (VI) - Regulation 1774/2002/EC (XII) - Regulation 183/2005/EC (IX)</p>
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4.4 Product Recall

The Pet food Manufacturer shall have an effective product recall procedure for all products in the distribution network.

<p>a) The Pet food manufacturer shall implement a system for the prompt recall of products in the distribution network.</p> <p>b) Should a product be delivered, which does not meet the food safety requirements, the Pet food manufacturer has to recall these products from the distribution network. The manufacturer has to take care that the products will not be put back into circulation unless they have undergone a risk assessment and, if required, treated in an appropriate way. The manufacturer, therefore, must have a recall procedure implemented. A Rapid Alert System should be in place, which is the obligation to inform the competent authority, in case a product recall is necessary.</p> <p>c) The procedure shall be: appropriate; formalised; capable of being operated at any time; The procedure shall be regularly reviewed and revised as appropriate.</p> <p>d) The procedure shall be regularly tested in a manner that is appropriate to ensure its effective operation.</p>	<p>Regulation 183/2005/EC Annex II (Complaints and Product Recall) (IX)</p>
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5 PLANT DESIGN AND MAINTENANCE

(AS PART OF THE PRE-REQUISITE PROGRAMMES)

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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5.1 Location

The site shall be located and maintained so as to prevent contamination and enable the production of safe and legal pet foods.

<ul style="list-style-type: none"> a) Measures necessary to protect the site from any potential undesirable contaminants should be in place and periodically reviewed to ensure they continue to be effective. b) The site boundaries should be clearly defined. 	Regulation 183/2005/EC Annex II (Facilities and Equipment) (IX)
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5.2 Perimeter and Grounds

All grounds within the site shall be finished and maintained to an appropriate standard.

<ul style="list-style-type: none"> a) Where natural drainage is inadequate, additional drainage shall be installed to avoid the risk of contamination of feedingstuffs. b) Where external storage is necessary, items shall be protected from contamination and deterioration. c) Wherever possible, all buildings should be surrounded by a clear space. All immediate surrounding areas shall be kept clean, and effective pest control programmes shall be implemented. d) Waste collection should take place in a well-defined area. 	Regulation 183/2005/EC (Facilities and Equipment) (IX)
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5.3 Layout/Product Flow

Premises and plant shall be designed, constructed and maintained to control the risk of product contamination.

<ul style="list-style-type: none"> a) The production process from reception to dispatch, shall be designed to permit adequate cleaning and/or disinfection in order to prevent personnel, product, facilities and equipment contamination and cross-contamination. b) Premises shall allow sufficient working space and storage to enable all operations to be carried out properly under safe and hygienic conditions. c) The systems of working shall, where appropriate, be such as to reduce any potential physical, chemical or microbiological contamination risks. d) There shall be an appropriate segregation between unprocessed and processed materials to minimise the risk of product cross-contamination. e) Segregation shall take into account the product flow, nature of materials, equipment, personnel, waste management, airflow, and air quality and services provision. f) Pet food plants must have adequate facilities for disposing of unused animal by-products remaining after the production of the products. Alternatively this material must be sent to a processing plant or to an incineration or co-incineration plant. 	Regulation 183/2005/EC Annex II (Facilities and Equipment) (IX) Regulation 1774/2002/EC Annex VIII, Chapter I (XII)
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5.4 Fabric – Raw materials handling, preparation, processing, packing and storage area

The fabric of the site, buildings and facilities shall be suitable for the intended purpose. The use of glass should be avoided.

5.4.1 Walls

<p>a) Walls should be designed, constructed, finished and maintained to prevent the accumulation of dirt, to reduce condensation and mould growth and to facilitate cleaning.</p> <p>b) Wall/floor junctions and corners should be coved to facilitate cleaning and disinfection. Cavities in the surface of walls should be avoided, where necessary, to prevent debris from accumulating and pest harbourage.</p>	Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.4.2 Floors

<p>a) Drainage shall not compromise product safety and shall flow away from high-risk areas.</p> <p>b) Drainage facilities must be adequate for the purpose intended and shall be designed and maintained to minimise risk of product contamination.</p> <p>c) Floors should be designed to meet the demands of the process, and withstand cleaning materials and methods. They should be impervious and maintained in good conditions.</p> <p>d) Floors should have adequate falls to cope with the flow of any water or effluent towards suitable drainage.</p> <p>e) Careful consideration to the siting of machinery. Suitable drainage should be provided so that any discharge or overspill from processing goes directly into a drain rather than on the floor.</p>	Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.4.3 Ceilings/Overheads

<p>a) Where false ceilings are used, adequate access to the void shall be provided to facilitate cleaning, maintenance of services and inspection for pest activity.</p> <p>b) Where necessary, 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 that can affect the safety and quality of pet food.</p>	Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.4.4 Windows and glass

<p>a) The use of glass close to production machinery. must be avoided and wherever necessary it must be protected against breakage.</p> <p>b) Where windows are designed to be opened for ventilation purposes, they shall, where necessary, be adequately screened to prevent the ingress of pests.</p>	Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.4.5 Doors

<ul style="list-style-type: none">a) Doors should be kept closed at all times, when not in use.b) Doors must be close-fitting and proofed against pests when closed.c) Where external doors to raw material handling, processing, packaging and storage areas are kept open, suitable precautions shall be taken to prevent the ingress of pests.	Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.4.6 Lighting

<ul style="list-style-type: none">a) Facilities must have adequate natural and/or artificial lightingb) Shatterproof plastic diffusers or sleeve covers shall protect all bulbs and strip lights, including those on electric fly killer units, where they constitute a risk to the product. For high temperature lights, where plastic covers are not viable, a fine mesh metal screen shall be fitted. Where full protection cannot be provided, the glass management system shall take this into account.	Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.4.7 Air

<ul style="list-style-type: none">a) Where the process requires screened or filtered air, the equipment used for this purpose shall be adequately maintained.b) Dust extraction equipment for dry powder handling areas should be installed.c) Compressed air in contact with products should be filtered	
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5.4.8 Water, Ice and Steam

<ul style="list-style-type: none">a) All water supplies used for cleaning shall, where appropriate, be potable, either being drawn from mains supply or suitably treated according to its source.b) Water used in Pet food manufacture shall be of suitable quality for animals. All piping etc. should be of inert nature.c) The quality of water, steam or ice that comes in contact with pet food shall be regularly monitored and shall present no risk to product safety.d) Water supply systems should be properly labelled and segregated between potable and non-potable supplies.	- Directive 98/83/EC (XIV) - Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.5 Equipment / Instruments

Equipment shall be suitably designed for the intended purpose and shall be used so as to minimise the risk of product contamination

<ul style="list-style-type: none"> a) Equipment shall be designed, so as to minimize the risk of error and to avoid contamination, cross-contamination and any adverse affect, generally on the safety and quality of the products. When appropriate, machinery coming into contact with feed shall be dried following any wet cleaning process. b) Equipment should be positioned so as to allow easy access for cleaning and/or disinfection and servicing. c) All equipment should be properly specified prior to commissioning, and should be adequately maintained, serviced and operated to allow for the production of safe, quality and legally compliant pet food. d) All equipment surfaces coming into contact with the product should be impervious and non-reactive. e) All equipment must be designed so that it does not in itself contaminate the product due to leaking seals, lubrication or through subsequent modification. f) All food contact lubricants should be of food grade quality. 	<ul style="list-style-type: none"> - Directive 76/211/EEC (XIII) - Regulation 183/2005/EC Annex II (Facilities and equipment) (IX) - Directive 2002/72/EC (XVII)
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5.6 Maintenance

A system of planned maintenance shall be in place covering all items of equipment, which are critical to product safety, legality and quality.

<ul style="list-style-type: none"> a) Equipment shall undergo appropriate and regular maintenance, in accordance with written procedures pre-established by the equipment manufacturer. b) The Pet food manufacturer shall ensure that the safety, quality or legality of product is not jeopardised during and after maintenance operations. Particular attention should be drawn to the risk of foreign body contamination. c) Third party contractors and all engineers shall be aware of and adhere to the Pet food manufacturer's hygiene standards, with particular focus on both high and low risk areas. d) Cleaning or replacing light fittings and glass shall be done in a manner as to minimise the potential of product contamination. 	<ul style="list-style-type: none"> - Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)
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5.7 Staff Facilities

<i>Staff facilities shall be designed, and used to minimise the risk of product contamination.</i>	
<ul style="list-style-type: none"> a) Where specific workwear is required, changing facilities shall be provided for all personnel, whether staff, visitor or contractor, prior to entry to production or packing areas, and where appropriate, prior to entry to storage areas. b) Suitable and sufficient hand washing facilities shall be provided. c) Toilets doors shall not open directly into production, packing or storage areas. d) Smoking shall only be permitted in appropriate designated areas. e) Where catering facilities are provided, these shall be suitably controlled to prevent contamination of product. f) Where appropriate, changing facilities shall be located to allow personnel direct access to the packing or storage area, without first passing through areas external to the factory buildings. g) Suitable provisions shall be made for the storage of food brought onto the premises by staff. h) Outdoor clothing and other personal items shall be stored separately from workwear within the changing facilities. i) The use of workwear should be restricted to the work premises. 	- According to national legislation

5.8 Risk of Physical and Chemical Product Contamination

<i>Appropriate facilities and procedures shall be in place to control the risk of physical or chemical product contamination.</i>	
<ul style="list-style-type: none"> a) The Pet food manufacturer shall adopt all measures to comply with the maximum permitted levels of physicochemical residues laid down in Community legislation. b) Appropriate storage facilities shall be provided for the control and storage of any hazardous chemicals. c) Written procedures for handling glass and hard clear plastic breakages in raw material handling, preparation, processing, packing and storage areas shall be in place to ensure the necessary precautions are taken. These procedures should form part of a formal glass policy. d) The use of wood within raw material handling, preparation, processing, packing and storage areas shall, be minimised. 	- Codex Alimentarius, 1997 (II) - Regulation 1774/2002/EC (art. 25(1cii)) (XII)

5.9 Housekeeping and Hygiene

<i>Appropriate standards of hygiene and housekeeping shall be maintained at all times.</i>	
<ul style="list-style-type: none"> a) Cleaning and/or disinfection programmes shall be implemented and effective in order to minimise the risk of contamination. Programme must be documented. b) All cleaning staff should be trained and competent to perform the required tasks. c) The effectiveness of the cleaning and sanitation procedures in processing areas shall be verified. d) Only approved food grade cleaning agents should be used. 	- Regulation 183/2005/EC Annex II (Facilities and equipment) (IX)

5.10 Waste/Waste Disposal

There shall be adequate systems for the collation, collection and disposal of waste material.

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| <ul style="list-style-type: none"> a) Sewage, waste and rain water shall be disposed of in a manner which ensures that the safety and quality of feed is not affected. Spoilage and dust shall be controlled to prevent pest invasion. b) Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed. c) Systems shall be in place to minimise the accumulation of waste in production areas, and shall prevent the use of unfit materials. Defined waste areas should be established. d) Waste disposal shall meet legislative requirements and, where appropriate, removed by licensed contractors. e) External waste collection containers and compactors should be closed and/or covered. f) All waste containers should be clearly marked and designated for that purpose only. | <ul style="list-style-type: none"> - Regulation 1774/2002/EC (XII), - Directive 94/62/EC (XVI) - Regulation 183/2005/EC Annex II (Facilities and equipment and Production) (IX) |
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5.11 Pest Control

The Pet food Manufacturer shall be responsible for minimising the risk of pest infestation on the site.

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| <ul style="list-style-type: none"> a) Pest control programmes shall be implemented. b) The Pet food manufacturer shall either contract the services to a competent, and where appropriate licensed, pest control organisation, or shall 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 shall be clearly defined and reflect the activities of the site. c) Detailed records of the pest control inspections, recommendations and necessary action undertaken shall be kept. d) Permanently operational electric fly killers shall, where appropriate, be provided and correctly positioned. e) Drains shall be fitted with screens and traps to prevent pest entry. f) Incoming raw materials shall, where appropriate, be thoroughly checked on arrival for the absence of pests. g) Raw materials, packaging and finished products shall be stored so as to minimise the risk of pest infestation. Where stored, product may attract pests, appropriate measures shall be included in the control programme. h) Documentation shall provide detailed information on the safe use and application of baits. i) The location of all pest control measures shall be identified on a plan/diagram of the site. | <ul style="list-style-type: none"> - Codex Alimentarius, 1997 (II) - Regulation 183/2005/EC Annex II (Facilities and equipment) (IX) |
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6 PET FOOD DESIGN AND FORMULATION

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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6.1 Product, Packaging and Process Design

A hazard analysis study (HACCP) shall be undertaken during the design/development phase of the product, packaging and process to identify and assess all potential safety hazards (Codex Alimentarius, 1997 (II)).

<ul style="list-style-type: none"> a) The pet food must be designed to produce a safe pet food and meet the nutritional requirements of the pet. b) The Pet food manufacturer shall, where appropriate, undertake factory trials and carry out testing to verify if product formulation and manufacturing processes are capable of producing a nutritionally-well balanced, safe and legal product. c) Shelf life shall be established, taking into account the product formulation, production process, packaging process and packaging and subsequent storage conditions. d) Packaging, process and the material used in the manufacture must assure pet food safety. 	<ul style="list-style-type: none"> - FEDIAF "Nutritional Guideline for Complete and Complementary Pet Food for Dogs and Cats".(IV) - FEDIAF "Nutritional knowledge - Small pets" (V) - Directive 2002/72/EC (XVII)
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6.2 Formulation

Feed materials have to be mixed to produce a safe pet food.

<ul style="list-style-type: none"> a) The presence of prohibited feed materials, undesirable substances, prohibited substances and pathogens in relation to animal or human health shall be monitored and appropriate control strategies to minimise the risk shall be in place. b) The EU legislation establishes a list of products whose use as feed materials is prohibited. The manufacturer must make sure that the products included on the list of prohibited products are not used. Certain feed materials and additives are subject to restriction for use in certain species. The manufacturer must make sure that they are used accordingly and that the risks of accidental contamination are controlled/eliminated. c) Only permitted additives can be used and mixed in appropriate quantities and homogeneously with the feeding materials, in order to ensure that they are only present in non-toxic quantities. 	<ul style="list-style-type: none"> - Regulation 1831/2003/EC (VII) - Directive 2002/32/EC (VIII) - Recommendation 2006/576/EC (XXIII) - Decision 2004/217/EC (X) - FEDIAF "Nutritional Guideline for Complete and Complementary Pet Food for Dogs and Cats".(IV) - FEDIAF "Nutritional knowledge - Small pets"(V); - Regulation 183/2005/EC Annex II (Production) (IX) - Regulation 1774/2002 (XII) - Regulation 1829/2003/EC (XXI)
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7 PURCHASING AND DELIVERY

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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7.1 Supplier assurance

The Pet food Manufacturer shall operate procedures for approval and monitoring of its suppliers, including finished and semi-finished products manufactured by third parties.

<p>a) A Vendor/Supplier Assurance (VA) programme must exist to control the purchase of raw materials and packaging materials from approved suppliers. This programme must document all standards and monitoring procedures dealing with primary production, inbound raw material and packaging and transport.</p> <p>b) Specifications, based on risk assessment, for raw materials, semi-processed products (where supplied to other factories) and packaging materials must be documented and implemented. The specification may include detail on analytical, nutritional requirements as well as food safety and hygiene requirements. There shall be a list of approved suppliers.</p> <p>c) Appropriate methods of assessment/inspection of suppliers shall be performed with the frequency and type of audit being determined by risk assessment. Assessment may take the form of monitoring performance through in-house checks, certificates of analysis or extend to supplier inspection, as appropriate. For example, the quality and safety of a pet food or a premix can be influenced by mistakes in the addition of micro-components or veterinary medical substances. When used without caution or inappropriately, additives and medical substances can produce serious adverse effects on the pet.</p> <p>d) Supplier assessment must include the suppliers's 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.</p> <p>e) The procedures shall define how materials of unknown origin are handled.</p>	<p>- Regulation 183/2005/EC (IX) - Regulation 1829/2003/EC (XXI) - Regulation 1830/2003/EC (XXII)</p>
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7.2 Deliveries

The Pet food Manufacturer shall operate procedures for monitoring the quality and safety of raw material at delivery.

<p>a) Each feed material, additive and packaging material must have a written specification which is regularly updated. In addition to the nutritional and analytical characteristics of the feed material, this written specification should include a list of approved origins and sources, details of any processing that the material has undergone, types of feedstuffs in which its use is approved, notes on any hazards or limitations on its use and any special characteristics of the feed material.</p> <p>b) Monitoring at delivery must ensure that the feed materials and additives are traceable, conform to quality and safety specifications, delivered by an approved or registered supplier, when the products are covered by an approval or registration procedure.</p> <p>c) A record shall be kept of the origin of each feed material and additive delivered.</p> <p>d) Suppliers delivering animal by-products must meet specific registration, production process and analytical requirements.</p> <p>e) A raw material/packaging acceptance procedure must exist and each material must be checked (against the specification) following a schedule of examination that takes into account its critical importance, as identified by risk assessment, in the final product, for example using certificates of analysis, sampling of the material on arrival.</p>	<ul style="list-style-type: none"> - Regulation 183/2005/EC (IX) - Regulation 1829/2003/EC (XXI) - Regulation 1830/2003/EC (XXII) - Regulation 1774/2002/EC (XII) - Regulation 1831/2003/EC (VII) - Decision 2004/217/EC (X) - Directive 2002/32/EC (VIII) - Recommendation 2006/576/EC (XXIII)
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8 PRODUCTION

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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8.1 General requirements

Clear responsibilities and procedures for the production process must be in place.

<ul style="list-style-type: none"> a) A qualified employee must be designated as the person responsible for the production process. b) The manufacturer must ensure that the different production stages are carried out in accordance with written procedures and instructions. In order to obtain the desired quality of pet food, these procedures must define the critical points of the manufacturing process. c) Measures shall be taken to avoid contamination, cross contamination and human error to maintain the hygiene and safety standards. 	<p>- Regulation 183/2005/EC Annex II Production (IX)</p>
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8.2 Feed materials of animal origin

The Pet food manufacturer shall use feed materials conforming with the EU legislation.

<ul style="list-style-type: none"> a) The only animal by-products that may be used to produce pet food and dog chews are those referred to in article 6(1)(a) to (j) of Regulation 1774/2002/EC. However, raw pet food may be manufactured only from animal by-products referred to in article 6(1) (a) of Regulation 1774/2002/EC. b) Raw pet food must be supplied in packaging designed to prevent leakage. Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale. The wording "pet food only" must be visibly and legibly displayed on the packaging. 	<p>Regulation 1774/2002/EC Annex VIII, Chapter II (XII)</p>
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8.3 Weighing

The accuracy of weighing and metering equipment, both for bulk and hand tipped ingredients, is essential for the production of a safe pet food.

- a) All scales and metering devices used in the manufacture of pet food shall be appropriate for the range of weights or volumes to be measured and a regular programme of calibration and testing of weighing and metering equipment is essential. Guidance from equipment manufacturers should be taken in developing written procedures for calibration and testing.
- b) A regular maintenance programme should also be in place in order to ensure that weighing equipment is kept clean and that worn parts are replaced when necessary.

- Regulation 183/2005/EC Annex II (Facilities and Equipment) (IX)

8.4 Mixing

A homogenous mixture is essential for nutritional balance and pet food safety. The accuracy of mixing must be assured and verified.

- a) All mixers used in the manufacture of pet food shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing homogeneous mixes or homogenous solutions.
- b) Cleanliness of the mixer is essential for efficacy and pet food safety.
- c) 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.
- d) The mixers must operate for a pre-set time, determined by pre-production trials to ensure homogenous mixes and/or solutions.
- e) The efficiency of the mixing process must be regularly checked to ensure that additives are evenly dispersed throughout the mix.
- f) An unacceptable carry over of additives, veterinary medical substances or any other undesirable substance must be prevented.
- g) Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

- Regulation 183/2005/EC Annex II (Facilities and Equipment) (IX)

8.5 Quality Control and Product Analysis

A Quality Control Plan must be drawn up and implemented for the use of raw materials, premixtures and finished products. The Pet Food Manufacturer shall undertake or sub-contract analysis, critical to product safety, legality and quality, using appropriate procedures and facilities

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| <p>a) The Quality Control Plan must identify checks on critical control points in the manufacturing process, sampling procedures as well as determine the frequency of these checks and sampling procedures. The plan has also to specify which methods of analysis are to be used and how frequently. The quality control plan must mention actions to be taken in case of non-compliance with the specifications.</p> <p>b) The manufacturer shall, based on risk assessment (including HACCP), determine what level of analytical testing (microbiological, physical or chemical) that needs to be performed to verify that the food safety management system is under control, and comply with the feed legislation.</p> <p>c) For pet food and dog chews made from animal by-products, random samples must be taken during production and/or finished products (before dispatching) to verify compliance with the following standards: Salmonella (absence in 25g, n=5, c=0, M=0); and Enterobacteriaceae (n=5, c=2, m=10, M=300 in 1g). However, for canned pet food and other hermetically sealed heat treated containers that has undergone heat treatment described in the production section (temperature), sampling and testing for Salmonella and Enterobacteriaceae may not be necessary.</p> <p>d) Procedures shall be in place to ensure reliability of test results.</p> <p>e) Personnel undertaking analyses shall be suitably qualified, and/or trained and shall be competent to carry out the analyses required.</p> <p>f) Where the Pet food manufacturer undertakes or sub-contracts analyses critical to product safety or legal compositional verification, the laboratory shall be independently accredited by a competent authority.</p> | <ul style="list-style-type: none"> - Regulation 1774/2002/EC (XII) - Directive 2002/32/EC (VIII) - Recommendation 2006/576/EC (XXIII) - Decision 2004/217/EC (X) - Regulation 183/2005/EC Annex II (Quality Control) (IX) |
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8.6 Temperature/Time Control

The Pet food Manufacturer shall be able to demonstrate effective control of all operations undertaken. Where temperature control of the raw materials, intermediate or finished product, process and/or environment is critical to product safety, legality and quality, this shall be adequately controlled, monitored and recorded.

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| <p>a) In circumstances where temperature and/or time control is critical to product safety, quality or legality (e.g. thermal processing, freezing or chilling), temperature and/or time recording equipment, linked to a suitable failure alarm system, shall be used to monitor at an appropriate frequency, the process status.</p> <p>b) Canned pet food and other hermetically sealed heat treated containers must be subject to heat treatment to a minimum Fc value of 3.</p> <p>c) Processed pet food other than canned pet food or other hermetically sealed heat treated containers must be subject to a heat treatment of at least 90°C throughout its substance. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.</p> <p>d) Dog chews must be subject to a heat treatment during processing sufficient to destroy pathogenic organisms (including <i>salmonella</i>). After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.</p> | <ul style="list-style-type: none"> - Regulation 1774/2002/EC (XII); - Codex Alimentarius, 1997 (II) - Regulation 1774/2002/EC Annex VIII Chapter II (XII) |
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8.7 Foreign Body Detection / Metal Detection

The Pet food Manufacturer shall ensure that all necessary steps are taken to identify, avoid, eliminate or minimise the risk of metal or other foreign body contamination.

<ul style="list-style-type: none"> a) The Pet food manufacturer shall use hazard analysis and determine the critical control points to avoid foreign body contamination. When necessary, metal or other foreign body detection equipment shall be installed. b) Where a metal or foreign body detector is required, the Pet food manufacturer shall establish and apply the best practice critical limits for detection, having due regard to the nature of the pet food, the location of the detector and any other factors influencing the sensitivity of the detector. c) The Pet food manufacturer shall establish and implement procedures for the operation, routine monitoring and testing of the metal and other foreign body detectors. d) The Pet food manufacturer shall establish and implement corrective action and reporting procedures, in the event of the monitoring and testing procedure identifying any failure of the metal or foreign body detector. These will include the isolation, quarantining and re-inspection of all products since the last acceptance test of the metal or other foreign body detector. 	<ul style="list-style-type: none"> - Codex Alimentarius, 1997 (II) - HACCP handbook for SMEs (III/5087/96) (III)
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8.8 Product Release

The Pet food Manufacturer shall ensure that the product is not released before all the procedures have been followed.

<ul style="list-style-type: none"> a) The Pet food manufacturer shall ensure that the product is only released by authorised personnel in line with release procedures ensuring product safety. 	<ul style="list-style-type: none"> - Regulation 183/2005/EC Annex II Quality Control (IX)
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8.9 Control of Non-conforming Goods

The Pet food Manufacturer shall ensure all out-of-specification raw materials and semi- or finished products are clearly identified, labelled and quarantined.

<ul style="list-style-type: none"> a) Clear procedures for the control of non-conforming material, including rejection, acceptance by concession, or agreement to use for another purpose, shall be in place and understood by all authorised personnel. b) Corrective actions shall be implemented to avoid recurrence of non-conformance and adequate records of the action taken. c) All non-conforming products shall be handled or disposed of according to the nature of the problem and/or specific requirements. 	<ul style="list-style-type: none"> - Regulation 1774/2002/EC (XII) - Directive 2002/32/EC (VIII) - Recommendation 2006/576/EC (XXIII) - Directive 96/25/EC (XI) - Directive 82/471/EEC (XV) - Regulation 999/2001/EC (XIX)
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8.10 Quantity Control

Checks shall be carried out to demonstrate that a package conforms with the EU legal requirements and with any additional recognised industry sector codes/guides.

<p>a) The frequency and methodology of quantity checking shall meet the minimum requirements of legislation appertaining to quantity verification, irrespective of the nature of the pre-packaged material (e.g. average quantity, weight/volume).</p> <p>b) All equipment used for quantity measurement shall be legally acceptable and regularly calibrated.</p>	<p>- Directive 76/211/EEC (XIII)</p>
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8.11 Equipment and Process Validation

The Pet food Manufacturer shall operate procedures that verify that the process and equipment employed are capable of producing consistent, safe and legal products with the desired quality characteristics.

<p>a) In the event of changes to product formulation, processing methods, equipment or packaging, the Pet food manufacturer shall, where appropriate, re-establish process characteristics and validate product data, to ensure product safety, legality and quality.</p> <p>b) In the case of equipment failure or process deviation, procedures shall be in place to establish the safety status of the product, prior to release.</p>	<p>- Directive 79/373/EEC (VI) - Regulation 183/2005/EC Annex II (IX) - Regulation 1831/2003 (VII) - Directive 76/211/EEC (XIII)</p>
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8.12 Calibration

Equipment used to monitor critical control points and product legality shall be calibrated and traceable.

<p>a) Where necessary, equipments shall:</p> <ul style="list-style-type: none"> • be calibrated or verified at specified intervals or prior to use and the basis used for calibration or verification shall be recorded; • be adjusted or re-adjusted as necessary; • 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. <p>b) Records of the results of calibration and verification shall be maintained.</p> <p>c) For the control of pre-packages placed on the market, procedures implemented have to be recognised by the Competent authorities in the Member state .</p>	<p>- Draft International Standard ISO 22000 - Directive 76/211/EEC, Annex 1.4 (XIII)</p>
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8.13 Specific Handling Requirements

Where materials require special handling procedures, these shall be in place to ensure that product safety, legality and quality are maintained.

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| <ul style="list-style-type: none"> a) Where packaging materials (e.g. glass containers) pose a risk to the product safety, special handling procedures shall be in place to prevent product contamination or spoilage. Records of failures and corrective actions taken shall be maintained. b) Where re-processing is used, or reworking operations carried out, procedures shall be implemented to ensure the safety, legality and quality of the finished product. | |
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8.14 Product Packaging

Product packaging shall be appropriate for the intended use and stored under proper conditions to minimise the risk of contamination and deterioration.

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| <ul style="list-style-type: none"> a) Proper packaging materials shall be used. b) Procedures shall be in place to confirm that product packaging conforms to specification. c) Where staples or other items likely to cause damage or contamination in packaging are used, appropriate precautions shall be taken to minimise the risk of product contamination. d) Any packaging material surplus to a specific production run shall be protected before being returned to storage. e) Packaging material should be stored apart from raw materials to avoid cross-contamination | <ul style="list-style-type: none"> - Directive 79/373/EEC (VI) - Directive 94/62/EC (article 11 and annex II) (XVI) - Regulation 1774/2002 (XII) - Regulation 183/2005/EC Annex II (IX) |
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9 STORAGE AND TRANSPORT

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION
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9.1 Transport and Warehousing

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

<p>a) The Pet food manufacturer shall make sure that, the goods delivered match with those ordered, the pet food is properly labelled in accordance with legal requirements; and that all measures have been taken to ensure the quality and safety of the pet food delivered.</p> <p>b) All containers used for transporting or warehouses used for storing raw materials and finished products should be kept free of potential contaminants, whether chemical, odour, pests (e.g. microorganisms, rodents, insects, birds) and domestic animals.</p> <p>c) Only persons authorised by the Pet food manufacturer shall have access to the storage facilities.</p> <p>d) The name and the address of the carrier should be registered.</p> <p>e) Raw materials, packaging materials and 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.</p> <p>f) Refrigerated transport or storage shall be capable of maintaining product/raw material temperature within specification, under maximum load, and whilst the product/raw material is stored on the vehicle or in the warehouse.</p> <p>g) Procedures shall, where appropriate, be in place in the case of equipment failure (e.g. refrigeration). These procedures shall ensure product safety, legality and quality.</p> <p>h) Where the raw material, packaging materials or finished product transported is susceptible to damage by the weather, vehicles shall be weather proofed and must be loaded and unloaded in covered bays to protect the material.</p> <p>Animal by-products</p> <p>i) Animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.</p> <p>j) 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 clean and dried before use.</p> <p>k) Reusable containers must be dedicated to the carriage of a particular product in order to avoid cross contamination.</p> <p>l) 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.</p> <p>m) Packaging material must be incinerated or disposed of in accordance with instructions from the competent authority.</p>	<p>- Directive 79/373/EEC (VI)</p> <p>- According to national Legislation</p> <p>- Regulation 183/2005/EC Annex II (Storage and Transport) (IX)</p> <p>- Regulation 1774/2002/EC (XII)</p> <p style="padding-left: 40px;">Annex II: Chapter II, Chapter VI</p>
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9.2 Segregation

Storage segregation procedures shall be in place to prevent the cross-contamination of finished products, packaging and raw materials.

a) Processed pet food and packaging material shall be separated from unprocessed feed materials and additives, in order to avoid any cross-contamination of the processed feed and/or of the packaging material.	- Directive 2002/32/EC (VIII) - Directive 82/471/EEC (XV) - Regulation 1774/2002/EC (XII) - Regulation 999/2001/EC (XIX) - Regulation 183/2005/EC Annex II (Storage and Transport) (IX)
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9.3 Stock Rotation

Procedures shall be in place to ensure that materials and products are used in the correct order and within the allocated shelf life.

a) Receipt documents and/or product labelling shall facilitate correct stock rotation (F.I.F.O. - first in first out).	
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10 References and Relevant Documents

I. International Standards Organization (ISO) – ISO 9000 series , Quality Management Systems
II. Codex General Principles of Food Hygiene. Annex on Hazard Analysis and Critical Control Point (HACCP) System Guidelines for its application. Published in Codex Alimentarius Food Hygiene Basic Texts; Rome, 1997; ISBN 92-5-104021-4
III. Guide for the introduction of an HACCP system on the hygiene on foodstuffs in small and medium-sized businesses in the food industry (HACCP Handbook) III/5087/96-5087EN1.doc
IV. FEDIAF " Nutritional Guideline 2005 for Complete and Complementary Pet Food for Dogs and Cats".
V. FEDIAF " Nutritional knowledge – Small pets" 2003.
VI. Directive on the Circulation of compound feedingstuffs (79/373/EEC)
VII. Regulation on additives used in animal nutrition (1831/2003/EEC)
VIII. Directive on undesirable substances in animal feed (2002/32/EC)
IX. Regulation of the European Parliament and the Council laying down requirements for feed hygiene (183/2005/EC)
X. Decision establishing a list of ingredients whose use is prohibited (2004/217/EC)
XI. Directive on the circulation of feed materials (96/25/EC)
XII. Regulation of the European Parliament and the Council laying down health rules concerning animal by-products not intended for human consumption (1774/2002/EC).
XIII. Directive 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 (76/211/EEC)
XIV. Directive on the quality of water intended for human consumption (98/83/EC)
XV. Directive concerning certain products used in animal nutrition (82/471/EEC)
XVI. Directive on packaging and packaging waste (94/62/EC)
XVII. Directive on plastic materials and articles intended to come in contact with foodstuffs (2002/72/EC)
XVIII. Technical Standard and Protocol for Companies Supplying Retailer Branded Food Products". British Retail Consortium, 2000 (BRC)
XIX. Regulation laying down the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (999/2001/EC)
XX. Regulation 178/2002/EC 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
XXI. Regulation 1829/2003/EC on genetically modified food and feed
XXII. Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
XXIII. Commission Recommendation 2006/576/EC on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding

Annex I European Pet Food legislation Summary

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.

76/211/EEC: Directive 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

- Nominal quantity requirements and tolerable negative errors for net weight.
- Reference method for statistical checking batches of pre-packages

79/373/EEC: Directive on the Circulation of compound feedingstuffs

- Pet food may not represent a danger to animal or human health.
- Pet food may only be marketed if they are wholesome, unadulterated and of merchantable quality.
- Labelling requirements for pet food (statutory box).

82/471/EEC: Directive concerning certain products used in animal nutrition

- Concerns products which act as direct or indirect protein sources and are manufactured by certain technical processes.
- Lists authorised products, composition, animal species for which the product is authorized and special provisions, if any.

2004/217/EC: Decision establishing a list of ingredients whose use is prohibited in compound feedingstuffs

- Banning certain ingredients for use in compound feedingstuffs

94/62/EC: Directive 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.

96/25/EC: Directive on the circulation and use of feed materials

- Feed materials must not represent any danger to animal or human health or to the environment.
- Feed materials 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.

98/83/EC: Directive on the quality of water intended for human consumption

- Health related quality parameters (microbiological, chemical, physical, organoleptic) for water intended for human consumption.
- Laid down monitoring programmes

999/2001/EC: Regulation 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 5 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 raw materials and pet food.

2002/32/EC: Directive 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.

2002/72/EC: Directive 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

178/2002/EC : Regulation 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 183/2005/EC on Feed Hygiene, 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)

1774/2002/EC : Regulation laying down health rules concerning animal by-products not intended for human consumption

- 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 raw materials, processed animal proteins and pet food with regards to raw material origin (Category 3), heat treatment, prevention of recontamination, packaging and microbiological testing.
- Health requirements and health certificates for import of animal by-products including raw materials, processed animal proteins and pet food from 3rd countries.

1829/2003/EC: Regulation 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

1830/2003/EC: Regulation 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.

The objective is to facilitate accurate labelling of feed products and to monitor the implementation of the appropriate risk management.

1831/2003/EEC: Regulation concerning additives in animal nutrition

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

183/2005/EC: Regulation of the European Parliament and the Council laying down requirements for feed hygiene

- Registration of all establishments manufacturing pet food
- Approval of establishments-
- 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 mandatory.
- Conditions and arrangements ensuring full traceability of feed materials and compound feed.
- Voluntary Industry Guides.

2006/576/EC: Commission Recommendation on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding

- Increase the monitoring for the presence of deoxynivalenol, zearalenone, ochratoxin A and fumonisin B1 + B2, T-2 and HT-2 toxin in cereals and cereal products intended for animal feeding and compound feedingstuffs.
- List of certain guidance levels on feed materials, complementary and complete feedingstuffs for the presence of these mycotoxins.
- Pet food manufacturers should use the guidance levels, as well as industry recommendations, in their HACCP system to determine the critical limits, which separate acceptability from unacceptability.

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

Annex II Principles of the HACCP System

The HACCP system consists of the following seven principles, and assumes the implementation of Pre-requisite programmes :

Implement Pre-requisite Programmes* before following the 7 principles of the HACCP system		
Principle 1	Conduct a hazard analysis	<ul style="list-style-type: none"> • Assemble HACCP Team • Describe product • Identify intended use • Construct Flow diagram • Confirm flow diagram on site • List all potential hazards • Conduct a hazard analysis • Consider control measures
Principle 2	Determine the Critical Control Points (CCPs)	Use decision tree to determine CCPs
Principle 3	Establish critical limits	Establish action and critical limits for each CCP
Principle 4	Establish CCP monitoring procedures	Establish monitoring systems for each CCP
Principle 5	Establish corrective action plans	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control
Principle 6	Establish verification procedures	Establish procedures for verification to confirm that the HACCP system is working effectively
Principle 7	Establish documentation and recordkeeping systems	Establish documentation concerning all procedures and records appropriate to these principles and their application

* Pre-requisite programmes do not exist in the Codex but are part of ISO Food Safety Management Systems.

Notes for implementing HACCP

Implementing pre-requisite programmes

Prior to application of HACCP the manufacturer should have in place prerequisite programs. Such prerequisites are largely detailed along this Guide to Good Practice by means of its "General Requirements" and it must be stressed here that their implementation has to be well established in order to facilitate the successful application and implementation of the HACCP system. Otherwise, and in the absence of such pre-requisite programmes, an ever-changing nature and likelihood of occurrence of hazards shall not allow their systematic control. Like for any other type of management system, management awareness and commitment is necessary for implementation of an effective HACCP system. The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate.

a) Assemble the HACCP 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

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including A_w , pH etc), microbial / static treatments (heat-treatment, freezing, brining, smoking etc), packaging, durability and storage conditions and methods of distribution.

c) Identify intended use

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 be considered.

d) Construct flow diagram

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation

e) On site confirmation of the flow diagram

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

f) List all potential hazards associated with each step, conduct a hazard analysis, consider any measures to control identified hazards (*see principle 1*)

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.

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, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in pet foods of toxins, chemicals or physical agents; and
- conditions leading to the above.

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

g) Determine Critical Control Points (*see principle 2*)

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when considering CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision is recommended

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.

h) Establish critical limits for each CCP (*see principle 3*)

Critical limits must be specified and validated if possible for each Critical Control Point. 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.

i) Establish a monitoring system for each CCP (*see principle 4*)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. 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. 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 is in control. Most monitoring procedures for CCPs 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 must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company

j) Establish corrective actions (*see principle 5*)

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP 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

k) Establish verification procedures (*see principle 6*)

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;
- Review of the deviations and product dispositions;
- 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

I) Establish Documentation and Record keeping (*see principle 7*)

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 determination;
- Critical limit determination

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Modifications to HACCP system

Non-exhaustive pet food specific HACCP examples

The examples mentioned in the present section should only be regarded as general possible HACCP outcomes for the production of different types of pet food. The pet food manufacturer is responsible to validate, verify and review periodically its own prerequisite programme and HACCP system and identify the CCPs depending on the risk assessment that reflect specific conditions (e.g. location, raw materials used, production method) of each production unit. The present examples cannot be representative for all types and sizes of pet food manufacturers.

A non-exhaustive list of hazards include:

Nature	Examples
Chemical	Non-exhaustive examples: <ul style="list-style-type: none"> ▪ PCBs ▪ Dioxins ▪ Heavy metals ▪ Pesticides ▪ Veterinary drugs ▪ Mycotoxins ▪ Toxins ▪ Cleaning substances
Biological	Non-exhaustive examples of bacteria: <ul style="list-style-type: none"> ▪ Aeromonas ▪ Clostridium perfringens ▪ Clostridium botulinum ▪ Campylobacter ▪ Pathogenic E.coli ▪ Listeria monocytogenes ▪ Salmonella ▪ Staphylococcus aureus
	Non-exhaustive examples of viruses: <ul style="list-style-type: none"> ▪ Hepatitis A ▪ Rotavirus ▪ Norwalk-like viruses
	Non-exhaustive examples of parasites: <ul style="list-style-type: none"> ▪ Trichinella spiralis ▪ Taenia ▪ Fasciola hepatica
Physical	Non-exhaustive examples: <ul style="list-style-type: none"> ▪ Metal ▪ Glass ▪ Wood

1 Pet food specific example Wet

The following is an example of an HACCP outcome when applied to WET Pet food, e.g. cans, trays, pouches. It is not intended to be complete. **Manufacturers should use this for guidance only – The example does not replace a site, process and product specific HACCP study for each pet food manufacturing unit.**

Critical Control Point	Hazard to be controlled	Typical Control Method
Transport / storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Raw Materials conform spec.	Incorrect or contaminated raw materials (e.g. SRM)	Supplier Assurance programme + 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 FO less than 3	Calibration and monitoring
Cooling	Microbiological ingress 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

2 Pet food specific example Semi-Moist

The following is an example of an HACCP outcome when applied to Semi-moist Pet food. It is not intended to be complete. **Manufacturers should use this for guidance only – The example does not replace a site, process and product specific HACCP study for each pet food manufacturing unit.**

Critical Control Point	Hazard to be controlled	Typical Control Method
Transport / storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Raw Materials conform spec.	Incorrect or contaminated raw materials (e.g. SRM)	Supplier Assurance programme + 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) + risk 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

3 Pet food specific example Dry

The following is an example of an HACCP outcome when applied to Dry Pet food. It is not intended to be complete. **Manufacturers should use this for guidance only – The example does not replace a site, process and product specific HACCP study for each pet food manufacturing unit.**

Critical Control Point	Hazard to be controlled	Typical Control Method
Transport / storage	Contamination or deterioration (e.g. humidity)	Assurance and inspection programme
Raw Materials conform spec.	Incorrect or contaminated raw materials (e.g. SRM)	Supplier Assurance programme + 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 + 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

4 Pet food specific example Chews

The following is an example of an HACCP outcome when applied to Chews Pet food. It is not intended to be complete. **Manufacturers should use this for guidance only – The example does not replace a site, process and product specific HACCP study for each pet food manufacturing unit.**

Critical Control Point	Hazard to be controlled	Typical Control Method
Transport / storage	Contamination or deterioration (e.g. temp))	Assurance and inspection programme
Raw Materials conform spec.	Incorrect or contaminated raw materials (e.g. SRM)	Supplier Assurance programme + incoming inspection
Processing	Growth of spoilage bacteria in process (e.g. High number 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

5 Pet food specific example Frozen

The following is an example of an HACCP outcome when applied to Frozen Pet food. It is not intended to be complete. **Manufacturers should use this for guidance only – The example does not replace a site, process and product specific HACCP study for each pet food manufacturing unit.**

Critical Control Point	Hazard to be controlled	Control Method
Transport / storage	Contamination or deterioration (e.g. temp))	Assurance and inspection programme
Raw Materials conform spec.	Incorrect or contaminated raw materials (e.g. SRM)	Supplier Assurance program + incoming inspection
Processing	Growth of spoilage bacteria in process (e.g. High number of Salmonella due to poor processing conditions; AW, time and temperature, cross contamination)	Monitoring / inspection, shelf life control
Metal detection	Metal contamination	Permanent magnets, electric metal detection device
Cooling / Freezing	Microbiological ingress during cooling	
Storage, transport, including point of sales	Contamination or deterioration, Growth of micro-organisms	Warehouse assurance and inspection program, temperature monitoring
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

6 Pet food specific example Fresh / Chilled

The following is an example of an HACCP outcome when applied to Fresh Pet food. It is not intended to be complete. **Manufacturers should use this for guidance only – The example does not replace a site, process and product specific HACCP study for each pet food manufacturing unit.**

Critical Control Point	Hazard to be controlled	Control Method
Transport / storage	Contamination or deterioration (e.g. temp))	Assurance and inspection programme
Raw Materials conform spec.	Incorrect or contaminated raw materials (e.g. SRM)	Supplier Assurance program + incoming inspection
Processing	Growth of spoilage bacteria in process (e.g. High number of Salmonella due to poor processing conditions, AW ,time and temperature ,cross contamination)	Monitoring / inspection, shelf life control
Filling	Microbiological ingress	Temperature monitoring / inspection / shelf life control
Metal detection	Metal contamination	Permanent magnets, electric metal detection device
Cooling / Chilling	Microbiological ingress during cooling	
Storage, transport, including point of sales	Contamination or deterioration, Growth of micro-organisms	Warehouse assurance and inspection program, temperature monitoring , shelf life control
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

7 Pet food specific CCPs for pet foods for small pets

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

Example of Decision Tree to Identify Critical Control Points

