GMP+ Feed Certification scheme

B

Module: Feed Safety Assurance

GMP+ B8
Productie en handel
huisdiervoeders

8

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NL

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Feed for Food

Historie van het document

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Redactionele opmerking:
Alle wijzigingen in deze versie van het document zijn zichtbaar gemaakt. Dit is hoe u:
- Nieuwe tekst
- ~~Oude tekst~~

kunt herkennen.
De wijzigingen moeten door de deelnemer uiterlijk op de uiterste implementatie datum worden geïmplementeerd.

INHOUDSOPGAVE

1 Inleiding

1.1 Algemeen

Het GMP+ Feed Certification scheme is geïniteerd en ontwikkeld in 1992 door de Nederlandse diervoederindustrie als reactie op verschillende ernstige en minder ernstige incidenten met betrekking tot de besmetting van voedermiddelen. Het werd in eerste instantie opgezet als een nationaal schema, maar is uitgegroeid tot een internationaal schema dat wordt beheerd door GMP+ International in samenwerking met verschillende internationale belanghebbenden.

Hoewel het GMP+ Feed Certification scheme is ontstaan vanuit het perspectief van de veiligheid van diervoeder, is in 2013 de eerste standaard voor verantwoord diervoeder gepubliceerd. Daartoe zijn twee modules ontwikkeld; GMP+ Feed Safety Assurance (gericht op diervoederveiligheid) en GMP+ Feed Responsibility Assurance (gericht op verantwoord diervoeder).

GMP+ Feed Safety Assurance is een complete module met normen voor de waarborging van veilig diervoeder in alle schakels van de diervoederketen. Aantoonbare waarborging van veilig diervoeder geldt als een 'license to sell' in veel landen en markten en deelname aan de GMP+ FSA module kan dit uitstekend faciliteren. Op basis van praktijkbehoeften, zijn verschillende componenten geïntegreerd in de GMP+ FSA-normen, zoals voorwaarden voor een feed safety management system, voor de toepassing van HACCP-beginselen tot aan traceerbaarheid, monitoring, basisvoorwaardenprogramma's, ketenaanpak en het Early Warning System.

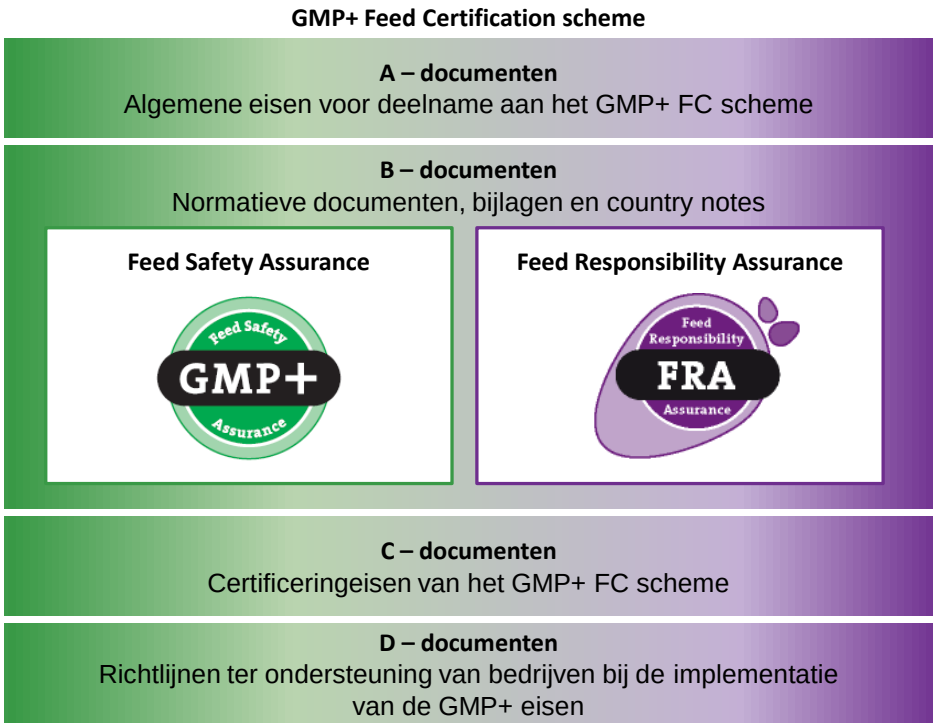
Met de ontwikkeling van de GMP+ Feed Responsibility Assurance module, reageert GMP+ International op de wensen van GMP+-deelnemers. Men verlangt van de diervoedersector dat zij op verantwoordelijkere wijze te werk gaat. Dit omvat bijvoorbeeld het inkopen van soja en vismeel die zijn geproduceerd en worden verhandeld met respect voor mensen, dieren en het milieu. Om aan te kunnen tonen dat de productie en handel op verantwoordelijke wijze plaatsvindt, kan een bedrijf zich laten certificeren voor de GMP+ Feed Responsibility Assurance. GMP+ International faciliteert de behoeften vanuit de markt via onafhankelijke certificering.

Samen met de partners van GMP+, definieert GMP+ International op transparante wijze voorwaarden in de Feed Certification scheme. Certificatie-instellingen kunnen zelfstandig GMP+-certificatie uitvoeren.

GMP+ International ondersteunt de GMP+ deelnemers met nuttige en praktische informatie door middel van een aantal hulpdocumenten, databases, nieuwsbrieven, vraag- en antwoordlijsten en seminars.

1.2 Structuur van het GMP+ Feed Certification scheme

De documenten in het GMP+ Feed Certification scheme zijn onderverdeeld in een aantal reeksen. De volgende pagina toont een schematische weergave van de inhoud van het GMP+ Feed Certification scheme:



Al deze documenten zijn beschikbaar via de website van GMP+ International (www.gmpplus.org) .

Het onderhavige document wordt aangeduid als de standaard GMP+ B8 *Productie en handel huisdiervoeders* en maakt onderdeel uit van de GMP+ FSA module.

1.3 Specifieke achtergrond van deze GMP+ standaard

De GMP+standaard voor de productie van en handel in huisdiervoeders (GMP+ B8 *Productie en handel huisdiervoeders*) is reeds in 2003 ontwikkeld op verzoek van de petfood sector met als doelstelling het zeker stellen van de veiligheid en deugdelijkheid van producten, bestemd als voeding voor het gezelschapsdier. In dit kader wil de Nederlandse petfood sector een geloofwaardig en effectief kwaliteitsborgingssysteem voor de bedrijven in de petfood sector. Dit is van toepassing op het hele productieproces van selectie van grondstoffen tot en met het gereed product.

De Europese Commissie heeft in het kader van de Diervoederhygiëneverordening een Europese Gids goedgekeurd voor de productie van huisdiervoeders, nl. de FEDIAF Guide to Good Practice for the Manufacture of Safe Pet Foods.
FEDIAF vertegenwoordigt de nationale huisdiervoederorganisaties in de EU en in Noorwegen en Zwitserland. Het gaat daarbij om ongeveer 450 bedrijven door heel Europa.
De ‘Fediaf Gids Goede Praktijken voor Producenten van Veilig Voer voor Huisdieren’ biedt een kader en dient als instrument voor producenten van huisdiervoeder bij het voldoen aan de wettelijke eis voor het ontwikkelen van hun individuele bedrijfsprocedures om te borgen dat er veilig huisdiervoeder wordt vervaardigd.

De reikwijdte hiervan omvat de productie, opslag en distributie van huisdiervoeder in blik (waaronder ook trays en pouches vallen) en niet-ingeblikt huisdiervoeder (waaronder droogvoer en halfnat), alsook kauwsnacks en ruwvoer voor huisdieren dat in Europa vervaardigd is of uit niet-EG komt en daarna geëxporteerd is naar de EU.

Deze gids gaat uit van de eigen verantwoordelijkheid van de individuele producenten van huisdiervoeder op basis van de volgende principes:

a. De huidige beste praktijken binnen de voedings- en huisdiervoedersectoren;
b. bestaande Europese wetgeving, waaronder de nieuwe verordening van het Europese Parlement en de Raad waarin vereisten zijn vervat omtrent diervoederhygiëne (183/2005/EG) hetgeen ook gevolgen heeft voor huisdiervoeder;
c. vereisten met betrekking tot HACCP (Hazard Analysis Critical Control Point) als bedoeld in de Codex Alimentarius (II);
d. EN ISO 9000:2000 (I)
e. EN ISO 22000:2005 (E)
f. standaardvereisten die ontwikkeld zijn door andere belanghebbende partijen, waaronder gerelateerde bedrijfssectoren en winkelbedrijven.

De basisprincipes van dit document zijn:

a. het vastleggen van doelstellingen van veilige huisdiervoederproducten zonder daarbij de specifieke middelen te omschrijven, zodat de bedrijven ruimte hebben voor flexibiliteit en zelf kunnen beslissen hoe deze veiligheidsdoelstellingen het best bereikt kunnen worden;
b. gerichtheid op veiligheidsaspecten omtrent huisdiervoeder, niet op normen voor de samenstelling hiervan;
c. het inbouwen van een traceerbaarheidsaspect in de gehele aanvoerketen, zowel opwaarts als neerwaarts;
d. het in balans brengen van algemene regelgeving en regels specifiek voor huisdiervoeder.

De huisdiervoedersector vindt het wenselijk dat de GMP B8-standaard zoveel mogelijk aansluit bij deze goedgekeurde gids. Derhalve is de vernieuwde FEDIAF guide in zijn geheel als certificeerbare standaard opgenomen in de GMP+ FSA module. Om te garanderen dat producten die in de markt worden gezet worden gelabeld in overeenstemming met de van kracht zijnde wetgeving, moet de FEDIAF Code of Good Labelling Practice for Pet Food worden gebruikt.

1.4 Scope en toepassing van deze standaard

Deze standaard bevat de voorwaarden en eisen voor de voederveiligheid van de productie van of de handel in petfood of grondstoffen voor petfood, waarbij geldt dat huisdieren zijn:

a. ~~producten van huisdieren niet bedoeld zijn voor humane consumptie~~.
   Ieder niet-voedselproducerend dier dat behoort tot het soort dat wordt gevoerd, gefokt of gehouden, maar dat in de Gemeenschap doorgaans niet wordt gebruikt voor menselijke consumptie en / of
b. ~~huisdieren niet op een (professionele wijze) worden gehouden om producten voor humane consumptie of humaan gebruik te verkrijgen~~.
   Ieder voedselproducerend dier dat niet voor professionele doeleinden wordt gehouden voor het verkrijgen van producten voor menselijke consumptie en / of menselijk gebruik.

N.B. De Fediaf-code is bedoeld om toe te passen door producenten van en handelaren in petfood, maar deze standaard kan ook toegepast worden door producenten van en handelaren in petfoodgrondstoffen resp. halffabrikaten voor petfood. Zij dienen bij het lezen en implementeren van de voorwaarden termen als 'petfood' of 'producent' te vervangen door begrippen die voor hun specifieke situatie van toepassing zijn.
De eisen uit deze standaard zijn van toepassing op organisaties, ongeacht het type of de omvang, met activiteiten die onder de scope van deze standaard vallen. Het is niet van belang of deze activiteiten voor eigen rekening of in loondienst worden uitgevoerd.

Elke deelnemer moet de bedrijfsspecifieke gevaren met betrekking tot de veiligheid van diervoeders vast stellen, analyseren en beheersen met behulp van toepassing van de HACCP principes. Deze standaard beschrijft zo nauwkeurig mogelijk voor activiteiten en diervoederingrediënten welke onder de reikwijdte van deze standaard vallen wat de eisen met betrekking tot verschillende risico's zijn en de bijbehorende beheersmaatregelen. Een deelnemer kan deze beheersmaatregelen in een basisvoorwaardenprogramma opnemen of deze uitvoeren als specifieke maatregelen voor het beheersen van een bepaald kritisch beheersingspunt. Deze standaard geeft ook eisen voor inspecties en controles.

Indien een producent van huisdiervoeder ook diervoeder produceert voor voedselproducerende dieren, dan de certificatie voor GMP+ B1 *Productie, Handel en Diensten* toereikend voor de certificatie van de productie van beiden soorten diervoeder. Aan alle van toepassing zijnde voorschriften moet worden voldaan. Extra certificering voor GMP+ B8 *Productie van en Handel in Huisdiervoeder* is niet vereist.
NB: De borging van de huisdiervoederproductie kan worden uitgesloten van het feed safety management systeem. Zie ook GMP+ B1 *Productie, Handel en Diensten*, bepaling 4.1

De deelnemer mag diervoeder afnemen van een leveranciers die niet GMP+-gecertificeerd is, zolang de deelnemer garandeert dat het diervoeder voldoet aan de GMP+ voorwaarden. Diervoeder dat wordt aangekocht onder dit zogenaamde poortwachtersprincipe, mag alleen worden verkocht als GMP+ diervoeder als het bedoeld is als voeder voor gezelschapsdieren.

Indien een deelnemer activiteiten uitvoert met diervoeders, die buiten de scope van deze standaard vallen, kan het noodzakelijk zijn een andere GMP+ FSA standaard toe te passen in plaats van of als aanvulling op deze standaard.

Voor de exacte details wordt verwezen naar GMP+ C1 *Acceptatievoorwaarden en acceptatieprocedure certificatie instellingen,* Annex 1.

De deelnemer blijft te allen tijde verantwoordelijk voor de veiligheid van de diervoederingrediënten en de daaraan gerelateerde activiteiten, alsook voor het controleren van naleving van de eisen. Dit moet door de deelnemer zelf te worden uitgevoerd. Door naleving van de eisen die in deze standaard worden weergegeven en door hiervoor gecertificeerd te worden kan de deelnemer de veiligheid en kwaliteit van zijn diensten of diervoederingrediënten aan derden aantonen

Ongeacht de verplichtingen die uit deze standaard voortvloeien, dient de deelnemer alleen diervoeder in de handel te brengen of diensten m.b.t. diervoeder aan te

bieden, die veilig zijn voor het dier en (indirect) voor de verbruiker van dierlijke producten.

De deelnemer mag geen diervoederingrediënten in de handel brengen die een risico voor de gezondheid van mens en dier of voor het milieu vormen.

1.5 De structuur van deze standaard

Deze standaard omvat de “FEDIAF Guide to Good Practice for the Manufacture of Safe Pet Foods”, die een specifieke structuur heeft.

GMP+ Bijlagen (GMP+ BAxx), waar ook naar wordt verwezen, zijn aparte GMP+ documenten binnen de B-serie. Als er naar verwezen wordt, zijn ze in het kader van deze standaard van toepassing. Zie ook hoofdstuk 2.

1.6 Uitsluiting van eisen

Mogelijkheden voor uitsluiting van de scope van het feed safety management systeem:

1. Indien de deelnemer voedermiddelen koopt of produceert die alleen worden verwerkt in huisdiervoedsel, dan is het niet nodig om een generieke risicobeoordeling van die voedermiddelen onderdeel uit te laten maken van de Feed Support Products.

2. Indien de deelnemer gebruik maakt van externe opslag of een externe vervoerder voor de opslag en het transport van huisdiervoeder, dan hoeft deze externe opslag of vervoerder geen GMP+ certificatie of gelijksoortige certificering te hebben. Risicobeoordelingen moeten alle mogelijke gevaren overwegen en ervoor zorgen dat de beheersing alle ernstige risico’s op besmetting van diervoeder effectief elimineren.

Het is mogelijk dat bepaalde overige eisen niet van toepassing zijn op een deelnemer. Een deelnemer mag deze eisen eveneens uitsluiten. Hij dient de uitsluitingen uiteraard te motiveren en vast te leggen. De uitsluitingen mogen er in ieder geval niet toe leiden dat de deelnemer diervoeders levert die niet voldoen aan de voederveiligheid, zoals vastgelegd in de GMP+ FSA module.

Er mogen geen eisen worden uitgesloten omdat de deelnemer deze niet relevant vindt, bijv. omdat afnemers er niet om vragen of omdat het voldoen aan deze eisen geen wettelijke verplichting is, of omdat een bedrijf klein is.

2 Doelstelling van het Feed Safety Management System

De invoering van deze standaard heeft tot doel het opzetten van een management systeem, dat de veiligheid en kwaliteit van de diervoederproducten en diervoederdiensten borgt, zoals bepaald in de scope van deze standaard.

Deze standaard is bedoeld in overeenstemming te zijn met de van toepassing zijnde diervoederwetgeving alsmede voederveiligheidsbeginselen en normen omtrent diervoeder die algemeen geaccepteerd zijn in de diervoedersector en waar rekening mee moet worden gehouden bij de productie en levering van veilig diervoeder.

Het feed safety management system dient ervoor te zorgen dat aan de van toepassing zijnde wettelijke vereisten en sectorspecifieke voorwaarden wordt voldaan, evenals aan de van toepassing zijnde wettelijke, reglementaire en contractuele regelingen.

N.B.:

- Met betrekking tot de diervoederwetgeving is – bij het opstellen van deze standaard – extra aandacht besteed aan het opnemen van de betreffende voorwaarden uit de van toepassing zijnde diervoederwetgeving. Echter, het blijft de verantwoordelijkheid van de deelnemer om ervoor te zorgen dat volledig aan de desbetreffende diervoederwetgeving wordt voldaan.
- Aanvullend is – met betrekking tot de sectorvoorwaarden – in een aantal GMP+ Bijlagen (genummerd als GMP+ BAxx), een aantal sectorspecifieke normen en voorwaarden voor veilig diervoeder vastgelegd, waarvan naleving wereldwijd noodzakelijk wordt geacht voor de productie en levering van veilig diervoeder. Wanneer er in deze standaard naar zo'n GMP+ Bijlage wordt verwezen, dan wordt van de deelnemer verwacht dat deze er voor zorgt dat het vereiste feed safety management system afdoende voldoet aan deze sectorspecifieke voederveiligheidsnormen.
- Echter, het kan zijn dat zowel deze standaard als de bijlagen, niet alle sectorspecifieke voederveiligheidsnormen dekken. Daarom geldt ook hier, dat het de verantwoordelijkheid van de deelnemer blijft om alle van toepassing zijnde sectorspecifieke voederveiligheidsnormen vast te stellen en ervoor te zorgen dat het feed safety management system in staat is deze te beheersen..

Certificering van het feed safety management system tegen de voorwaarden van deze standaard, garandeert niet dat wordt voldaan aan de juridische- of sectorvoorwaarden, maar toont aan dat de deelnemer een effectief feed safety management system heeft, ter realisatie en handhaving van wettelijke naleving, evenals naleving van sectorspecifieke voederveiligheidsvoorwaarden.

De deelnemer moet ook voldoen aan de van toepassing zijnde voorwaarden, zoals opgenomen in de GMP+ A - documenten.

Deze documenten zijn beschikbaar op de website van GMP+ International. (www.gmpplus.org) .

Version 2010

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

GUIDE TO GOOD PRACTICE FOR THE MANUFACTURE OF SAFE PET FOODS

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(REVISION 1 – OCTOBER 2003)
(REVISION 2 – FEBRUARY 2004)
(REVISION 3 – DECEMBER 2004)
(REVISION 4 – MAY 2005)
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(REVISION 9 – SEPTEMBER 2007)
(REVISION 10 – MAY 2009)
(REVISION 12 – MARCH 2010)

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

Table of Contents

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	Substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3): - favourably affect characteristics of feed; - favourably affect characteristics of animal products; - favourably affect the colour of ornamental fish and birds; - satisfy the nutritional needs of animals; - favourably affect the environmental consequences of animal production; - favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs; - have a coccidiostatic or histomonostatic effect.	Regulation 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))
Audit	Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. Internal ~~audits~~, first party audits – are conducted by, or on behalf of, the organization itself for management review and other internal purposes. External audits are second–and third-party audits. Second-party audits are conducted by parties having an interest in the organization such as customers, or by other persons on their behalf. Third-party audits are conducted by external independent organizations providing certification~~s~~.	EN ISO 9000:2005 (E)
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. means an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together	Regulation 1774/2002/EC on animal by-products (Annex I, 2) 767/2009/EC on the marketing and use of feed (art. 3 (2) r)
Calibration	Set of operations required to ensure that measuring equipment conforms to the requirements for its intended use.	EN ISO 9000:2005 (E)
Canned pet food	Heat-processed pet food contained within a hermetically sealed container.	Regulation 1774/2002/EC on animal by-products (Annex I, 7)
Clean Water	Clean –natural, artificial or purified seawater or brackish water, that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food and fresh water of similar quality. Water used in feed manufacture shall be of suitable quality for animals; the conduits for water shall be of an inert nature	Regulation No 852/2004 on the hygiene of foodstuffs 183/2005/EC on feed hygiene (Annex II(6))
Codex Alimentarius	Internationally recognized food and hygiene standards of which HACCP is one such standard which are published in the Codex Alimentarius. These non-binding (voluntary) global references become enforceable when accepted as national standards by the member countries. It works under the auspice of FAO/WHO.	"Understanding of Codex Alimentarius Third Edition", WHO, FAO, Rome 2006 ISBN 978-92-5-105614-1

Competent authority	The central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country.	Regulation 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))
	The authority of a Member State or of a third country designated to carry out official controls.	Regulation 183/2005/EC on feed hygiene (art. 3(e))
Complete feed/pet food	A compound feed/pet food which, by reason of its composition, is sufficient for a daily ration	Regulation 767/2009/EC (art 3 (2) (i))
Complementary feed/pet food	A compound feed/pet food which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed/pet food.	Regulation 767/2009/EC (art 3 (2) (j))
Commissioning	Process by which equipment, machinery, production line, facility or plant (which is complete or near completion) is tested and optimized in order to function according to its objectives or specifications	Internal Definition of Fediaf
Contamination	The presence or introduction of a hazard. Hazard may be posed by any contaminant (e.g. biological or chemical agent, foreign matter, or other substance not intentionally added to food which may compromise food safety or suitability.	Regulation (EC) No 852/2004 on the hygiene of foodstuffs Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003
Control measure	Action or activity that can be used to prevent or eliminate a (pet) food safety hazard or reduce it to an acceptable level.	Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003
Correction	Action to eliminate a detected nonconformity	EN ISO 9000:2005
Corrective action	Action to eliminate the cause of a detected nonconformity or other undesirable situation.	EN ISO 9000:2005
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 Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003 and ISO 22000:2005(E)
Critical Limit	Criterion which separates acceptability from unacceptability.	Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003 and ISO 22000:2005(E)
Cross-contamination	The passing of microorganisms, chemicals or other harmful substances indirectly from one material to another through improper design and layout , unsterile equipment, air, procedures, or products.	Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-

		1969,Rev. 4-2003
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 that does not exceed 14 %.	Internal definition of Fediaf
Exposure assessment	Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivates).	OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44
Fc value of 3	Fc3 is a processing standard that specifies that the core temperature of the product has reached 121 degrees Celsius for 3 minutes. – Equivalent time-temperature parameters to 121 degrees Celsius for 3 minutes (Fc3) involve the product reaching one of the following minimum core temperature/time parameters: 110 degrees Celsius for 40 minutes; or 111 degrees Celsius for 32 minutes; or 112 degrees Celsius for 25 minutes; or 113 degrees Celsius for 20 minutes; or 114 degrees Celsius for 16 minutes; or 115 degrees Celsius for 13 minutes; or 116 degrees Celsius for 11 minutes; or 117 degrees Celsius for 9 minutes; or 118 degrees Celsius for 7 minutes; or 119 degrees Celsius for 6 minutes; or 120 degrees Celsius for 5 minutes; or 121 degrees Celsius for 3 minutes; or 122 degrees Celsius for 3 minutes; or 123 degrees Celsius for 3 minutes; or 124 degrees Celsius for 3 minutes; or 125 degrees Celsius for 2 minutes; or 126 degrees Celsius for 1 minute; or 127 degrees Celsius for 46 seconds; or 128 degrees Celsius for 37 seconds; or 129 degrees Celsius for 29 seconds; or 130 degrees Celsius for 23 seconds; or 131 degrees Celsius for 18 seconds; or 132 degrees Celsius for 15 seconds; or 133 degrees Celsius for 12 seconds; or 134 degrees Celsius for 9 seconds; or 135 degrees Celsius for 7 seconds; or 136 degrees Celsius for 6 seconds .	Internal definition of Fediaf
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	Products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures	Regulation 767/2009/EC on the marketing and use of feed (art. 3 (2) g)
Feed materials of animal origin	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, gelatine and hydrolysed proteins, dicalcium phosphate, milk, milk-based products and colostrum.	Regulation 1774/2002/EC on animal by-products (Annex I, 23)
Feed (or Feedingstuffs)	Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.	Regulation 178/2002/EC on general food law
Feedingstuffs	Products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding.	Directive 2002/32/EC on undesirable substances (art. 2(a))
Finished (end) product	Product that will undergo no further processing or transformation by the organisation.	EN ISO 22000:2005(E)
Flow diagram	Schematic and systematic presentation of the sequence of, and interactions of steps.	EN ISO 22000:2005(E)
Food safety management system	A system to define food safety policy, related objectives, documented procedures, records, and responsibility to ensure that all products will not harm the consumer when prepared and/or eaten according to the intended use.	EN ISO 22000:2005(E)

Food safety policy	Overall intentions and direction of an organization related to food safety (3.1) as formally expressed by top management. In particular, a commitment to the implementation and ongoing maintenance of its Food Safety Management System.	EN ISO 22000:2005(E)
GMO	An organism, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC are excluded from the scope of definition.	Directive 2001/18/EC, Article 2(2) Regulation No 1829/2003 on genetically modified food and feed
Genetically modified feed (pet food)	Feed containing, consisting of or produced from GMOs. For pet food products which are not required to be labelled "contains GMO" or "produced from GMO", the operator is required to ensure that the pet food product does not contain, consists of or is produced from GMO in excess of 0.9% per incorporated feed material provided that this presence is adventitious (accidental, non-intentional) or technically unavoidable.	Regulation No 1829/2003 on genetically modified food and feed
HACCP (Hazard Analysis and Critical Control Point)	A system which identifies, evaluates, and controls hazards which are significant for food safety.	Codex Alimentarius Commission Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003
HACCP plan	A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.	Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003
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.	Internal definition prepared by Fediaf
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.	Internal definition of Fediaf
Monitoring	Conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.	EN ISO 22000:2005(E)
Nonconformity	Non-fulfilment of a requirement.	EN ISO 9000:2005 (E)
Operational Prerequisite Programme (OPRP)	Prerequisite programme identified by a hazard analysis as essential in order to control the likelihood of either the pet food product or the process environment being exposed to safety hazards, that either will be contaminated, or that the hazards will proliferate. It will not eliminate the hazard on its own.	EN ISO 22000:2005(E)
Pesticide residue	means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2, point 1 of Directive 91/414/EEC, which are present in or on the products covered by Annex I to this Regulation, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide	Regulation 369/2005/EC
Pet or pet animal	Any non-food producing animal belonging to species fed, bred or kept, but not normally used for human consumption in the Community	Regulation 767/2009/EC on the marketing and use of feed (art. 3 (2) f)
Pet food	Any product produced by a pet food manufacturer, whether processed, partially processed or unprocessed, intended to be ingested by pet animals after placing on the market. The legislator sometimes uses "feed" or "feedingstuff" as synonyms.	Regulation 178/2002 laying down the general principles and requirements of food law
(Pet) food chain	Sequence of the stages and operations involved in the processing, distribution, and handling of a pet food and its feedmaterials/additives, from production to consumption.	EN ISO 22000:2005(E)
(Pet)food safety	Assurance that (pet) food will not cause harm to the animal, human or environment when it is prepared and/or eaten according to its intended use.	EN ISO 22000:2005(E)
(Pet) food safety hazard	Biological, chemical or physical agent in, or condition of, (pet) food with the potential to cause an adverse health effect.	EN ISO 22000:2005(E)
Potable water	Water meeting the minimum requirements laid down in Council Directive 98/83/EC on the quality of water intended for human consumption (1);	Regulation 852/2004 on the hygiene of foodstuffs
Pouch	A sealed plastic, foil or composite hermetically sealed container used in packaging pet food.	Internal definition of Fediaf
Premixtures	Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals.	Regulation 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. PRP is a combination of all of good practices like GMP, GHP, GLP;	EN ISO 22000:2005(E)
Preventive action	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.	EN ISO 9000:2005
Processing aids	Any substance intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residue of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on finished feed.	Regulation 1831/2003 on additives for use in animal nutrition
Produced from GMOs'	Derived, in whole or in part from GMOs but not containing or consisting of GMOs. (e.g. refined oils directly derived from GM soy are "produced from GMOs" even if	Regulation No 1829/2003 on genetically modified food and feed FEDIAF Guide to

	the end product does not contain GMOs; vitamins using processing aids such as GM microorganisms are not "produced from GMOs" but indirectly produced with GMOs). [1]	Good Practice for the communication on Pet Food 2007
Product Recall	Any measures aimed at achieving the return of an unfit product from consumers and customers.	Internal definition of Fediaf
Product Withdrawal	Any measures aimed at achieving the return of an unfit product from customers but not final consumers.	Internal definition of Fediaf
Quality control	Part of quality management focused on fulfilling quality requirements.	EN ISO 9000:2005
Quality control plan	Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract to control quality.	EN ISO 90002005
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 9000:2005 (E)
RASFF	The Rapid Alert System for Food and Feed (RASFF) is a system established as a network between the Commission and Member States for the notification of a direct or indirect risk to human, animal health and environment deriving from food and feed which provide the control authorities an effective tool for exchange of information on measures taken to ensure food and feed safety. Scope and procedure of RASFF are defined in Articles 50, 51 and 52 of the Regulation 178/2002 and Article 29 of 183/2005	Regulation 178/2002/EC on general food law. Regulation 183/2005/EC on feed hygiene
Raw pet food	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	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	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	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	The interactive exchange of information and options throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.	Regulation 178/2002/EC on general food law (art. 3(13))
Risk evaluation	Establishment of a quantitative relationship between risks and benefits of exposure to an agent, involving the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the agent.	OECD Environment, Health and Safety Publications – Series on Testing and Assessment No. 44
Risk management	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control	Regulation 178/2002/EC on general food law

[1] Standing Committee on the food chain and animal health – Section on genetically modified food and feed and environmental risk, summary record of the 3rd meeting of 24 September 2004

	options.	(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 exceeding 14 % and not exceeding 60 %.	Internal definition of Fediaf
Senior (Top) management	Person or group of people at the highest level in an organization.	Internal definition of Fediaf
Shelf-life	The period during which the product maintains its microbiological safety, nutritional and sensory qualities at specific storage conditions. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used.	
Supplier	Organization or person that provides a product like a producer, distributor, retailer, vendor of a product, contractor. Suppliers can be internal or external to the organization.	EN ISO 9000:2005
Traceability	The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.	Regulation 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
Trader	An operator engaged in exchanging commodities for money without being the producer of the commodity.	Internal definition of Fediaf
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	Obtaining evidence that the control measures managed by the HACCP plan and by the operational PRPs (3.9) are capable of being effective	EN ISO 22000:2005€
Verification	Confirmation, through the provision of objective evidence, that specified 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 9000:2005 (E)

INTRODUCTION

FEDIAF represents the national Pet food industry associations in the EU and from, Norway, Switzerland and Russia 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 FEED MATERIAL/ADDITIVES 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 does not replace national regulatory requirements and
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 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 Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003***
- ***EN ISO 9000:2005 (E)***
- ***EN ISO 22000:2005 (E)***

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.

More details on quality and management principles can be found in specific guides[2].

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.

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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. These include:

- National Authorities
- European Commission - DG SANCO
- European Food Safety Authority- EFSA
- Food and Veterinary Office - FVO
- European sister associations, e.g. FEFAC (European Feed Manufacturers' Federation)
- Retail/trade organizations, e.g. BRC (British Retail Consortium), IFS (International Food Standard), CIES (International Committee of Food Retail Chains)
- EuroCommerce
- European Consumers' Organisation (BEUC)
- National pet food industry associations
- Training seminars at national level with participation of pet food companies, including those not being members of the national pet food association
- Lloyd's Quality Register

Details and specific endorsements can be obtained through FEDIAF Secretariat.

[2] Information about the safety standards of AIB can be found on www.aibonline.org;

information about safety standards of International Food Standards can be found on www.food-care.info,

information about safety standards of British Retail Consortium can be found on

www.brcnorthamerica.com/

1 PERSONNEL

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

1.1 Training

The Pet food Manufacturer shall ensure that all employees are adequately trained, instructed and supervised, commensurate with their activity.	
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 food safety management. The person responsible for supervising quality control and pet food safety 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 maintained records (e.g. programme content, name of the trainer, final assessment of trainees, and establishment of the requirement of retraining) e) The company shall ensure that in particular the personnel responsible for food safety monitoring, corrections, corrective actions, preventive actions is trained and shall routinely review the competencies of staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, monitoring or on the-the-job-experience.	Regulation 183/2005/EC Annex II, (Personnel) (XVIII) EN-ISO 22000:2005, par. 6.2.2 (Competence, Awareness and Training) (XXI) ISO 22000:2005

1.2 Personal Hygiene – Feed materials/additives 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.	
a) The requirements for personal hygiene shall be documented and communicated to all personnel. Compliance with the requirements shall be checked regularly. Based on risk assessment the company shall document its jewellery policy including the rules for watches and rings or studs in exposed and visible parts of the body (e.g. noses, tongues eyebrows). The exception could be a plain wedding ring unless identified as a food safety hazard or occupational safety hazard to the individual. b) All cuts and grazes on exposed skin shall be covered (e.g. by a coloured bandage or detectable blue metal strip plaster, different from the product colour). If metal detection is implemented, a sample from the bandage shall be successfully tested through a metal detector and records shall be kept. 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) Personnel (including visitors) known, or suspected, to be suffering from a disease likely to be transmitted to pet food, should not be allowed to enter any pet food area where direct contact with pet food is possible and there is a likelihood of contaminating the pet food, posing a risk to the safety of the product, the target animal and to humans handling the pet food.	Current best available practices

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.	
f) Where appropriate, all hair shall be fully covered to prevent product contamination. g) Suitable safety footwear shall be worn within the factory environment. h) All protective clothing shall be laundered effectively on a regular basis. i) Gloves, if worn, should be subject to adequate control to avoid product contamination. j) Based on risk assessment, the company shall document and communicate to all employees, contractors and visitors the rules regarding the wearing and changing of protective clothing in work areas. Protective clothing shall be available in sufficient numbers for each employee and in suitable design to prevent contamination of the product (e. g. No external pockets or sewn on buttons)	Current best available practices

2 Quality and Pet food safety Management System – The requirements of the quality and Pet food safety management systems are based on the internationally recognised Standards, e.g. EN-ISO 9000:2005 series and ISO 22000:2005

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

2.1 Quality and Pet food safety Policy and Objectives

The Pet food Manufacturer shall have a clearly defined and documented quality and pet food safety policy statement and associated objectives.	
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 management system. b) Quality and pet food safety objectives must be established, implemented and reviewed. Targets need to be defined and indicators must be monitored in order to follow 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 and Pet Food Safety 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.	All relevant legislation in force (EU and National) ISO 9000:2005 (XX) EN-ISO 22000:2005, par. 5.1 (Management commitment), 5.2 (Food safety policy), 5.3 (Food safety management system planning), 6.1 (Provision of resources) (XXI)

2.2 Pet Food Safety and Quality Management Manual

The Pet food Manufacturer shall have a Manual which states the Pet food manufacturer's commitment to quality and pet food safety and which covers the requirements of this Guide to Good Practice.	
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.	EN ISO 9000:2005 (XX) Regulation 183/2005/EC Annex II (XVIII)

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.	
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. 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. 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, and legality and quality systems. To this end, job descriptions and an organisation chart setting out structure of the organization, qualifications and responsibilities of the supervisory staff must be drawn up, communicated to key staff members responsible for quality and safety, 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. 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. e) The pet food manufacturer shall ensure that adequate resources are available for training all employees, in particular new employees.	Regulation 1831/2003/EC (XII) Regulation 767/2009/EC (XXIX) EN-ISO 9000:2005 (XX) Regulation 183/2005/EC Annex II (Personnel and Quality Control) (XXVIII) EN-ISO 22000:2005, par. 5.4 (Responsibility and Authority) and 5.5 (Food Safety Team Leader) (XXI)

2.4 Management review

The Management shall review the management system for quality and pet food safety on a regular basis.	
a) Senior management shall review the organisation's management system for quality and pet food safety~~,~~ 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 management system, including the quality and pet food safety policy and associated objectives.	EN-ISO 9000:2005 (XX) Regulation 183/2005/EC Annex II (XVIII) EN-ISO 22000 :2005, par. 5.8 (Management review) (XXI) EN-ISO 22000:2005, par. 8.5.2 (Updating the food safety system) (XXI)

2.5 Quality and Pet Food Safety 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.	
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.	EN-ISO 9000:2005 (XX) Regulation 183/2005/EC Annex II (XVIII) EN ISO 22000:2005(E) (XXI)

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. ***Documents shall be legible, clear and accessible to relevant staff at all times.***	
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. 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. c) The commercial documents and health certificates must be kept for a period of at least 2 years for presentation to the competent authority. d) All documents in use shall be properly authorised and be in the correct versions as issued by the Pet food manufacturer. A procedure shall be in place to ensure obsolete documents are removed and, when applicable, replaced with a revised version.	Regulation 183/2005/EC Annex II (XVIII) EN-ISO 9000:2005 (XX) Regulation 1774/2002/EC (art. 9 and Annex II chapter V) (IX) EN-ISO 22000:2005, par. 4.2.2 (Control of documents) (XXI)

2.7 Quality and Pet Food Safety 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.	
a) The Pet food manufacturer must have access to a laboratory with adequate staff and equipment. 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. The Pet food manufacturer shall operate procedures for collation, review, maintenance, storage and retrieval of all records appertaining to product safety, legality and quality. c) The records (documentation) shall be legible, genuine, appropriately authorized, retained in good condition for a period appropriate for the use to which the products are placed on the market (but not less than two years in case of pet food containing animal by-products), so they can be reviewed. d) Samples of the finished products must be kept for a period appropriate to the use for which the feed is placed on the market, as an indicative period, six months after production is considered appropriate. However, this period of six months may be prolonged as suitable for pet food products with low turnover for a period to be defined in the HACCP plan of up until the end of the shelflife on the basis of the realistically expected sell-off and use time according to just-in-time management.	EN-ISO 9000:2005 (XX) Regulation 183/2005/EC Annex II (Quality Control) (XVIII) Regulation1774/2002/EC (IX) EN-ISO 22000:2005, par. 4.2.3 (Control of records) (XXI)

2.8 Specifications and customer requirements/contract review

The Pet food Manufacturer shall ensure that appropriate specifications exist for: ♦ ***Feed materials*** ♦ ***Packaging materials*** ♦ ***Processing*** ♦ ***Finished products*** ♦ ***Intermediate/semi-processed products (where appropriate)*** ♦ ***Transport & Warehouse***	
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, and the company shall be able to demonstrate that they have taken steps to ensure a formal agreement is in place. c) There shall be a documented procedure for the amendment and approval of specifications for all parts of the process.	All relevant legislation in force (EU and National) Regulation 1774/2002/EC (IX) EN-ISO 9000:2005 (XX)

2.9 Customer satisfaction

The Pet food Manufacturer shall monitor information relating to customer perception, such as whether the customer requirements and expectations with regard to product safety and quality have been met or not.	
a) The company shall clearly identify those individuals responsible for communication with customers and shall have an effective system for communication. b) Key performance indicators (KPI) on customer satisfaction are an important tool for a continuous improvement of the product and service delivered. These shall be communicated to appropriate staff and performance reviewed against targets. The KPIs should be developed in agreement with the customer, whenever possible.	EN-ISO 9000:2005 (XX)

2.10 Internal Audit and other verification of the quality and pet food safety system

The Pet food Manufacturer shall verify those systems and procedures, which are critical to product safety, legality and quality, to ensure they are in place, appropriate and complied with.	
Internal audits: a) An audit programme shall be planned, taking into consideration all aspects of the food safety and quality management system as well as any updating actions resulting from previous audits. 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 maintained and brought to the attention of the personnel responsible for the activity audited. Corrective actions and time scales for their implementation shall be agreed and followed up. Other verification activities shall confirm that: -the PRP(s), including hygiene and cleaning procedures, are implemented -input to the hazard analysis is continually updated, -the operational PRP(s) and the elements within the HACCP plan are implemented and effective, -hazard levels are within identified acceptable levels, -other procedures required by the organization are implemented and effective. These internal audits, and/or the other verification activities, may lead to an update or improvement of the food safety management system and should be used to identify trends which indicate a higher incidence of potentially unsafe products.	Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003 ISO 9000:2005 (XX) EN-ISO 22000:2005, par. 7.8 (Verification planning) (XXI) EN-ISO 22000:2005, par. 8.4.1 (Internal audit) (XXI)

2.11 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 pet food safety (according to HACCP principles and procedures), legality and quality.	
a) Causes of problems, when clearly identified, should be used to re-engineer processes and/or procedures to avoid reoccurrence 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) 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. d) Changes in existing or new production lines, equipment or products, must be based on HACCP study/review.	ISO 9000:2005 (E) Regulation 183/2005/EC (XVIII) EN-ISO 22000:2005, par. 7.10.2 (Corrective action) (XXI) Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003

2.12 Complaint Handling

The Pet food Manufacturer shall have a system in place for the effective capture registration and management of product complaints.	
a) The Pet food manufacturer shall implement a system for registering and processing complaints and a system for the prompt recall of supplied products. Recalled products can be put back into circulation only after undergoing a safety-control reassessment. b) Appropriate actions to the seriousness and frequency of the problems identified, shall be carried out promptly and effectively and by appropriately trained staff. c) Complaint records and data shall be analysed, where appropriate, be used to improve the pet food safety, legality and quality, and seek to avoid a reoccurrence. This analysis shall be made available to relevant staff. 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.	EN-ISO 9000:2005(XX) Regulation 183/2005/EC Annex II (Complaints and product recall) (XVIII)

2.13 Continuous improvement

The Pet food Manufacturer shall continuously improve the management system for quality and pet food safety.	
a) The Pet food Manufacturer shall continuously improve the effectiveness of the management system through the use of the quality and pet food safety policy, associated objectives, audit results, analysis of data, corrective and preventive actions and management review.	EN-ISO 9000 :2005 (XX) EN-ISO 22000 :2005, par. 8.5.1 (Continual improvement) (XXI)

2.14 Internal Communication

The Pet food Manufacturer shall establish, implement and maintain effective arrangements for communicating with personnel on issues having an impact on pet food safety and quality.	
a) In order to maintain the effectiveness of the Quality and Pet Food Safety management system, the Pet food Manufacturer shall ensure that the pet food safety team is informed in a timely manner of changes, including but not limited to, the following: - Products or new products; - Feed materials, additives or services; - Production systems and equipment; - Production premises, location of equipment, surrounding environment; - Cleaning and sanitation programmes; - Packaging, storage and distribution programmes; - Personnel qualification levels and/or allocation of responsibilities and authorizations; - Statutory and regulatory requirements; - Knowledge regarding pet food safety hazards and control measures; - Customer, sector and other requirements that the pet food manufacturer observes; - Relevant enquiries from external interested parties; - Complaints indicating a pet food safety hazard associated with the product; - Other conditions that have an impact on pet food safety. b) The pet food safety team shall ensure that this information is included in the updating of the Quality and Pet Food Safety management system. c) Top management shall ensure that relevant information is included as input to the management review.	EN-ISO 9000 :2005 (XX) EN-ISO 22000 :2005, par. 5.6.2 (Internal communication) (XXI)

2.15 External Communication in case of serious animal or public health hazards

The Pet food Manufacturer shall have in place a procedure to inform, as appropriate, stakeholders up and down the pet food chain, customers and competent authorities in case of hazards related to the product	
a) To ensure that sufficient information on issues concerning food safety is available throughout the food chain, the pet food manufacturer shall establish, implement and maintain effective arrangements for communicating in line with legislative requirements and the FEDIAF Guide to Good Practice for the Communication on Petfood with: - suppliers and contractors - customers or consumers in particular in relation to product information (including instructions regarding intended use, specific storage requirements and, as appropriate, shelf life), enquiries, contracts or order handling (including amendments), and customer feedback (including customer complaints), - statutory and regulatory authorities, and - other organizations that have an impact on, or will be affected by, the effectiveness or updating of the food safety management system. b) Such communication shall provide information on food safety aspects of the organization's products that may be relevant to other organizations in the petfood chain. This applies especially to known food safety hazards that need to be controlled by other organizations in the petfood chain. Records	Regulation 1774/2002/EC (art. 18 (2) (a) (v)) (IX) Regulation 183/2005 (XVIII) Regulation 178/2002 (VIII) EN-ISO 22000:2005, par. 5.6.1 (External communication) (XXI) FEDIAF Code for Good Communication on Pet Food (XXVII)

of communications shall be maintained. c) In every case when laboratory examination of any sample, or any other information available, reveals the existence of a serious animal health or public health hazard, the pet food manufacturer who is processing animal by-products shall inform the competent authority.	

3 HACCP (Hazard Analysis Critical Control Points)

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

3.1 Establishing a HACCP plan

The basis of the pet food manufacturer's Pet food safety system shall be a HACCP Plan which shall be systematic, comprehensive and thorough and fully implemented and maintained. It shall be based on the Codex Alimentarius HACCP principles (Ref. II) and reference shall be made to relevant legislation, codes of practices or guidelines.	
a) The Pet food manufacturer shall use the 7 Codex HACCP principles to : • Conduct a hazard analysis, • Determine the Critical Control Points (CCP) and Operational Prerequisite Programmes (OPRP), • Establish the Critical Limits, • Establish a system to monitor control of the CCP and the OPRP, • 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 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: • Maximum limits, objectives, targets or end product and/or process criteria for a specific hazard/product combination, set by legislation and regulatory authorities. • 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. c) HACCP shall have Senior Management commitment and shall be implemented through the Pet food manufacturer's quality management system. d) The Pet Food safety team leader (HACCP team leader) or nominated team representative shall be able to demonstrate competence in the understanding of HACCP principles and their application. e) Key personnel identified as pet food safety team members shall have adequate training and experience. f) The HACCP System shall be specific to the application, practical to implement and effective in controlling the associated hazards of the operation. 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. h) Change management needs to be applied to make sure all hazards are taken in account before implementing the change. i) Critical Control Points, identified in relation to the operation, shall be controlled and monitored within predetermined Critical Limits. Records of	Codex Alimentarius, 1997 (IV) HACCP handbook for Small and Medium-sized Enterprises (III/5087/96) (III) Regulation 1774/2002 (IX) Regulation 183/2005/EC, Article 6 (XVIII) EN-ISO 22000:2005, par. 7.3 (Preliminary steps to enable hazard analysis), 7.4 (Hazard analysis), 7.6 (Establishing the HACCP Plan), 7.7 (Updating the preliminary information and documents specifying the PRPs and the HACCP plan), 7.8 (Verification planning) (XXI)

conformance and effective corrective action resulting from non-conformance shall be maintained. j) An operational prerequisite programme (OPRP) needs to be documented to control significant hazards in those process steps not being a CCP. k) The pet food safety management system shall consist of both a validated and verified prerequisite programme and HACCP system (including the OPRP's and CCP's), and through these, the pet food manufacturer shall be able to demonstrate effective pet food safety control of all operations undertaken. l) The HACCP study shall be carried out by a multi-disciplinary team.	

4 TRACEABILITY

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

4.1 Registration and Approval

Registration and/or approval of the Pet food Manufacturer by the competent authority is compulsory.	
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. 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.	Regulation 183/2005/EC Article 9 (XVIII) Regulation 1774/2002 (IX)

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 (feed materials, additives, packaging materials), including the finished product and be able to trace (in both directions) what occurred in all phases of production up to the distribution to the customer in a timely manner

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 and reversely from a given pet food to the feed materials/additives and suppliers which were used. b) Relevant traceability objectives, including accuracy requirements, shall be defined for each stage of production, processing and distribution and the corresponding product level. c) 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: • The name and address of the suppliers (e.g. feed materials, additives/premixtures, packaging/finished products) and the sources of these feed materials/packaging/finished goods, including the batch number, quantity and delivery date. • The approval or registration number of the suppliers of feed materials/additives covered by an approval or registration procedure according to EU feed legislation. • The nature, formulation and quantity of the finished products manufactured, along with the manufacturing date and batch number. Samples and records of each batch must be retained in accordance with the feed hygiene regulation. • The name and address of the site where the batch of semi-finished or finished products are delivered. d) Where rework or any reworking operation is performed, traceability shall be maintained. e) Traceability in case of co-packed products should be guaranteed. f) The implemented traceability system shall be regularly reviewed and tested (in both directions) in order to assess if its defined objectives are met. The review of the system shall consider the reconciliation of the mass balance between inputted materials and rendered finished products. The review may lead to the establishment of improvement actions.	Regulation 183/2005/EC Annex II (Quality Control, Record-keeping 1, 2 (b) (iv)) (XVIII) Regulation 1774/2002/EC (IX) Regulation 1830/2003 art. 4 & 5 (XI) EN-ISO 22000:2005, par. 7.9 (Traceability system) (XXI) ISO 22005:2007 (XXIV) Fediaf Code for Good Communication on Pet Food (XXVII) Regulation 178/2002/EC, art 18 (VIII) Commission traceability guidance (XVII) Regulation 767/2009/EC (XXIX)

4.3 Product Identification and Labelling of Traceability Tools

The Pet food Manufacturer shall identify each individual sales unit.	
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 of the batch.	Regulation 767/2009/EC (XXIX) Regulation 1774/2002/EC (IX) Regulation 183/2005/EC (XVIII)

4.4 Product Recall and Product Withdrawal

The Pet food Manufacturer shall have an effective product recall and withdrawal procedure for all products in the distribution network.	
a) The pet food manufacturer shall implement a system (procedures, responsibilities, tools, etc) for the prompt recall or withdrawal of products in the distribution network. b) Should the pet food manufacturer consider or have reason to believe that a product which he has imported, produced, processed manufactured or distributed does not satisfy the feed safety requirements, he shall immediately initiate procedures to withdraw the product in question from the market c) 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 or withdrawal procedure implemented. d) The pet food manufacturer must inform and collaborate with the Competent Authorities in case of a serious risk to human or animal health or to the environment, following the RASFF process (see also point 2.15 of this Guide on External Communication). The procedure shall be regularly tested and revised where needed in a manner that is appropriate to ensure its effective operation. These tests need to be recorded.	Regulation 183/2005/EC Annex II (Complaints and Product Recall) (XVIII) Regulation 183/2005/EC Article 29 (RASFF) (XVIII) Regulation 178/2002/EC, Chapter IV on rapid alert system (RASFF), crisis management and emergencies (VIII) EN-ISO 22000:2005, par. 5.7 (Emergency preparedness and response), 7.10.4 (Withdrawals) (XXI) Regulation 767/2009/EC (XXIX)

5. PLANT DESIGN AND MAINTENANCE

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

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.	
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) (XVIII)

5.2 Perimeter and Grounds

All grounds within the site shall be finished and maintained to an appropriate standard.	
a) Where natural drainage is inadequate, additional drainage shall be installed to avoid the risk of contamination of feed materials and pet food. 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) (XVIII)

5.3 Layout / Product Flow

Premises and plant shall be designed, constructed and maintained to control the risk of product contamination.	
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. a) Premises shall allow sufficient working space and storage to enable all operations to be carried out properly under safe and hygienic conditions. b) The systems of working shall, where appropriate, be such as to reduce any potential physical, chemical or microbiological contamination risks. c) There shall be an appropriate segregation between unprocessed and processed materials to minimise the risk of product cross-contamination. d) Segregation shall take into account the product flow, nature of materials, equipment, personnel, waste management, airflow, and air quality and services provision. e) 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) (XVIII) Regulation 1774/2002/EC Annex VIII, Chapter I (IX), Regulation 183/2005/EC Requirements for the approval of petfood and technical plants (XVIII)

5.4 Fabric – Feed 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

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. 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.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

5.4.2 Floors

a) Drainage shall not compromise product safety and shall flow away from high-risk areas. b) Drainage facilities must be adequate for the purpose intended and shall be designed and maintained to minimise risk of product contamination. 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. d) Floors should have adequate falls to cope with the flow of any water or effluent towards suitable drainage. 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.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

5.4.3 Ceilings/Overheads

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. 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.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

5.4.4 Windows and glass

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

5.4.5 Doors

a) Doors should be kept closed at all times, when not in use. b) Doors and dock levellers must be tight-fitting and adequately seal- proofed against pests when closed. c) Where external doors to feed material handling, processing, and 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) (XVIII)

5.4.6 Lighting

a) Facilities must have adequate natural and/or artificial lighting b) Shatterproof plastic diffusers or sleeve covers shall protect all fluorescent lights, 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 or where full protection cannot be achieved wire mesh screens shall be provided. The glass management system shall take the above mentioned precautions into account.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

5.4.7 Air, Air Condition, Ventilation

a) Adequate ventilation and air flow shall be provided in product storage and the processing environment to prevent condensation or excessive dust. b) Where the process requires screened or filtered air, the equipment used for this purpose shall be adequately maintained. c) Dust extraction equipment for dry powder handling areas should be installed. d) Compressed air in contact with products should be filtered. e) Ventilation systems should be designed and constructed in an effective manner in order to prevent the flow of air from higher to lower risk areas.	

5.4.8 Water, Ice and Steam

a) All water supplies used for cleaning, or as feed material in preparation of the product, shall, where appropriate, be potable or pose no risk of contamination according to regulations, 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. Pipes and other elements of the water distribution network in contact with water should be of inert nature. c) The quality of water, steam or ice, that comes in contact with pet food shall comply with applicable quality regulations and be regularly monitored in order to assure that it presents no risk to product safety or quality and comply with governmental regulations. d) Water supply systems should be properly labelled and segregated between potable and non-potable supplies.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

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	
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 petfood. When appropriate, machinery coming into contact with feed materials/pet food shall be dried following any wet cleaning process. b) Equipment should be positioned so as to allow easy access for cleaning and/or disinfection, inspection and servicing. When permanently installed, it shall be properly secured and sealed to the floor. c) All equipment should be properly specified prior to purchase and commissioning. Commissioning activities shall verify that the new equipment is capable of producing 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 such 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.	Directive 76/211/EEC (I) Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII) Directive 2002/72/EC (VII)

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.	
a) Equipment shall undergo appropriate and regular maintenance, in accordance with written procedures pre-established by the equipment manufacturer, to minimize the risk of contamination. 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) 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. Third party contractors shall be under the supervision of a designated person. d) Cleaning or replacing light fittings and glass shall be done in a manner as to minimise the potential of product contamination.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

5.7 Staff Facilities

Staff facilities shall be designed, and used to minimise the risk of product contamination.	
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 and advisory signs to prompt hand washing 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) Eating facilities shall be designed as to prevent contamination of product and provide disposition and control of waste and waste containers. i) Outdoor clothing and other personal items shall be stored separately from workwear within the changing facilities. j) The use of workwear should be restricted to the work premises.	According to national legislation

5.8 Risk of Physical, Chemical and biological Product Contamination

Appropriate facilities and procedures shall be in place to control the risk of physical, chemical and biological product contamination.	
a) The Pet food manufacturer shall adopt all measures to comply with the maximum permitted levels of physicochemical residues (including veterinary drugs) laid down in Community legislation and as mentioned in section III Annex II of this guide 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 feed 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 feed material handling, preparation, processing, packing and storage areas shall be minimised.	Regulation 1774/2002/EC (art. 25(1cii)) (IX) Directive 2002/32/EC (VI) Recommendation 2006/576/EC (XXIII) Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003 EN ISO 22000:2005(E) (XXI)

5.9 Housekeeping and Hygiene

Appropriate standards of hygiene and housekeeping shall be maintained at all times.	
a) Documented cleaning and/or disinfection programmes shall cover the building, utilities, plant and equipment and shall be validated and verified for their effectiveness in reducing the risk of contamination. b) Only approved food grade cleaning agents should be used. c) Cleaning staff should be trained according to guidelines mentioned in ~~point~~ 1.1 of this Guide.	Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

5.10 Waste / Waste Disposal

There shall be adequate systems for the collation, collection and disposal of waste material.	
a) Sewage, waste and rain water shall be disposed of in a manner which ensures that the safety and quality of feed materials and pet food are not affected. Spoilage and dust shall be controlled to prevent pest invasion. b) Waste and materials not suitable as feed material or pet food (due to e.g. cross-contamination) 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 animal 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 and emptied at appropriate frequencies. f) All waste containers should be clearly marked, designed to allow effective cleaning, and used for holding waste only.	Regulation 1774/2002/EC (IX), Directive 94/62/EC (II) Regulation 183/2005/EC Annex II (Facilities and equipment and Production) (XVIII) Directive 2002/32/EC (VI) Regulation 767/2009, annex III (XXIX) Recommendation 2006/576/EC (XXIV) Regulation 767/2009/EC Annex III(XXIX)

5.11 Pest Control

The Pet food Manufacturer shall be responsible for minimising the risk of pest infestation on the site.	
a) Pest control programmes shall be implemented and be regularly reviewed for effectiveness. 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 and other pest trap methods shall, when in use, be positioned so as to avoid risk of contaminating the product. e) Drains shall be fitted with screens and traps to prevent pest entry. f) Incoming feed materials shall, where appropriate, be thoroughly checked on arrival for the absence of pests. g) Feed 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. The location of all pest control measures shall be identified on a plan/diagram of the site.	- Codex Alimentarius, 2003 (XIV) - Regulation 183/2005/EC Annex II (Facilities and equipment) (XVIII)

6 PET FOOD DESIGN AND FORMULATION

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

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, 2003 (IV)).	
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 pet food. c) Shelf life shall be established, taking into account the pet food formulation, production process, packaging process and packaging and subsequent storage conditions. Records of shelf life assessments shall be kept. Shelf life shall be validated against microbiological, chemical, nutritional and sensory analysis. d) Packaging, process and the material used in the manufacture must assure pet food safety.	Directive 2002/72/EC (VII) FEDIAF "Nutritional Guideline 2008 for Complete and Complementary Pet Food for Dogs and Cats". (XXVI) FEDIAF "Nutritional knowledge – Small pets" (XIII) EN-ISO 22000:2005, par. 7.3.3 (Product characteristics) (XXI)

6.2 Formulation

Feed materials have to be mixed to produce a safe pet food.	
a) The presence of prohibited feed materials, undesirable substances (including residues of veterinary products), 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. Systems should be in place to minimise the risk of dosing permitted additives above the authorized level Systems should be in place to define risk level of suppliers and feed materials/additives and the frequency of monitoring of undesirables. The example of a tool is mentioned in Annex 3 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 authorized quantities.	Regulation 1831/2003/EC (XII) Regulation 183/2005/EC Annex II (Production) (XVIII) Regulation 1774/2002 (IX) Regulation 1829/2003/EC (X) Directive 2002/32/EC (VI) Recommendation 2006/576/EC (XXIII) Regulation 767/2009, annex III (XXIX) FEDIAF "Nutritional Guideline 2008 for Complete and Complementary Pet Food for Dogs and Cats".(XXVI) FEDIAF "Nutritional knowledge – Small pets"(XIII) Register of feed additives (XXX)

7 PURCHASING AND DELIVERY

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

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.

a) A Vendor/Supplier Assurance (VA) programme must exist to approve the supplier and to control the purchase of feed materials/additivesand packaging materials, additives, finished and semi finished product from approved suppliers. This programme must document all standards and monitoring procedures dealing with primary production, inbound feed materials and packaging and transport. b) Specifications, based on risk assessment, for feed 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 pet food safety and hygiene requirements. There shall be a list of approved suppliers. c) Appropriate methods of assessment/inspection and monitoring of suppliers shall be performed with the frequency and type of audit being determined by risk assessment as provided in Annex III of this Guide. Assessment may take the form of monitoring performance through in-house checks, certificates of analysis or extend to supplier inspection, as appropriate. 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. d) Supplier assessment must include the suppliers' ability to trace back to their supplier, evaluation of HACCP systems, pet food safety information and legislative requirements. The methods and frequency of assessment should be based on formal risk assessment. e) The procedures shall define how materials / suppliers which are not covered by the above mentioned (a to d) are handled. Additionally, the procedures shall define how exceptions are handled e.g. the use of products or services where audit or monitoring has not been undertaken.	Regulation 183/2005/EC (XVIII) Regulation 1829/2003/EC (X) Regulation 1830/2003/EC (XI)

7.2 Deliveries

The Pet food Manufacturer shall operate procedures for monitoring the quality and safety of feed materials/additives at delivery.	
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. b) Monitoring at delivery must ensure that: • the feed materials, additives and packaging are traceable, • they conform to quality and safety specifications, • they are delivered by an approved or registered supplier, when the products are covered by an approval or registration procedure. • the facility maintains documentation of temperature checks for perishable goods at receiving points. • the facility maintains documentation of rejected shipments, that includes defect specification and reason for rejection • a record shall be kept of the origin of each feed material and additive delivered. c) Suppliers delivering animal by-products must meet specific registration, production process and analytical requirements. d) A feed 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 (HACCP), in the final product, for example using certificates of analysis, sampling of the material on arrival. e) Damaged, infested or dirty transports/containers are rejected. Materials shipped in damaged, infested or dirty vehicles are rejected. f) Perishable or frozen materials meet specific minimum temperature requirements at points of shipment, transportation and receipt. It is recommended to observe the minimum temperature of -12°C as required for human food.	Regulation 183/2005/EC (XVIII) Regulation 1829/2003/EC (X) Regulation 1830/2003/EC (XI) Regulation 1774/2002/EC (IX) Regulation 1831/2003/EC (XII) Regulation 767/2009, annex III (XXIX) Directive 2002/32/EC (VI) Recommendation 2006/576/EC (XXIII) EN-ISO 22000:2005, par. 7.3.3.1 (Raw materials, additives and product contact materials) (XXI)

8 PRODUCTION

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

8.1 General requirements

Clear responsibilities and procedures for the production process must be in place.	
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.	Regulation 183/2005/EC Annex II Production (XVIII)

8.2 Adventitious and unavoidable presence of Genetically Modified Organisms

EU approved feed materials of GMO origin do not pose a pet food safety hazard. ***When used, they are subject to specific regulations and must be declared in the label. For this purpose, the Pet food manufacturer shall have effective procedures in place to control the presence of feed materials containing, consisting of or produced from genetically modified organisms.***	
a) For pet food products which are not required to be labelled "contains GMO" or "produced from GMO", the operator has to ensure that the pet food product does not contain, consist of or is produced from GMO. b) A presence of GMO up to 0.9% per incorporated feed materials does not require labelling provided that this presence is adventitious or technically unavoidable. "Adventitious" (accidental, non-intentional) and "technically unavoidable" presence of GMO shall be prevented by: • Identity preservation and/or equivalent certifications • Non GMO declaration by suppliers or traders (see also Chapter 7.1 Supplier Assurance) • and/or by effective segregation. c) Plant using and storing both GMO and non-GMO materials shall take all precautions in order to prevent cross-contamination between GMO and non GMO materials. d) In case of cross-contamination cleaning of production line and equipment is obligatory. For further actions see Chapter 4.2 (Traceability).	Regulation No 1829/2003 on genetically modified food and feed (X) Regulation No 1830/2003 on traceability and labelling of genetically modified food and feed (XI) FEDIAF Code for Good Communication on Pet Food , paragraph 3.2.1.13 and Annex 3 (XXVII)

8.3 Feed materials of animal origin

The Pet food manufacturer shall use feed materials conforming with the EU legislation.	
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) and (b) 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.	Regulation 1774/2002/EC Annex VIII, Chapter II (IX)

8.4 Weighing

The accuracy of weighing and metering equipment, both for bulk and hand tipped feed materials/additives, 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. Records of the results of calibration and verification shall be maintained. 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. Where the quantity of products is not governed by legislative requirements the product must conform to customer specification. c) If the measuring equipment is non-conforming the organisation shall take action appropriate for the equipment and any previously product inspected.	Regulation 183/2005/EC Annex II (Facilities and Equipment) (XVIII) EN-ISO 22000:2005 par 8.3 Control of monitoring and measuring (XXI)

8.5 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 (XVIII)

8.6 Pet Food Safety and Quality Control measures and Product Analysis

A Pet Food Safety and Quality Control Plan must be drawn up and implemented for the use of feed materials, premixtures and finished products. The Pet Food Manufacturer shall undertake or sub-contract analysis, critical to pet food safety, legality and quality, using appropriate procedures and facilities	
a) The Pet Food Safety and Quality Control Plan must identify checks determined in the HACCP study as well as the frequency of these checks and sampling procedures. The plan must also specify which methods of analysis are to be used and how frequently. The Pet Food Safety and Quality Control Plan must mention actions to be taken in case of non-compliance with the specifications. The results shall be recorded and reviewed regularly. b) Appropriate actions shall be implemented promptly to address results outside of the specification. c) A system of ongoing shelf life assessment is in place. This shall be based on risk and shall include microbiology and sensory analysis as well as relevant chemical factors. d) For pet food and dog chews made from animal by-products, random samples of Salmonella and Enterobacteriaceae must be taken during production and/or finished products (before dispatching) to verify compliance with the standards. For canned pet food and other hermetically sealed heat treated containers that have undergone heat treatment described in the production section (temperature), sampling and testing for Salmonella and Enterobacteriaceae is not necessary. e) Procedures shall be in place to ensure reliability of test results. f) Personnel undertaking analyses shall be suitably qualified, and/or trained and shall be competent to carry out the analyses required. g) Where the Pet food manufacturer undertakes or sub-contracts analyses critical to pet food safety or legal compositional verification, the laboratory shall be independently accredited by a competent authority.	Regulation 1774/2002/EC (IX) Regulation 183/2005/EC Annex II (Quality Control) (XVIII) Directive 2002/32/EC (VI) Recommendation 2006/576/EC (XXIII) Regulation 767/2009, annex III (XXIX) EN-ISO 22000 :2005, par. 8.4.2 (Evaluation of individual verification results) and 8.2 (Validation of control measure combinations) (XXI)

8.7 Temperature/Time Control

The Pet food Manufacturer shall be able to demonstrate effective control of all operations undertaken. Where temperature control of the feed 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 in accordance to the outputs from the HACCP study.	
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. b) Canned pet food and other hermetically sealed heat treated containers must be subject to heat treatment to a minimum Fc value of 3. 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. d) Dog chews must be subject to a heat treatment during processing sufficient to destroy pathogenic organisms (including *Salmonella*). 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.	Regulation 1774/2002/EC (IX) ; Regulation 1774/2002/EC Annex VIII Chapter II (IX) Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003

8.8 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.	
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. Detection equipment shall be situated to maximize foreign body detection within the finished product. 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 and maintain records. 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.	Codex Alimentarius, 1997 (IV) HACCP handbook for SMEs (III/5087/96) (III) Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003

8.9 Product Release

The Pet food Manufacturer shall ensure that the product is not released before all the procedures have been followed.	
a) The Pet food manufacturer shall ensure that the product conforms to specification and is only released by authorised personnel in line with release procedures ensuring product safety.	Regulation 183/2005/EC Annex II Quality Control (XVIII)

8.10 Control of Non-conforming Goods

The Pet food Manufacturer shall ensure all out-of-specification rew materials and semi- or finished products are clearly identified, labelled and quarantined.	
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) Decisions shall be approved by authorized staff. c) Corrective actions shall be implemented to avoid recurrence of non-conformance and adequate records of the action taken. d) All non-conforming products shall be handled or disposed of according to the nature of the problem and/or specific requirements. Corrections are made when the non-conforming product is affecting pet food safety. e) The procedures for the control of non-conforming material and all corrective actions shall be recorded and maintained.	Regulation 1774/2002/EC (IX) Regulation 999/2001/EC (V) Directive 2002/32/EC (VI) Recommendation 2006/576/EC (XXIII) EN-ISO 22000:2005, par. 7.10 (Control of non-conforming goods) (XXII) Regulation 767/2009/EC art. 20 (XXIX)

8.11 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.	
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). b) All equipment used for quantity measurement shall be legally acceptable and regularly calibrated.	Directive 76/211/EEC (I)

8.12 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 pet food with the desired quality characteristics.	
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 pet food safety, legality and quality. 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.	Regulation 1831/2003 (XII) Regulation 767/2009/EC (XXIX) Regulation 183/2005/EC Annex II (XVIII) Directive 76/211/EEC (I) EN-ISO 22000:2005, par. 8.2 (Validation of control measure combinations) (XXI)

8.13 Calibration

Equipment used to monitor critical control points, Operational Prerequisite Programmes and product legality shall be calibrated and traceable.	
a) A system needs to be in place to ensure that equipment shall: • 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. b) Records of the results of calibration and verification shall be maintained. 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.	Directive 76/211/EEC, Annex 1.4 (I) EN-ISO 22000:2005, par. 8.3 (Control of monitoring and measuring) (XXI)

8.14 Specific Handling Requirements

Where materials require special handling procedures, these shall be in place to ensure that pet food safety, legality and quality are maintained.	
a) Where packaging materials (e.g. glass containers) pose a risk to the pet food 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.	

8.15 Product Packaging

Product packaging shall be appropriate for the intended use and stored under proper conditions to minimise the risk of contamination and deterioration.	
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 feed materials to avoid cross-contamination and, if appropriate, away from finished product.	Regulation 1774/2002 (IX) Regulation 183/2005/EC Annex II (XVIII) Regulation 767/2009/EC (XXIX) Directive 94/62/EC (article 11 and annex II) (II) EN-ISO 22000:2005, par. 7.3.3.1 (Feed materials, ingredients and product contact materials) (XXI)

9. STORAGE AND TRANSPORT

GENERAL REQUIREMENTS	LEGAL AND USEFUL DOCUMENTATION

9.1 Transport and Warehousing

All vehicles or warehouses used for the transportation or storage of feed 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.	
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. b) All containers used for transporting or warehouses used for storing feed materials and finished products should be kept free of potential contaminants, whether chemical, odour, pests (e.g. microorganisms, rodents, insects, birds) and domestic animals. c) Only persons authorised by the Pet food manufacturer shall have access to the storage facilities. d) The name and the address of the carrier should be registered. e) Feed materials/additives, 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. f) Refrigerated transport or storage shall be capable of maintaining product/feed material/additive temperature within specification, under maximum load, and whilst the product/feed material/additive is stored on the vehicle or in the warehouse. 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. h) Where the feed material/additive, 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. **Animal by-products** i) Animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles. 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. k) Reusable containers must be dedicated to the carriage of a particular product in order to avoid cross contamination. 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. m) Packaging material must be incinerated or disposed of in accordance with instructions from the competent authority.	Regulation 183/2005/EC Annex II (Storage and Transport) (XVIII) Regulation 1774/2002/EC (IX) Annex II : Chapter II, Chapter VI national legislation Regulation 767/2009/EC (XXIX) EN-ISO 22000 :2005, par. 7.3.3 (Product characteristics) (XXI)

9.2 Segregation

Storage segregation procedures shall be in place to prevent the cross-contamination of finished products, packaging and feed 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.	Regulation 1774/2002/EC (IX) - Regulation 999/2001/EC (V) Regulation 183/2005/EC Annex II (Storage and Transport) (XVIII) Directive 2002/32/EC (VI)

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).	

10. References and Relevant Documents

I.	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**)
II.	Directive on packaging and packaging waste (**94/62/EC**)
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.	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
V.	Regulation laying down the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (**999/2001/EC)**
VI.	Directive on undesirable substances in animal feed (**2002/32/EC**)
VII.	Directive on plastic materials and articles intended to come in contact with foodstuffs (**2002/72/EC**)
VIII.	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 (**178/2002/EC)**
IX.	Regulation of the European Parliament and the Council laying down health rules concerning animal by-products not intended for human consumption **(1774/2002/EC)**
X.	Regulation on genetically modified food and feed (**1829/2003/EC)**
XI.	Regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms (**1830/2003/EC)**
XII.	Regulation on additives used in animal nutrition (**1831/2003/EEC**)
XIII.	FEDIAF "**Nutritional knowledge** – Small pets" 2003.
XIV.	Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP1-1969,REV.4-2003
XV.	Directive on the principles of good laboratory practice and the verification of their applications for tests on chemical substances **(2004/10/EC)**
XVI.	Regulation on the hygiene of foodstuffs **(852/2004/EC)**
XVII.	Guidance on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) 178/2002 on general food law – conclusions of the Standing Committee on the Food Chain and Animal Health, revision 7, December 2004 (http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf.)
XVIII.	Regulation of the European Parliament and the Council laying down requirements for feed hygiene (**183/2005/EC**)
XIX.	Regulation of the European Parliament and the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin (**396/2005/EC**)
XX.	International Standards Organization (ISO) – **ISO 9000:2005 series**, Quality Management Systems
XXI.	International Standards Organization (ISO) – **ISO 22000:2005**, Food Safety Management Systems
XXII.	Technical Standard and Protocol for Companies Supplying Retailer Branded Food Products". British Retail Consortium, January 2005 (BRC)
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
XXIV.	International Standards Organization (ISO) – ISO 22005:2007, Traceability in the Feed and Food Chain
XXV.	Commission Regulation (EC) No 429/2008 Regulation on detailed rules for the implementation of

	Regulation No 1831/2003 **(429/2008/EC)**
XXVI.	FEDIAF "**Nutritional Guideline** 2008 for Complete and Complementary Pet Food for Dogs and Cats".
XXVII.	FEDIAF **Code for Good Communication on Pet Food 2009,** version 26 October 2009
XXVIII.	Regulation laying down the methods of sampling and analysis for the official control of feed **(152/2009/EC)**
XXIX.	Regulation on the Marketing and Use of Feed (**767/2009/EC)**
XXX.	European Register for Feed Additives (http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm)

Annex I Summary of European Pet Food legislation

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

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
The prepackages may bear the so called "e mark" constituting a guarantee that they meet the weight and measures requirements of this Directive, including tolerances for packaging up to 10kg (annex I).

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

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.

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

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.

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

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

852/2004/EC Regulation on the hygiene of foodstuffs

- This regulation does not apply to pet food, as pet food is in the scope of regulation 183/2005 (feed hygiene).
- It is included here for definitions in the glossary.

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

- Provides the primary responsibility of the feed business operator for feed safety.
- Registration of all establishments manufacturing pet food.
- Approval of establishments (only feed business operators producing certain additives).
- Minimum manufacturing conditions requirements with regards to facilities & equipment, personnel, production, quality control, storage, and register, which must be fulfilled by the pet food manufacturer.
- HACCP implementation is mandatory; permanent, written procedures shall be based on HACCP principles as mentioned in Article 6.
- Conditions and arrangements ensuring full traceability of feed materials and compound feed.
- Industry Guides are voluntary, they shall take into account the relevant codes of practice of the Codex Alimentarius; they are finally assessed by the Community and periodically reviewed; published in C series OF Official Journal of European Union;
- Provides that the Rapid Alert System applies to feed animals not kept for food production including pet food.

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

- Increases 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.
- Lists 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.

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

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

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

- Help to prepare the dossier for the authorization of additives.
- The following documents mention detailed requirements:
    - "Guidance for the preparation of dossiers for the re evaluation of certain additives already authorised under Directive 70/524/EEC"
    - "Guidance for the preparation of dossiers for the additives already authorised for use in food"
    - Guidances for the preparation of dossiers for the technological, sensory, nutritional and zootechnical additives

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

152/2009/EC: Regulation laying down the methods of sampling and analysis for the official control of feed.

- Lays down the methods of sampling and analysis for the official control of feed.
- Specifies method for sampling to determine of constituents, additives and undesirable substances in Annex I.
- Includes provisions relating to preparation of samples, reagents and apparatus used in methods of analysis in Annex II.
- Provides information on analytical methods and expression of results in Annex III.
- Describes quality assurance requirements, requirements for laboratories and methods of analysis to control undesirable substances including the determination of total gossypol, level of dioxins (PCDD/PCDF) and dioxin-like PCBs in Annex V.

- Provides information on interpreting results for PCDD and PCBs: The batch is accepted if the analytical results of a single analysis do not exceed the respective maximum level as laid down in Directive 2002/32/EC taking into account the measurement uncertainty.
- The lot is non-compliant with maximum level as laid down in Directive 2002/32/EC if the upperbound analytical result confirmed by duplicate analysis exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.
- Lays down the methods of analysis to control illegal presence of no longer authorised additives in feed in Annex VIII.

767/2009/EC: Regulation on the Marketing and Use of Feed.

- Replaces amongst others directive 79/373/EEC and directive 96/25/EC
- Pet food may only be placed on the market if safe
- Lays down the rules for labelling and also the off-pack communication of pet food
- Regulates claims
- Catalogue of Feed Materials
    - **Note:** The publication of the first EU Catalogue of feed materials is pending and its entries shall consist of those listed in Part B of the Annex to Directive 96/25/EC and columns 2 to 4 of the Annex to Directive 82/471/EEC. Point IV of Part A of the Annex to Directive 96/25/EC shall constitute the glossary. Please contact FEDIAF for the final version of the Catalogue
    - Feed materials must not represent any danger to animal or human health or to the environment.
    - Feed may only be put into circulation if they are of sound, genuine and merchantable quality.
    - Labelling requirements for feed materials.
    - A non-exclusive list of feed materials with specific names, description and compulsory declarations.

Most Directives and regulations including later amendments are compiled in the European Pet Food Legislation Compendium issued by FEDIAF. All Regulations, Directives and Decisions are available from the FEDIAF Secretariat. For the current implementation of the directives and regulations above, please refer to national legislation within the Member State.

European Register of feed additives

- Listing all feed additives aurthorised in animal feed
- Available on-line and updated on a regular basis
- http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm
- The current version of the register has no legal value, but should be consulted for checking if additives are approved by referring to the authorising legal act

Annex II Principles of the HACCP System

SECTION I 7 principles of HACCP system

The HACCP system is carried out in 12 steps which follow the seven principles described in the Codex and assumes the implementation of Pre-requisite programmes : **Implement Pre-requisite Programmes* before following the 7 principles of the HACCP system**			**ISO 22000 § 7.2**
Codex Principle 1	**Conduct a hazard analysis**	• 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	7.3.2 7.3.3/ 7.3.5.2 7.3.4 7.3.5.1 7.3.5.1 7.4.2 7.4.3 7.4.4
Codex Principle 2	**Determine the Critical Control Points (CCPs) and Operational Pre-Requisite Programmes (OPRPs)**	Use decision tree to determine CCPs and OPRP's	7.6.2
Codex Principle 3	**Establish critical limits**	Establish action and critical limits for each CCP and OPRP	7.6.3/7.5
Codex Principle 4	**Establish CCP monitoring procedures**	Establish monitoring systems for each CCP and OPRP	7.6.4/7.5
Codex Principle 5	**Establish corrective action plans**	Establish the corrective action to be taken when monitoring indicates that a particular CCP or OPRP is not under control	7.6.5/7.5
Codex Principle 6	**Establish verification procedures**	Establish procedures for verification to confirm that the HACCP system is working effectively	7.8
Codex Principle 7	**Establish documentation and record keeping systems**	Establish documentation concerning all procedures and records appropriate to these principles and their application	4.2/7.7
	Establish Validation	Validation of control measures	8.2

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

SECTION II Notes for implementing HACCP

Implementing pre-requisite programmes
Prior to application of HACCP the manufacturer should have in place prerequisite programmes. 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.

Conduct a hazard analyses - points a to f (see principle 1)

a) Assemble the HACCP/pet food safety team
The pet food operation should assure that the appropriate product specific knowledge is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the pet food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes)

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

- origin of all feed materials - physical or chemical properties that impact food safety (e.g. pH, Aw) - treatment and processing (heating, freezing, salting) - packaging system (e.g. modified atm, vacuum) - storage and distribution conditions (chilled, ambient) - target shelf life under prescribed storage and usage conditions - instruction for use (e.g. storage , preparation)
- consideration of potential misuse e.g. storage, preparation

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 consider.

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

HACCP to a given operation , consideration should be given to steps preceding and following the specified operation:
- a map of the facility that includes the placement of production, equipment etc;
- feed materials including introduction of utilities and other contact materials (e.g. water, Packaging);
- sequence and interaction of all process steps;
- outsourced processes and subcontracted work;
- process parameters;
- potential for process delay;
- rework and recycling low/high and clean/dirty area segregation;
- finished products, intermediate/semi processed products, by-products and waste.

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

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;
- severity or the effects on consumer safety;
- vulnerability of those exposed;
- survival or multiplication of micro-organisms of concern;
- production or persistence in pet foods of toxins, chemicals or physical agents and foreign bodies; 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. Justification for acceptable levels in the finished product for each hazard shall be determined and documented.

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

There may be more than one step in the process at which control is applied to address the same hazard. The last step that will prevent or eliminate the hazard or reduce it to acceptable level will be defined as a CCP. The determination of a CCP or an OPRP in the HACCP system can be facilitated by the application of a decision tree which indicates a logic reasoning approach. 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 or OPRP's. 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 or OPRP *(see principle 3)*

Critical limits must be specified and validated if possible for each Critical Control Point or Operational Pre-requisite Programme. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurement of temperature, time, moisture level, pH, Aw, available chlorine and sensory parameters such as visual appearance, smell and texture. Critical limits shall be measurable wherever possible (e.g. time, temp, pH) and the rationale for their establishment clearly documented. The HACCP team shall take into account government regulations and guidelines and industry standards. Any critical limits based on subjective data (such as visual inspection) shall be supported with written protocols and clear examples. HACCP team shall validate each of the CCP. Documented evidence shall show that the control measures selected are capable of consistently controlling the hazard to the level specified in critical limit.

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

Monitoring is the scheduled measurement or observation of a CCP or OPRP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP or OPRP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP or OPRP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP or OPRP is in control. Most monitoring procedures for CCPs and OPRP's will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological status of the product. All records and documents associated with monitoring CCPs and OPRP's 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 and each OPRP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP or OPRP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping

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;
- Review of complaints
- Review of incidents with product recall

l) 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, OPRP determination;
- Critical limit determination

Record examples are:

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

SECTION III Non-exhaustive list of hazards in manufacturing

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 to identify the CCPs depending on the risk assessment that reflect specific conditions (e.g. location, feed materials used, production method) of each production unit. The present examples cannot be representative for all types and sizes of pet food manufacturers and should not be copied without a proper study.

A non-exhaustive list of hazards includes:

Nature	Examples
Chemical	Non-exhaustive examples: ▪ PCBs ▪ Dioxins ▪ Heavy metals ▪ Biocides (pesticides, cleaning substances) ▪ Veterinary drugs ▪ Mycotoxins ▪ Toxins ▪ Carry over of authorized substances for non-target species
Biological	Non-exhaustive examples of bacteria: ▪ *Aeromonas* ▪ *Clostridium perfrigens* ▪ *Clostridium botulinum* ▪ *Campylobacter* ▪ *Enterobacteriaceae* ▪ *Pathogenic E.coli* ▪ *Listeria monocytogenes* ▪ *Salmonella* ▪ *Staphylococcus aureus*
	Non-exhaustive examples of parasites: ▪ *Trichinella spiralis* ▪ *Taenia* ▪ *Fasciola hepatica*
Physical	Non-exhaustive examples: ▪ Metal ▪ Glass ▪ Wood

SECTION IV Non-exhaustive specific examples of prerequisite programmes

As for the list of hazards (above section III), the examples mentioned in the present section should only be regarded as general possible prerequisite programmes. The pet food manufacturer is responsible to validate, verify and review periodically its own prerequisite programme. The present examples cannot be representative for all types and sizes of pet food manufacturers.

- **Facilities**
  - Exterior, interior
  - Sanitary facilities
  - Water, steam, ice
- **Transport/Storage**
  - Receiving, shipping
  - Storage
  - Handling of dangerous and toxic substances
- **Cleaning and Sanitation**
  - Cleaning procedures
  - Pest control programme
  - Chemical control
  - Glass control
  - Pathogen monitoring
- **Personnel**
  - Training
  - Hygiene, Health
- **Equipment**
  - Design, installation
  - Maintenance
  - Calibration
- **Product Recall and Traceability**
- **Product/Feed Materials**
  - Supplier control
  - Specifications
  - Certificates of Authenticity
  - Food temperature control
  - Labelling
- **Product Information and Consumer Awareness**

SECTION V Non-exhaustive pet food specific examples of CCPs and OPRPs

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

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

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

The following is an example of an HACCP outcome when applied to wet pet food e.g: cans, trays, pouches. 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/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport / storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Feed materials conform spec	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Processing	Microbial growth due to incorrect processing	Monitoring time and temperature inspection, shelf-life control
Metal detection	Metal contamination (e.g. fish hooks)	Permanent magnets, electric metal detection device
Filling	Microbial growth due to under-sterilisation (caused by overfilling of chunks)	100% inspection by headspace control/weight control
Gravy addition	Microbial growth due to under-sterilisation (caused by overfilling of chunks)	100% inspection by headspace control/weight control
Seaming / Sealing	Growth micro-organisms (e.g. product inclusion in seal, damaged flanges)	Seam / seal control
Sterilisation	Microbial growth due to under-sterilisation (e.g. due to low initial temperature, low sterilisation time or low sterilisation temperature) which leads to a F0 less than 3	Calibration and monitoring
Cooling	Microbiological 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

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

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

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

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

Table 4 Specific examples of CCPs and OPRPs for Chews

Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Typical Control Method
Transport / storage	Contamination or deterioration (e.g. temp))	Assurance and inspection programme
Feed materials conform spec.	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance programme and incoming inspection
Processing	Growth of spoilage bacteria in process	Monitoring / inspection, shelf-life

	(e.g. High number of Salmonella due to poor processing conditions; Aw, time and temperature, cross contamination)	control
Bag Filling	Condensation (due to high filling temperature)	Monitoring / inspection filling temperature and external temperature
Metal detection	Metal contamination	Permanent magnets, electric metal detection device
Handling of primary package	Contamination or deterioration due to loss of packaging integrity	Visual control

Table 5 Specific examples of CCPs and OPRPs for frozen pet food

Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Control Method
Transport / storage	Contamination or deterioration (e.g. temp))	Assurance and inspection programme
Feed materials conform spec.	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance program and 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

Table 6 Specific examples of CCPs and OPRPs for Fresh / Chilled pet food

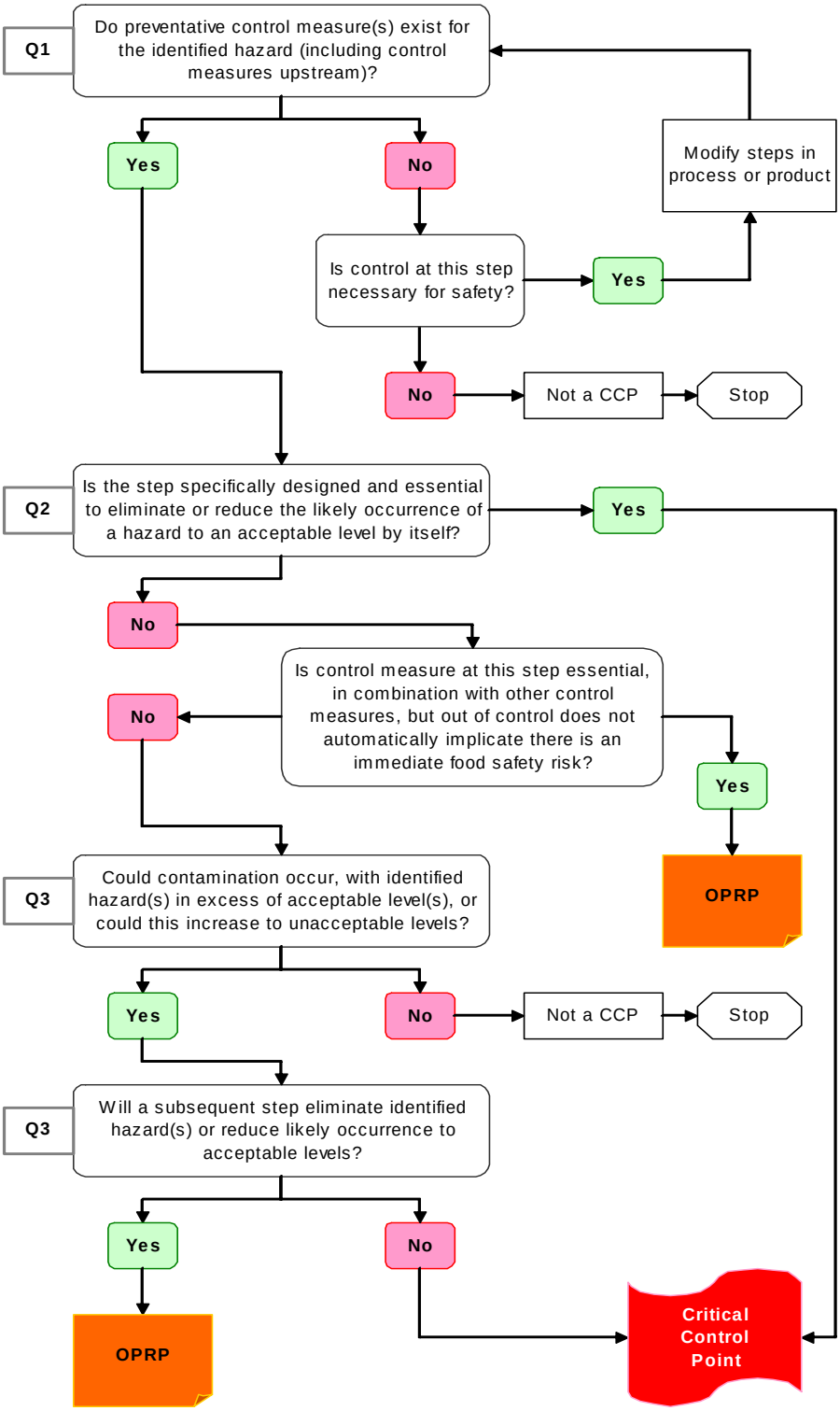
Critical Control Point/OPRP depending on your HACCP	Hazard to be controlled	Control Method
Transport / storage	Contamination or deterioration (e.g. temp)	Assurance and inspection programme
Feed materials conform spec.	Incorrect or contaminated feed materials (e.g. SRM)	Supplier Assurance program and 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

Table 7 Specific CCPs and OPRPs 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.

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

SECTION VI Example of Decision Tree to identify CCPs and OPRPs



SECTION VII Example of a HACCP worksheet[3]

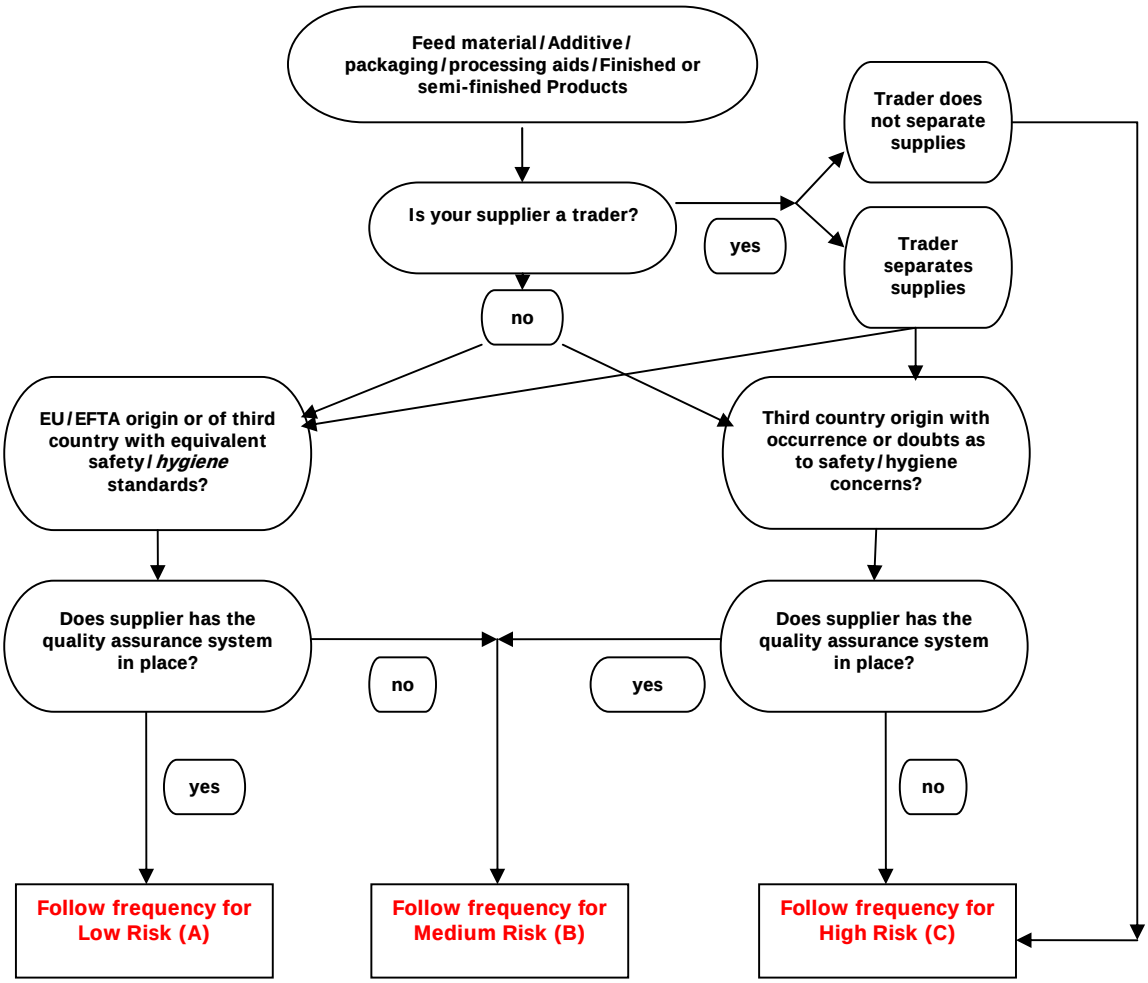
EXAMPLE OF HACCP WORKSHEET

Example of a HACCP Worksheet -CCPs							
1.1 Step	**Hazard(s)**	**Control Measure(s)**	**CCPs**	**Critical Limit(s)**	**Monitoring Procedure(s)**	**Corrective Action(s)**	**Record(s)**
-	…	…	…	…	…	…	…
3	• Microbial Contamination • Presence of insects	Temperature of the product	**Extrusion Temperature**	Temperature > 90ºC	Temperature automatically measured in continuous. Checked and registered each hour by the operator. Procedure PP 2.4	When below Critical Limit, 1. Isolate and block product. 2. increase steam /or raise temperature and/or reduce throughput, according WI 2.15 Supervisor to decide whether product is re-processed or it is kept on hold waiting for positive release after microbial testing, following WI 2.4	-Extrusion Records (WI 2.15 Annex1) -Microbial analysis records
4	• Growth of Mould	Moisture of finished product	**Extruded and dried Product Moisture**	Moisture finished product< Max limit of the product specification	Moisture test every two hours by the operator. Procedure PP 2.5	When above Critical Limit, 1. Isolate and block product. 2. Adjust drying air temperature. Supervisor to decide whether product is re-processed or it is kept on hold waiting for being mixed and stabilised with drier run. Result has to be validated by Lab. (WI 2.5)	-Extrusion Record (WI 2.15 Annex1) - Lab records on moisture
-	…	…	…	…	…	…	…
6	• Presence of harmful metallic foreign bodies	Effectiveness of the detection and ejection of the metal detection system	**Metal detection on Finished Product**	No presence of packs with metallic bodies bigger than a 3.5 mm Ø ferric ball	System verified at the beginning of every shift for detection and for ejection with controlled standard Metal detector always on during production. WI 2.9	Ejected packs are discarded. If metal detector or ejection system found out of condition: block production since earlier positive verification. Re-inspect if feasible – if not reprocess. WI 2.9	-Packaging record (WI 2.15 Annex 2)
-	…	…	…	…	…	…	…

[3] Codex Alimentarius Commission, Recommended International Code of Practice, CAC/RCP 1-1969,Rev. 4-2003

Annex III Assessment of suppliers with a view to undesirable substances and contaminants

SECTION 1 Decision Tree on undesirable substances/contaminants monitoring system in feed material/ /additive/packaging/ /finished products to determine monitoring frequencies



SECTION 2 Monitoring of undesirable substances according to legislation and Fediaf's guidance

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

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

- the outcome from the application of the Decision Tree for monitoring of undesirable substances as provided for in Annex III, Section 1, its implemented vendor assurance systems (including the existence of specific quality agreements with suppliers)
- the characteristics of products

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

Undesirable Substance	Potential source material	Reference
		Directive 2002/32/EC on undesirable substances in animal feed.
Ergot	Feedingstuffs containing ungrounded cereals	
As, Pb, Hg	Feed materials Complete/complementary feedingstuffs	
Cd	Feed materials of vegetable origin Mineral feedingstuffs	
Fluorine	Feed materials Complete feedingstuffs	
Nitrites	Fish meal	
Aldrin	All feedingstuffs	
Dieldrin	All feedingstuffs	
Camphechlor	All feedingstuffs	
Chlordane	All feedingstuffs	
DDT	All feedingstuffs	
Endosulphan	All feedingstuffs	
Endrin	All feedingstuffs	
Heptachlor	All feedingstuffs	
Hexachlorobenzene	All feedingstuffs	
Hexachlorocyclo hexane	All feedingstuffs	
Dioxin & Dioxin like PCB's	Feed materials Complete/complementary petfood	
Coccidiostats residues	Feed materials, complete/complimentary pet food	
Theobromine	Complete feedingstuffs	
Aflatoxin B1	Feed materials, specially cereals and seeds Complete/complementary feedingstuffs	

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