GMP+ International

# Productie en handel huisdiervoeders

## GMP+ B8

Versie NL: 1 April 2019

**GMP+ Feed Certification scheme**

Feed Safety Worldwide

gmpplus.org

## Historie van het document

| Revision no. / Date of approval | Amendment | Concerns | Final implementation date |
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| 0.0 / 09-2010 | Voorgaande versies kunnen worden geraadleegd bij found in History | | 01-01-2011<br>01-01-2012 |
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| 2.0 / 01-2019 | De nieuwste versie van onze Fediaf Code bevat nu monitoring van pathogenen en mycotoxinen, zoals gevraagd door de Europese Commissie in 2014. Verder is er een meer gedetailleerde inhoud over traceerbaarheid en HACCP. | 1.3 | 01.04.2019 |

**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.

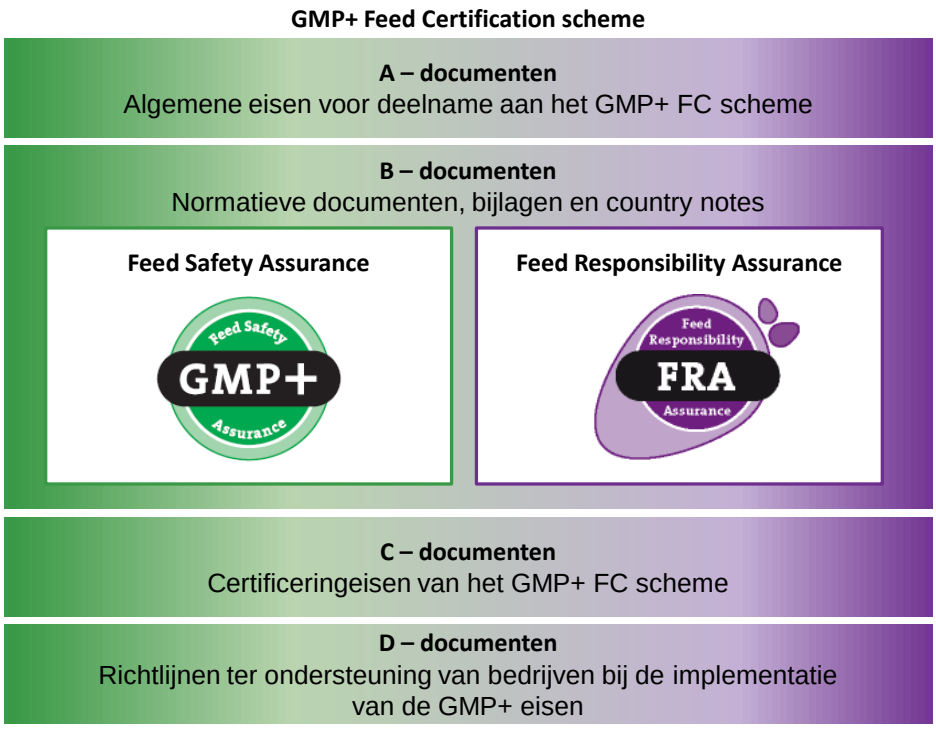
Met de ontwikkeling van de GMP+ Feed Responsibility Assurance module, reageert GMP+ International op de wensen van GMP+-deelnemers. Men verlangt van de diervoedersector dat zij op verantwoordelijkere wijze te werk gaat. Dit omvat bijvoorbeeld het inkopen van soja en vismeel die zijn geproduceerd en worden 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 kwaliteits-borgingssysteem 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. 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. 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.

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

<u>Mogelijkheden voor uitsluiting van de scope van het feed safety management systeem:</u>

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) .

# FEDIAF GUIDE TO GOOD PRACTICE FOR THE MANUFACTURE OF SAFE PET FOODS

## DECEMBER 2001

(REVISION 1 – OCTOBER 2003)
(REVISION 2 – FEBRUARY 2004)
(REVISION 3 – DECEMBER 2004)
(REVISION 4 – MAY 2005)
(REVISION 5 – JUNE 2005)
(REVISION 6 – SEPTEMBER 2005)
(REVISION 7 – SEPTEMBER 2006)
(REVISION 8 – NOVEMBER 2006)
(REVISION 9 – SEPTEMBER 2007)
(REVISION 10 – MAY 2009)
(REVISION 12 – MARCH 2010)
(REVISION 13 – JANUARY 2014)
(REVISION 14 – MAY 2015)
(REVISION 15 – FEBRUARY 2018)

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# INTRODUCTION

## Purpose and objective

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

Regulation (EC) No 183/2005 on feed hygiene acknowledges the importance of good hygiene practices and encourages the development of EU and national Guides to good practice to ease the interpretation and implementation of the EU legal framework[1].

This Guide to Good Practice for the Manufacture of Safe Pet Food (hereafter "the Guide") developed by FEDIAF[2] lays down good practices on the safety and hygiene of pet food processes and products. This document is meant to be a practical and useful tool for pet food manufacturers to help them in developing a robust pet food safety management system and complying with safety and hygiene legal requirements.

## Scope

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

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

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

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

[1] ⚖ Article 21 and 22 of Regulation (EC) No 183/2005

[2] FEDIAF represents the pet food industry in 21 European countries via 16 national or regional pet food industry associations before EU institutions and other international bodies, which corresponds to more than 150 companies and 650 manufacturing plants across Europe.

## Update

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

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

# GLOSSARY

The glossary contains definitions of key words used in this Guide followed by the source of the definition. Whenever appropriate, definitions are adapted to pet food. All defined terms are written in red throughout the Guide to facilitate the reading of the document.

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

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

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

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

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

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

External audits are second–and third-party audits.
Second-party audits are conducted by parties having an interest in the organization such as customers, or by other persons on their behalf.
Third-party audits are conducted by external independent organizations providing certification.
*(EN ISO 9000:2015)*

**Batch:**

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

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

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

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

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

**Competent authority**

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

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

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

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

**Contamination:**

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

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

**Correction:** Action to eliminate a detected nonconformity *(EN ISO 9000:2015)*

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

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

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

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

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

**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)*

**F value of 3: F**c3 is a processing standard that specifies that the core temperature of the product has reached 121 degrees Celsius for 3 minutes. – Equivalent time-temperature parameters to 121 degrees Celsius for 3 minutes (Fc3) involve the product reaching one of the following minimum core temperature/time parameters *(Internal definition of Fediaf)*

110 degrees Celsius for 40 minutes; or
111 degrees Celsius for 32 minutes; or
112 degrees Celsius for 25 minutes; or
113 degrees Celsius for 20 minutes; or
114 degrees Celsius for 16 minutes; or
115 degrees Celsius for 13 minutes; or
116 degrees Celsius for 11 minutes; or
117 degrees Celsius for 9 minutes; or
118 degrees Celsius for 7 minutes; or
119 degrees Celsius for 6 minutes; or
120 degrees Celsius for 5 minutes; or
121 degrees Celsius for 3 minutes; or
122 degrees Celsius for 3 minutes; or
123 degrees Celsius for 3 minutes; or
124 degrees Celsius for 3 minutes; or
125 degrees Celsius for 2 minutes; or
126 degrees Celsius for 1 minute; or
127 degrees Celsius for 46 seconds; or
128 degrees Celsius for 37 seconds; or
129 degrees Celsius for 29 seconds; or
130 degrees Celsius for 23 seconds; or
131 degrees Celsius for 18 seconds; or
132 degrees Celsius for 15 seconds; or
133 degrees Celsius for 12 seconds; or
134 degrees Celsius for 9 seconds; or
135 degrees Celsius for 7 seconds; or
136 degrees Celsius for 6 seconds

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

**Feed materials:** Products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures *(Regulation (EC) No 767/2009, art. 3 (2) g))*

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

**Feed (or Feedingstuffs):** Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals *(Regulation (EC) No 178/2002)*

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

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

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

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

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

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

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

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

**Genetically Modified Organisms (GMO):**

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

**Genetically modified feed (pet food):** Feed containing, consisting of or produced from GMOs.
For pet food products which are not required to be labelled "contains GMO" or "produced from GMO", the operator is required to ensure that the pet food product does not contain, consists of or is produced from GMO in excess of 0.9% per incorporated feed material provided that this presence

is adventitious (accidental, non-intentional ) or technically unavoidable *(Regulation (EC) No 1829/2003)*

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

**HACCP plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration *Codex Alimentarius Commission Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003)*

**Hazard:** A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect *(Regulation (EC) No 178/2002, art. 3(14))*

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

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

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

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

**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)*

**Non-conformity:** Non-fulfilment of a requirement *(EN ISO 22000:2005 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 (EC) No 369/2005)*

**Pet or pet animal:**

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

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

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

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

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

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

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

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

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

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

**Processing aids:** Any substance intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically 11unavoidable presence of residue of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on finished feed *(Regulation (EC) No 1831/2003)*

**Produced from GMOs:** Derived, in whole or in part from GMOs but not containing or consisting of GMOs (e.g. refined oils directly derived from GM soy are "produced from GMOs" even if the end product does not contain GMOs; vitamins using processing aids such as GM microorganisms are not "produced from GMOs" but indirectly produced with GMOs) *(Regulation (EC) No 1829/2003 on*

*genetically modified food and feed FEDIAF Guide to Good Practice for the communication on Pet Food 2015)*

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

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

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

**Raw pet food:** Pet food containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing. Pet food which has not undergone any preserving process other than chilling, freezing or quick freezing to ensure preservation (Regulation (EU) No 142/2011, Annex I, no. 20)

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

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

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

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

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

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

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

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

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

**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)*

**Shelf-life:** The period during which the product maintains its microbiological safety, nutritional and sensory qualities at specific storage conditions. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used *(Internal definition of Fediaf)*

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

**Traceability:**

- ✓ The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution (Regulation (EC) No 178/2002/EC, art. 3(15))
- ✓ Traceability means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains *(Regulation (EC) No 1830/2003)*

**Undesirable substance:** Substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production *(Directive 2002/32/EC, art. 2(l))*

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

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

**Verification:** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. It involves the application of methods, procedures, tests and other evaluations,

in addition to monitoring, to determine compliance with the specifications laid down in the HACCP plan and the effectiveness of the HACCP-based Food Safety System. *(EN ISO 22000:2005 E)*

# CHAPTER 1: PET FOOD SAFETY MANAGEMENT SYSTEM

## 1.1 Management responsibilities and resources

### 1.1.1 Management commitment, responsibility and policy

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

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

The management must:

- ✓ Establish a pet food safety policy, ensure that objectives are established and communicate the policy throughout the organisation.
- ✓ Ensure that these objectives and policies are in compliance with regulatory requirements as well as with the good practices laid down in this Guide.
- ✓ Define and document the scope of the pet food safety management system, by identifying the product categories, production sites/ process lines and outsourced activities which are covered by the system.
- ✓ Identify all other relevant activities at the location which might cause a risk for pet food production
- ✓ Ensure crisis management is in place with defined responsibilities.

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

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

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

### 1.1.2. Pet food safety organisation

#### 1.1.2.1. Organisational chart

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

#### 1.1.2.2. Competency, awareness and education

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

The management must:

[3] ⚖ Article 4§1 of Regulation (EC) No 183/2005

[4] ⚖ Annex II "PERSONNEL" of Regulation (EC) No 183/2005

- ✓ Identify and define clearly the necessary skills and competences for personnel whose activities have an impact on pet food safety in the job description.
- ✓ Provide the necessary education and/or training according to the job description to ensure and maintain the fulfilment of these necessary skills, including an introduction to HACCP principles.
- ✓ Ensure that personnel responsible for monitoring pet food safety processes are trained in proper monitoring techniques and the necessary actions to be taken when there is a loss of control of the processes.
- ✓ Evaluate the effectiveness of the activities above.
- ✓ Ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to pet food safety.
- ✓ Ensure that personnel are aware of the necessity of effective communication.
- ✓ Maintain appropriate records of education, training, skills and experience of all personnel having an impact on pet food safety.

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

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

### 1.1.3 Management review

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

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

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

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

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

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

The output of the review must address:

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

The report of the review must be readily available.

## 1.2. Traceability

### 1.2.1. Definition, scope and boundaries

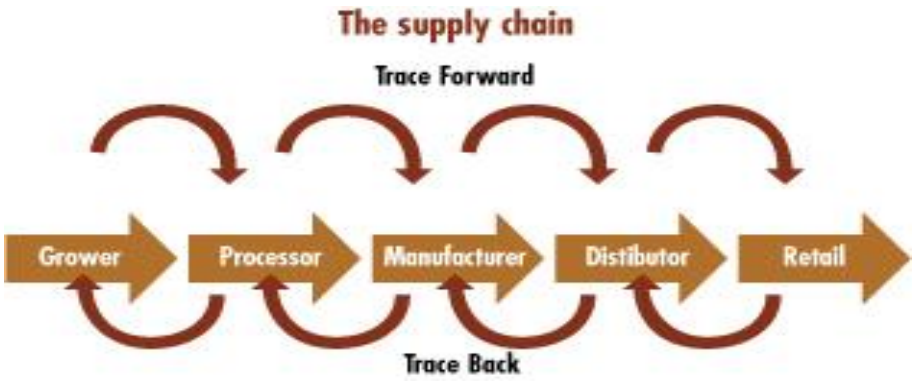
Traceability is the ability to track feed materials, additives, packaging material or any substances used at all stages of production, processing and distribution of pet food[5]. To this end, it is recommended to follow the F.I.F.O or F.E.F.O principles.

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

Traceability must be ensured through the full process:

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

Figure X:




### 1.2.2. Registration and approval of operators

The pet food manufacturer must apply for registration and/or approval to the competent authority for its relevant activities[1]. The following activities require mandatorily an approval:

[5] ⚖ Article 3(15) and 18 of Regulation (EC) No 178/2002 and Commission Guidance on the implementation of articles of General Food Law

[1] ⚖ Article 9 & 10 of Regulation (EC) No 183/2005

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

Establishments producing feed materials or complementary feed exceeding 100 times the relevant fixed maximum content in complete feed for a particular nutritional purpose in respect of the relevant intended use shall also be approved[6].

The manufacturing of pet food which makes use of animal by-products requires an additional approval procedure[7].

The pet food manufacturer must provide the competent authority with up-to-date information on any establishments under its control, including notifying the competent authority of any significant change in activities and any closure of an existing establishment[8].

### 1.2.3 Documentation system

The pet food manufacturer must work with a system of documentation designed to ensure an adequate level of traceability[9]. Traceability implies the use of unique batch number which gives the capability to identify feed materials during the process and the finished products.

In order to ensure product traceability, the pet food manufacturer must record[10] and keep the following information till the end of shelf life and any event at least two years[11] (the European Commission recommends up to five years) when the pet food contains animal-by-products (or five years if the product contains GMOs[12]):

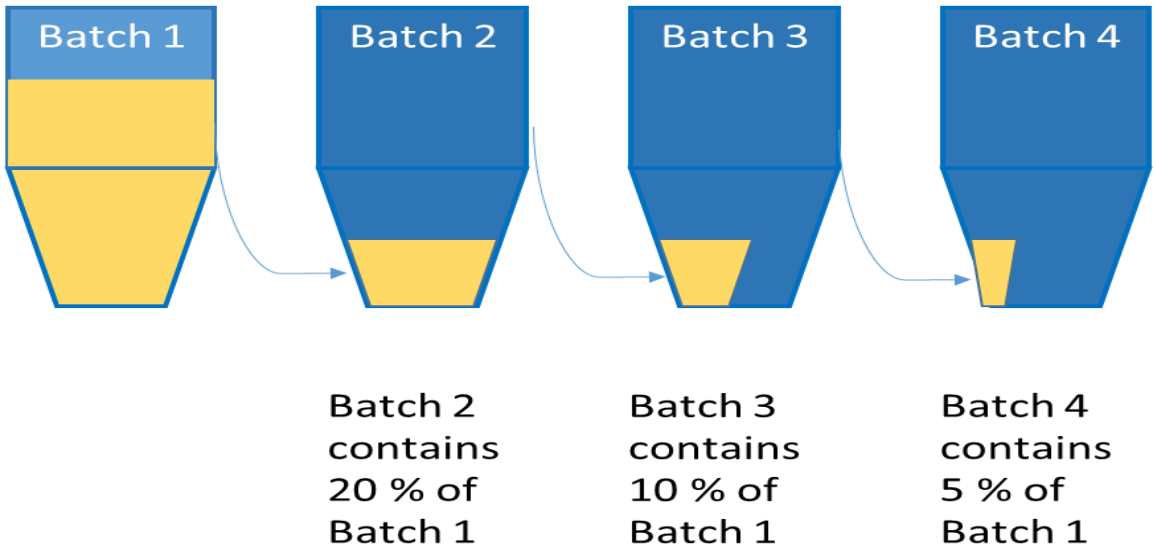
- The name and address of the suppliers (e.g. feed materials, additives/premixtures, packaging/finished products) and the sources of these feed materials/packaging/finished goods, including the batch number, quantity and delivery date.
- The approval or registration number of the suppliers of feed materials/additives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

[6] ⚖ Article 8 of Regulation (EC) No 767/2009
[7] ⚖ Article 23 of Regulation (EC) No 1069/2009
[8] ⚖ Article 9§2 of Regulation (EC) No 183/2005
[9] ⚖ Annex II "QUALITY CONTROL" of Regulation (EC) No 183/2005
[10] ⚖ Annex II "RECORD KEEPING" of Regulation (EC) No 183/2005
[11] ⚖ Annex IV, Chapter 2, Section 4 § 3 of Regulation (EU) No 142/2011
[12] ⚖ Article 4 & 5 of Regulation (EC) No 1830/2003

- The name and address of the site where the batch of semi-finished or finished products are delivered.

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

Figure X: Example of the non-segregation principle




### 1.2.4 Review and verification

The implemented traceability system (upstream/forward and downstream/backward) must be regularly reviewed, tested and recorded in order to assess if its defined objectives are met. The review of the system must consider the reconciliation of the mass balance between inputted materials and rendered finished products. The review may lead to the establishment of improvement actions.

### 1.2.5. Complaints and product recall[13] / product withdrawal

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

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

When there are signs of a pet food safety issue, immediate action must be taken by the pet food manufacturer according to the defined procedures (risk assessment, consideration of recall or

[13] ⚖ Annex II "COMPLAINTS AND PRODUCT RECALL" of Regulation (EC) No 183/2005

withdrawal actions, definition of the volume of products impacted by the recall/withdrawal procedure).

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

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

The pet food manufacturer must inform and collaborate with the competent authority in case of a serious risk to human or animal health or to the environment[14]. The procedure must be regularly tested and revised where needed in a manner that is appropriate to ensure its effective operation. These tests need to be recorded.

[14] ⚖ Article 19 of Regulation (EC) No 178/2002

# CHAPTER 2. PRE-REQUISITE PROGRAMMES

## 2.1. Facilities and plant design

### 2.1.1. Exterior

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

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

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

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

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

### 2.1.2. Food defence, biovigilance and bioterrorism

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

A risk assessment on pet food safety needs to be conducted to define reasonably expected occurrence by potential acts of sabotage, vandalism or terrorism and must put in place protective measures. Critical areas need to be identified and access needs to be controlled (e.g. inlet of silos).

### 2.1.3. Interior[15]

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

[15] ⚖ Annex II "FACILITIES AND EQUIPMENT" of Regulation (EC) No 183/2005

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

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

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

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

### 2.1.4. Construction

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

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

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

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

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

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

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

### 2.1.5. Sanitary facilities

Personnel hygiene facilities (e.g. hand washing, toilets and showers) must be available, clearly designated and maintained as necessary for pet food safety. These facilities should not directly be accessed from a production area.

## 2.2. Utilities

### 2.2.1. General requirements

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

- Supply of water or steam, as product ingredient or for product contact;
- Supply of air (or gas), as ventilation (natural or mechanical) or as compressed air or gas system;
- Supply of energy (for example electricity, light, or heat).

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

### 2.2.2. Water

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

Potable water should be used when available.

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

Use of recycled water must be justified by a hazard assessment. Recycled water must have a separate supply system to prevent from refluxing into potable water system.
In case chemicals are used for boilers that supply water or steam for direct inclusion or product contact, such chemicals must be either approved pet food additives or approved by relevant competent authority as safe for use.

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

### 2.2.3. Air (or gas)

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

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

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

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

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

### 2.2.4. Lighting[16]

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

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

## 2.3. Waste disposal

### 2.3.1. General requirements

[16] ⚖ Annex II "FACILITIES AND EQUIPMENT" §4 of Regulation (EC) No 183/2005

There must be adequate systems for the identification, collection, removal and disposal of waste materials, in a manner that prevents contamination of products or production areas.

### 2.3.2. Containers for waste

All waste containers must be:

- Clearly identified
- Located in a designated area;
- Designed to be effectively emptied and allow effective cleaning;
- Used for holding waste only; and
- Kept closed.

### 2.3.3. Waste management and removal

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

Waste and materials not suitable as feed material or pet food (due to e.g. cross-contamination) must be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards must be disposed of in an appropriate way and not used as pet food[17].

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

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

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

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

### 2.3.4. Drains and drainage

Drains must be designed, constructed and located so that the risk of contamination of materials or products is avoided.[18]

Drains must have sufficient capacity to remove expected flow loads and not be located in a manner that would contaminate if a leak occurred.

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

### 2.3.5. Spoilage and dust

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

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[17] ⚖ Article 12 & 13 of Regulation (EC) 1069/2009

[18] ⚖ Annex II "FACILITIES AND EQUIPMENT" §5 of Regulation (EC) No 183/2005

## 2.4. Equipment

### 2.4.1. Equipment

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

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

All equipment surfaces coming into contact with the product should be impervious and non-reactive.

All potential pet food contact lubricants must be of feed grade quality.

Equipment must undergo appropriate and regular maintenance, in accordance with written procedures pre-established by the equipment manufacturer, to minimize the risk of contamination.[19]

Safety, quality or legality of product must not be jeopardised during and after maintenance operations. Particular attention should be drawn to the risk of foreign body contamination. Third party contractors must be under the supervision of a designated person.

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

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

### 2.4.2. Calibration

When it is necessary to verify monitoring results (in case of CCPs, OPRPs, product legality or critical Quality) equipment used must be calibrated and traceable[20].

a) The equipment must be fit for the intended use. For instance, to weigh 500 grams, the balance used should not be one that is able to weight 100 kg with a 500 gram interval.
b) A system needs to be in place to ensure that equipment must:
   - ✓ Be calibrated or verified at specified intervals or prior to use and the basis used for calibration or verification must be recorded;
   - ✓ Be calibrated following a defined method using more than 2 measurement points to be able to determine the linear calibration graph;
   - ✓ Be adjusted or re-adjusted as necessary when outside the allowed deviation (corrective action);
   - ✓ Be able to track to the reference used;
   - ✓ Be identified to enable the calibration status to be determined;

[19] ⚖ Annex II "FACILITIES AND EQUIPMENT" §3 of Regulation (EC) No 183/2005

[20] ⚖ Annex II "FACILITIES AND EQUIPMENT" §3a of Regulation (EC) No 183/2005 and Article 25 §1 d) of Regulation (EC) 1069/2009

- ✓ Be safeguarded from adjustments that would invalidate the measurement results;
- ✓ Be protected from damage and deterioration.

c) Procedures must be in place to ensure that products produced under not controlled conditions should be checked and assessed as safe before release.

d) Records of the results of calibration and verification must be maintained.

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

| Measuring intrument /equipment calibration compliance overview | | | | | | | | | | Date: | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | |
| Identification number | Name of the instrument | Location | CCP/RCP /CP | Range of Measurement | Accuracy required | Deviation allowed | Calibration frequency | Calibration body | reference instrument | certificate number | last calibration | next calibration | Calibration status |
| 12345 | Static thermometer | Hydrostat | CCP | 100 - 150 °C | ± 0,1° C | 0,5 ° C | 6 months | STORK | T98765 | QC5436 | 15-nov-16 | May 2017 | OK |
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## 2.5. Mixing & homogeneity

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

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

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

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

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

The method used should consist in:

- Selecting a tracer: the tracers can be selected from additives or medicaments, trace elements or specific external tracer. It must be possible to dose the tracer with the aid of an exact, it should be repeatable and there have to be a sensitive analysis method to determine the quantity of the tracer in the mixture. The characteristics of the added tracer must not be influenced by the process which takes place between adding the tracer and the sampling point. The quantity of the mixture to be tested on the homogeneity should be representative of the production, according to internal recipes.
- Producing a mix in which the tracer is contained: the conditions (quantity, time, etc) during the homogeneity validation must coincide with the normal practices of the production plant.
- Sampling: the recommended sampling point is therefore a point which is as close as possible to output of the mixing point. Not fewer than 10 samples should be taken from a mixture. Results will improve if samples are taken from several locations at several different times. More samples is always better, but the cost of sampling should also be

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

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

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

## 2.6. Management of incoming materials

### 2.6.1. General requirements

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

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

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

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

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

### 2.6.2. Vendor/Supplier approval system

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

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

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

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

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

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

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

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

### 2.6.3. Specifications

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

The specification should include:

- ✓ Name, coding or other identification of the concerned material;
- ✓ Origin and production method;
- ✓ Composition;
- ✓ Relevant chemical, physical and microbiological characteristics regarding safety, including characteristics determined in the hazard analysis, and regarding quality attributes;
- ✓ Packaging (if any);
- ✓ Shelf life/storage conditions;
- ✓ Directions for application/intended use;
- ✓ Relevant legislation, incl. labelling and claims, types of feedstuffs in which usage is approved, notes on any hazards or limitations about usage.

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

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

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

### 2.6.4. Handling of incoming material

Vehicles, documentation and materials must be inspected prior to unloading to verify that the material is the correct one and it is in suitable conditions: for example, damaged, infested or dirty

transports/containers will be rejected; materials shipped in damaged, infested or dirty vehicles will be rejected as well.

The conformance of incoming materials to specifications must be verified, for example by checking the Certificate of Analyses provided by the supplier and/or by analyzing the material. A documented procedure of inspection, sampling and analysis must exist, addressing products and hazards, methods, frequency, qualifications and responsibilities. Such procedure will take into account the risk assessment (HACCP), for example with regard to the frequency of a specific analysis.

Validated procedures for sampling[21] incoming materials must exist. Adequate qualification and training of anyone dealing with sampling must be ensured.

A procedure must be established to deal with non-conforming materials and their rejection. Such procedure should be designed to prevent unintended use of non-conforming materials (e.g. holding).
Documentation of rejected shipments, including reason for rejection, must be maintained.

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

## 2.7. Cleaning and sanitation

### 2.7.1. Cleaning & sanitising procedures

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

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

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

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

Periodic cleaning and sanitizing activities must be recorded.

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

### 2.7.2. Integrated pest management system

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

Pest control programmes must be implemented and be regularly reviewed for effectiveness.

[21] Codex Alimentarius General Guidelines on Sampling CAC/GL 50-2004

When applied, programmes must include a list of chemicals which are approved for use in specified areas of the site.

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

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

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

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

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

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

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

### 2.7.3. Chemicals control policy

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

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

### 2.7.4. Foreign bodies control policy

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

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

Written procedures for wood, metal, glass and hard clear plastic breakages in feed material handling, preparation, processing, packing and storage areas must be in place to ensure the necessary precautions are taken. These procedures should form part of a formal foreign bodies control policy.

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

### 2.7.5. Pathogens monitoring

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

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

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

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

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

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

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

b) **Line samples** are taken by swabbing from product contact surfaces (e.g. internal surface of processing equipment, transport belts, nozzles etc.) and by collecting fines from build ups (for example, at the base of a conveying system) into sterile packs – after collecting the samples all materials should be removed and the area sanitised in order to make sure that the next sampling will represent the current status. Again, the number, frequency and location of line samples will be defined by the HACCP plan.

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

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

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

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

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

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

A plan should describe:

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

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

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

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

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

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

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

## 2.8. Personnel

### 2.8.1 Training

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

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

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

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

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

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

### 2.8.2 Hygiene and health

#### 2.8.2.1. Personnel hygiene

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

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

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

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

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

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

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

Personnel (including visitors) known, or suspected, to be suffering from a disease likely to be transmitted to pet food, should not be allowed to enter any pet food area where direct contact with pet food is possible and there is a likelihood of contaminating the pet food, posing a risk to the safety of the product, the target animal and to humans handling the pet food.

### 2.8.2.2 Workwear & Personnel protective clothing

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

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

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

Suitable safety footwear must be worn within the factory environment.

Gloves, if worn, should be subject to adequate control to avoid product contamination. This does not replace the obligation for the personnel to wash hands (see section on 2.7.5 on pathogens monitoring).

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

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

### 2.8.3 Staff facilities

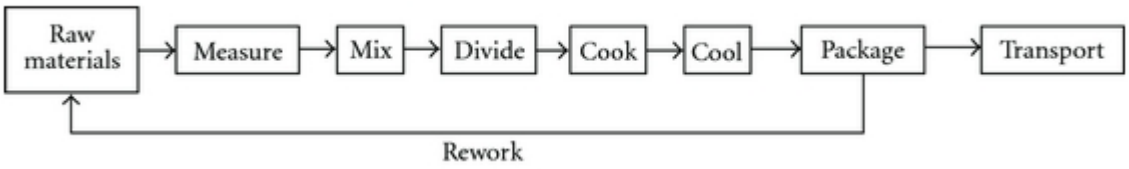
Personnel hygiene facilities must be available, clearly designated and maintained as necessary for pet food safety. Consumption of food and drinks as well as smoking must only be allowed in segregated and dedicated areas.

## 2.9 Rework

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

- Where rework or any reworking operation is performed, traceability must be maintained.
- Where re-processing is used, or reworking operations carried out, procedures must be implemented to ensure the safety, legality and quality of the finished product.

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





## 2.10. Transport and storage

### 2.10.1. General requirements

All vehicles or warehouses used for the transportation or storage of feed materials (including additives and packaging), intermediates/semi-processed products and finished product, must be suitable for the intended purpose, and be maintained in good repair and in a hygienic condition.[22]

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

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

Feed materials, additives and packaging materials, as well as finished products, must be stored and transported in such a way as to make them easily identifiable (product name, number, date and time of manufacture) and to prevent cross-contamination and deterioration.

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

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

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

[22] Regulation (EC) No 183/2005 Annex II (Storage and Transport), Regulation (EU) No 142/2011 (IX) Annex VIII: Chapter I 1 IV, Regulation (EC) No 767/2009, EN-ISO 22000 :2005, par. 7.3.3 (Product characteristics)

### 2.10.2. Transport

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

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

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

Where the feed material/additive, packaging materials or finished product transported is susceptible to damage by the weather, vehicles must be weather proofed and must be loaded and unloaded in covered bays to protect the material.

Animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles[23].

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[24]. Vehicles, containers, or packaging must have a label attached that says: 'category 3 material - not for human consumption'[25].

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

- cleaned, washed and disinfected after each use;
- maintained in a clean condition; and
- checked for cleanliness and dryness before new use.[26]

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

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

### 2.10.3. Storage

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

- Packed materials must be stored in appropriate packaging.

[23] ⚖ Annex VIII, Chapter 1, Section 1, point 1 of Regulation (EC) No 142/2011
[24] ⚖ Annex VIII, Chapter 1, Section 2, point 2a of Regulation (EC) No 142/2011
[25] ⚖ Annex VIII, Chapter 2, point 2b of Regulation (EC) No 142/2011
[26] ⚖ Annex VIII, Chapter 1, Section 1, point 2 of Regulation (EC) No 142/2011

Storage segregation[27] procedures must be in place to prevent the cross-contamination of finished products, packaging and feed materials.

- A separate area or other means of segregating materials identified as non-conforming must be provided. Non-conforming materials or finished products must be clearly identified.
- Product returned from distribution must be assessed for animal feed safety hazards and handled accordingly.
- Waste materials and chemicals (cleaning products, lubricants and pesticides) must be clearly identified and stored separately.

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

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

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

## 2.11. Product information and consumer awareness

### 2.11.1. General requirements

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

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

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

### 2.11.2 Product information

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

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

[27] Regulation (EU) No 142/2011, Regulation (EC) No 999/2001, Regulation (EC) No 183/2005 Annex II (Storage and Transport) , Directive 2002/32/EC

# CHAPTER 3: HACCP SYSTEM

## 3.1. Definition, scope and boundaries

### 3.1.1. Definition

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

HACCP is a management system in which pet food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material procurement and handling, to manufacturing and distribution of the finished product.

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

### 3.1.2. Scope and boundaries

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

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

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

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

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

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

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

- ✓ Changes in raw materials specifications, suppliers or origins of supplies;
- ✓ Changes in formulation of the finished products;
- ✓ Changes in technologies or processes
- ✓ Changes in factory equipment or layout;

- ✓ Changes in cleaning or maintenance practices;
- ✓ Changes in packaging, transport or storage;
- ✓ Changes in personnel;
- ✓ Changes in product type (e.g. wet or dry pet food) or target species (e.g. dogs, cats, small animals);
- ✓ Changes in legislation/other requirements;
- ✓ Feedback/complaints from customers;
- ✓ New scientific evidence/literature on hazards;
- ✓ A breach to operating and/or critical limits as set in the HACCP plan.

## 3.2. The HACCP system: step by step

The HACCP system is carried out in 12 steps which follow the seven principles described in the Codex Alimentarius based on the a priori implementation of Pre-requisite programmes. The seven principles can be summarised as follows and are further detailed in the below sections of the Guide.

| | | |
|---|---|---|
| **Codex Principle 1** | **Conduct a hazard analysis** | Assemble HACCP Team **(Step 1)**<br>Describe product **(Step 2)**<br>Identify intended use **(Step 3)**<br>Construct Flow diagram **(Step 4)**<br>Confirm flow diagram on site **(Step 5)**<br>List all potential hazards **(Step 6)**<br>Conduct a hazard analysis **(Step 6)**<br>Consider control measures **(Step 6)** |
| **Codex Principle 2** | **Determine the Critical Control Points (CCPs) and Operational Pre-Requisite Programmes (OPRPs)** | Use decision tree to determine CCPs and OPRP **(Step 7)** |
| **Codex Principle 3** | **Establish critical limits** | Establish action and critical limits for each CCP and OPRP **(Step 8)** |
| **Codex Principle 4** | **Establish CCP monitoring procedures** | Establish monitoring systems for each CCP and OPRP **(Step 9)** |
| **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 **(Step 10)** |
| **Codex Principle 6** | **Establish verification procedures** | Establish procedures for verification to confirm that the HACCP system is working effectively **(Step 11)** |
| **Codex Principle 7** | **Establish documentation and record keeping systems** | Establish documentation concerning all procedures and records appropriate to these principles and their application **(Step 12)** |

### 3.2.1. Principle 1: Conduct a Hazard analysis

The HACCP team and must have the responsibility and authority to:

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

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

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

**a) Assemble the HACCP/pet food safety team**

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

**b) Describe product and identify intended use**

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

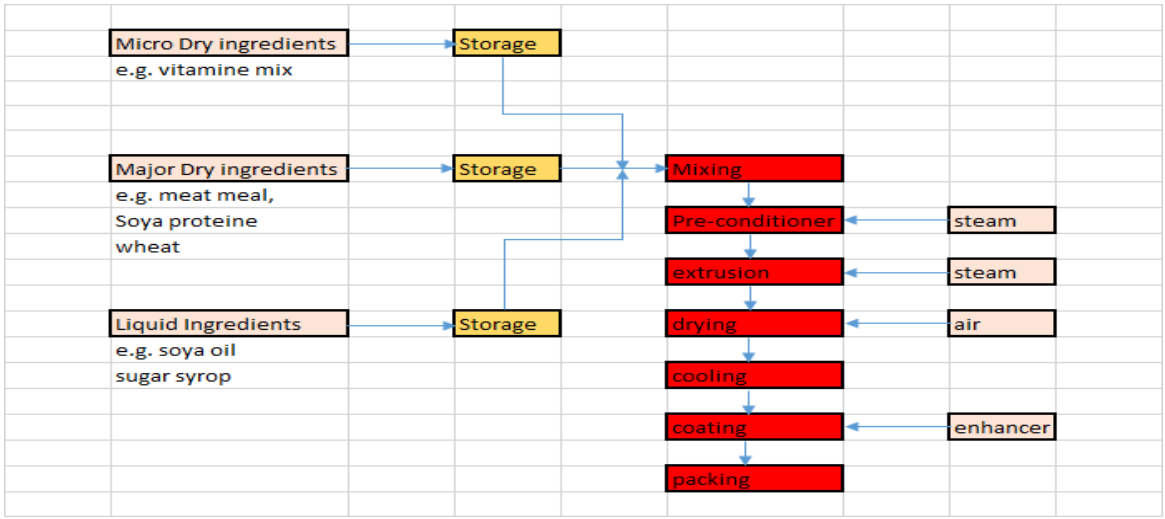
- ✓ Origin of all feed materials
- ✓ Physical or chemical properties that impact feed safety (e.g. pH, Aw)
- ✓ Treatment and processing (heating, freezing, salting)
- ✓ Packaging system (e.g. modified atm, vacuum)
- ✓ Storage and distribution conditions (chilled, ambient)
- ✓ Target shelf life under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

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

**c) Construct and confirm flow diagram**

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

*Example of a flow diagram for a processing progress*




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

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

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

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

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

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

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

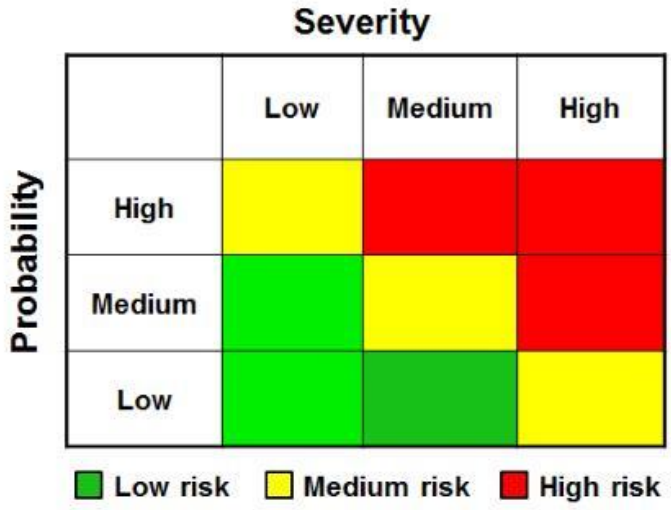
- ✓ The likely occurrence of hazards and severity of their adverse health effects;
- ✓ The qualitative and/or quantitative evaluation of the presence of hazards;
- ✓ Severity or the effects on consumer safety;
- ✓ Vulnerability of those exposed;
- ✓ Survival or multiplication of micro-organisms of concern;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

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

The 5 Ms method:

| | |
|---|---|
| Material | Cereals, oilseeds, protein crops |
| "Milieu" - Environment | Atmosphere, surrounding areas |
| Man | Hygiene |
| Method | Operating method |
| Machine | Installations, transport equipment |

Example of hazard assessment with a severity-probability matrix




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

Control measures should be validated, i.e. to obtain evidence that control measures are capable of being effective through the HACCP plan and the OPRPs, if properly implemented, by controlling the hazards to a specific outcome. Revalidation may be required in case of changes.
Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control. Validation involves measuring performance against a desired feed safety outcome or target, in respect of a required level of hazard control. Validation is performed at the time a control measure or a feed safety control system is designed, or when changes indicate the need for revalidation (i.e. system failure, process changes, new scientific or regulatory information)
Validation of control measures is, whenever possible, performed before their full implementation.

**Practical example of validation: control of metal fragments**

| Validation – Control of metal fragments | |
|---|---|
| **Step/phase** | **Actions** |
| *Pre-validation Tasks* | a. Hazard: Metal fragments<br>b. Food Safety Outcome: Less than 1 metal fragment over 2 mm in 100,000 kg of product.<br>c. Control Measure: Introduction of a sieve into a production line |
| *Approach* | Collection of data during normal operation |
| *Parameters and decision criteria* | Control measure will be considered validated if a metal detector indicates that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product.<br>Operational data will be collected for one month and reviewed to determine the size of any metal pieces in products rejected by the metal detector. |
| *Assemble relevant validation information* | a. Determine the size of metal fragments in products rejected by the metal detector.<br>b. Ensure that the metal detector is sensitive enough and calibrated to detect metal pieces of 2 mm or more in the specific product.<br>c. Ensure that the sieve remains intact during normal operations. |
| *Analyze results* | Determine the rate at which the sieve allowed fragments of 2 mm or more in the final product. |
| *Document and review the validation* | a. Document all findings from the metal detector.<br>b. Document the integrity of the sieve and the sensitivity and calibration of the metal detector. |
| *Conclusion* | a. Control measure can be implemented if data indicate that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product.<br>b. Validation will likely provide information on monitoring needed to ensure that sieve remains intact.<br>c. The metal detector can be used after the validation as an ongoing verification activity to ensure that the sieve is controlling the hazard as intended. |

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

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

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


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

| Type of control measure | PRP | OPRP | CCP |
|---|---|---|---|
| Scope | Measures related to creating the environment for safe food: measures impacting food suitability and safety | Measures related to the environment and/or product (or combination of measures) to prevent contamination, or to prevent, eliminate or reduce hazards to an acceptable limit in the end product. These measures are implemented after the implementation of PRPs. | |
| Relation to hazards | Not specific to any hazard | Specific to each hazard or group of hazards | |
| Determination | Development based on:<br>• Experience,<br>• Reference documents (guides, scientific publications, ..),<br>• Hazard or hazard analysis | Based on the hazard analysis taking PRPs into account.<br>CCPs and OPRPs are product and/or process specific | |
| Validation | Not necessarily carried out by operators. *(i.e. cleaning products manufacturer has validated the efficiency of the product and determined product spectrum and instructions of use – Feed Business Operator has to follow instructions and keep technical specification of product)* | Validation has to be carried out | |
| Criteria | / | Measurable or observable criteria | Measurable critical limit |
| Monitoring | Where relevant and feasible | Monitoring of the implementation of control measures: usually recorded | |
| Loss of control: corrections/corrective actions | Corrective actions and/or corrections on the implementation of PRPs where relevant | Corrective actions on the process<br>Possible corrections on the product (case by case)<br>Records kept | Pre-set corrections on the product<br>Possible corrective actions on the process<br>Records kept |
| Verification | Scheduled verification of implementation | Scheduled verification of implementation, verification of achievement of planned hazard control | |

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

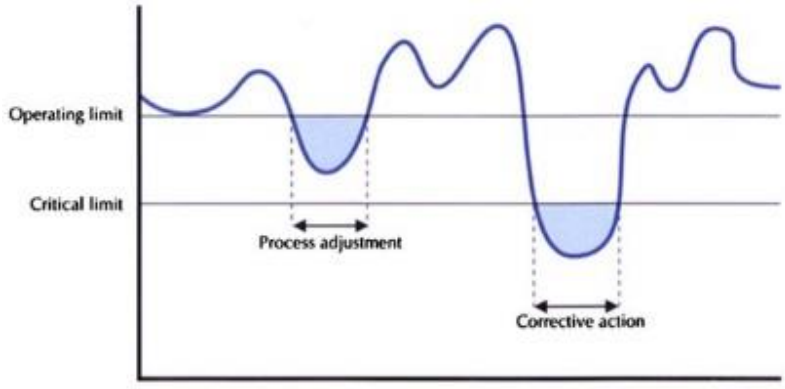
| Step | Hazard | Category | CCP | Monitoring | | | | Critical limits | Corrective Action | Records | Verification |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | What | How | When | Who | | | | |
| Filling | Metal Foreign Object | Physical | x | Metal detector prior to filler | - Detection of all test pieces<br>- Ejection system is working properly (belts stop for belt detectors or ejection valve is switched on for pipe detectors) | Twice a shift | Trained operator | One of the test pieces is not detected Ejection system is not working Operator is not trained | Product put on hold from the last control | Factory documents (ref xxx) | Consumer complaints Product panels |

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

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

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

Example of management of process monitoring




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

Monitoring is the scheduled measurement or observation of a CCP or OPRP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP or OPRP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP or OPRP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP or OPRP is in control. Most monitoring procedures for CCPs and OPRPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological status of the product. All records and documents associated with monitoring CCPs and OPRPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

### 3.2.5. Principle 5: Establish corrective actions

Specific corrective actions must be developed for each CCP and each OPRP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP or OPRP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

### 3.2.6. Principle 6: Establish verification procedures

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

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

### 3.2.7. Principle 7: Establish Documentation and Record keeping

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

Documentation examples are:

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

Record examples are:

- ✓ CCP and OPRP monitoring activities;
- ✓ Deviations and associated corrective actions;
- ✓ Modifications to HACCP system; and
- ✓ Confirmation that the CCPs are kept under control.

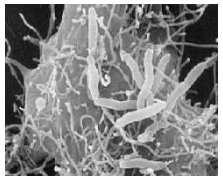
Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified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

## 3.3. List of hazards

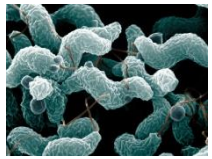
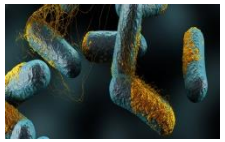
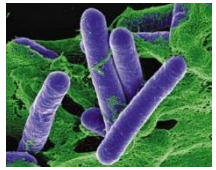
Hazards are biological, physical or chemical agents in animal feed that are reasonably likely to cause illness or injury for pets in the absence of their control. Whether a particular hazard named in the list below will need to be addressed in a HACCP plan, will depend on an evaluation of the actual risk and severity of the hazard in pet food. Hazards may be introduced into the pet food or raw material for pet food any time during harvesting, formulation and processing, packaging and labelling, transportation, storage, preparation and feeding.[28] For more details and information regarding the determination the significance of the hazards, the following websites can be used as an example:

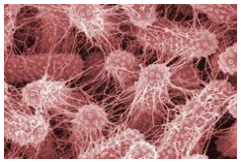
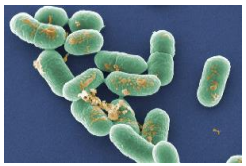
https://www.efsa.europa.eu/en/scientific-work
http://www.who.int/topics/foodborne_diseases/en

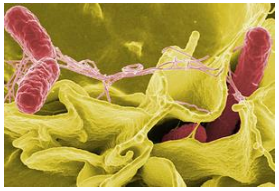
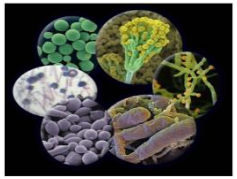
### 3.3.1. Table 1: List of hazards – Dry pet Food

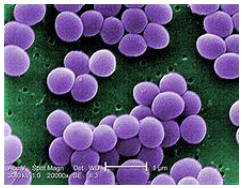
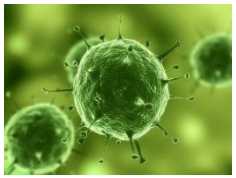
| Nature of hazards | Hazards | Description | Dry pet food (≤14% moisture) | Comments |
|---|---|---|---|---|
| Biological | ***Aeromonas***  | *Aeromonas* is a Gram-negative, non-spore-forming, tentatively anaerobic bacterium. This bacterium can be found in fresh or brackish water | Applicable | No spore forming. Risk for dry pet food is very low Biological contamination might occur so that adequate rules for product and personnel flows must be in place |
| | ***Campylobacter*** | *Campylobacter* is a Gram- | Applicable | Raw material contamination. |

[28] The information contained in the present section and tables is for general information purposes only. The information is provided by FEDIAF and while we endeavour to keep the information up to date and correct, we make no representations or warranties of any kind about the completeness, accuracy, reliability, suitability or availability with respect to the information provided. The Pet Food Safety Management System you implement within your factory/plant shall be based on your own hazard analysis is therefore strictly at your own risk.

| | | | | |
|---|---|---|---|---|
| |  | negative bacteria, non-spore forming bacterium.<br>Campylobacter species are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs and sheep.<br>They live harmlessly in the gut but during slaughter and processing of farm animals, the contamination can spread from the gut to other parts of the animal. | | Risk of occurrence may increase with standing time and temperature within the factory.<br>No risk when the aw-value is low.<br>Biological contamination might occur so that adequate rules for product and personnel flows must be in place |
| | ***Clostridium perfrigens***<br>  | *Clostridium perfringens* is a Gram-positive, rod-shaped, anaerobic, spore-forming.<br>C. perfringens is found frequently in the intestines of many animals and is present in soil and areas contaminated by human or animal feces | Applicable | Raw material contamination.<br>Risk of occurrence may increase with standing time and temperature within the factory.<br>Biological contamination might occur so that adequate rules for product and personnel flows must be in place |
| | ***Clostridium botulinum***<br>  | *Clostridium botulinum* is an anaerobic rod-shaped bacterium, i.e. it lives and grows in low oxygen conditions. The spore has a hard protective coating and is able to survive for | Applicable | Raw material contamination.<br>Risk of occurrence may increase with standing time and temperature within the factory. |

| | | | | |
|---|---|---|---|---|
| | | years. *C. botulinum* is responsible for a disease called botulism.<br>Clostridium botulinum is found in soil and untreated water throughout the world. | | Depending on the process C.b. remains in the product, because of anaerob conditions (folio). If C.b. has been in product, the toxin remains.<br>Sterilisation process is meant to destroy this bacterium and spore, not the toxin.<br>Biological contamination might occur so that adequate rules for product and personnel flows must be in place |
| | ***Enterobacteriaceae***<br>  | The *Enterobacteriaceae* are a large family of Gram-negative bacteria. They are not spore-forming. Many members of this family are a normal part of the gut flora found in the intestines of humans and other animals, while others are found in water or soil, or are parasites on a variety of different animals and plants. | Applicable | Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard.<br>Adequate rules for product and personnel flows must be in place to avoid biological contamination |
| | ***Listeria monocytogenes***<br>  | *Listeria monocytogenes* is a Gram-positive bacterium<br>*Listeria* is found in soil, plants and water. Animals, including cattle, sheep and goats, can also carry the bacteria.<br>Cooking at temperatures higher | Applicable | Non-spore-forming and not thermo resistant which make it low risk for dry pet food.<br>Adequate rules for product and personnel flows must be in place to avoid biological contamination |

| | | | | |
|---|---|---|---|---|
| | | than 65 °C kills the bacteria. | | |
| | ***Pathogenic E.coli***<br>  | *Escherichia coli* is a gram-negative, tentatively anaerobic, rod-shaped bacterium of the genus Escherichia that is commonly found in the lower intestine of warm-blooded organisms (endotherms) | Applicable | Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard.<br>Biological contamination might occur so that adequate rules for product and personnel flows must be in place |
| | ***Salmonella***<br>  | *Salmonella* is a gram-negative bacteria of the Enterobacteriaceae family. Salmonella species are non-spore-forming | Applicable | Indicator for microbiological infestation.<br>Infestation could occur via packaging personnel after thermal treatment or via droppings of animals when buildings are not closed<br>Adequate rules for product and personnel flows must be in place to avoid biological contamination |
| | ***Moulds and yeasts***<br>  | *Moulds* are fungus that grows in the form of multicellular filaments called hyphae. In contrast, fungi that can adopt a single-celled growth habit are called *yeasts*. | Applicable | Storage conditions of dry materials (cereals, vegetables…)<br>Heat treatment is required<br>Adequate rules for product and personnel flows must be in place to avoid biological contamination<br>Dry pet food can get mouldy depending on its residual moisture content and aw-value. Furthermore it's important to avoid condensation |
| | ***Staphylococcus aureus*** | *Staphylococcus aureus* is a | Applicable | Spores are not thermo-resistant but |

| | | | | |
|---|---|---|---|---|
| |  | gram-positive coccal bacterium Produces several enterotoxins generally highly resistant to enzymatic degradation and heat. Bacterium exists in soil | | the toxin is. Staphylococci are living in warm blood animals. It indicates bad cleaning conditions<br><br>Adequate rules for product and personnel flows must be in place to avoid biological contamination |
| | ***Pests (rodents, insects,…)***<br>  | *Pests* are rodents or insects may carry pathogenic organisms which are source of contamination. | Applicable | Clean facilities and proper pest control policy must be in place. May also occur via raw materials. |
| **Chemical** | ***Biocides (cleaning substances)***<br>  | *Biocides* are any substance or mixture consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. This includes insecticides, insect | Applicable | May occur at level of incoming materials as well as during production process via residues of sanitizing operations<br>Control measures after cleaning must be in place |

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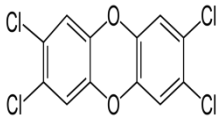
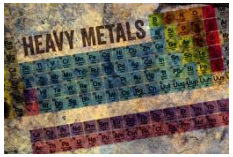
| | | repellents, disinfectants, preservatives for materials such as wood, plastics and fibers and anti-fouling paints for the protection of ship hulls. | | |
| | ***Carry over of substances for non-target species*** | *Carry over* is a transfer of any authorised substance or product from one production batch to the immediate subsequent batch destined to a different target specie. | Applicable | May occur during manufacturing process when different products are produced simultaneously or one after the other. |
| | ***Dioxins***<br>  | *Dioxins* and *dioxin-like compounds* (DLCs) are compounds that are highly toxic environmental persistent organic pollutants. | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk ( e.g. package by recycled material)<br><br>May also occur during production process (e.g. Crisis in Ireland back in 2008) |
| | ***Heavy metals***<br>  | *Heavy metals* are metals with a relatively high density, atomic weight or atomic number which presence may occur in pet food. Typical examples are lead, mercury and cadmium. | Applicable | Sources in the feed chains are pollution, soil, machines, water used for production… |
| | ***Mycotoxins*** | A *mycotoxin* is a toxic secondary metabolite produced by organisms of the fungus | Applicable | Raw material contamination or during transport and storage |

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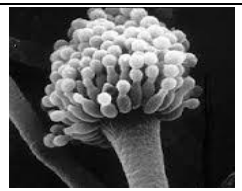
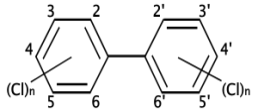
| |  | kingdom. The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops. One mold species may produce many different mycotoxins, and several species may produce the same mycotoxin. | | Higher risk depending on the geographical origin of incoming material and weather conditions.<br><br>The occurrence of risk is linked to the quantity of cereals and vegetables used in the recipes. |
| | ***PCBs***<br>  | A *polychlorinated biphenyl* (PCB) is an organic chlorine compound. PCBs cause cancer in animals and are probable human carcinogens. Because of PCBs' environmental toxicity and classification as a persistent organic pollutant, PCB production was banned by the United States Congress in 1979 and by the Stockholm Convention on Persistent Organic Pollutants in 2001. | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk<br>May also occur during production process, e.g.:<br>- Use of unappropriated combustion for heat treatment (e.g. bread meal)<br>- Residues of plastic used as folio, boxes etc. |
| | ***Toxins Veterinary drugs***<br>  | Hormones, growth regulators, antibiotics… used for feed animal treatments. | Applicable | The origin of animal by-products needs to be taken into account to ensure that no residues are found in the incoming materials.<br>Occurrence of toxins veterinary drugs may be the result of a cross- |

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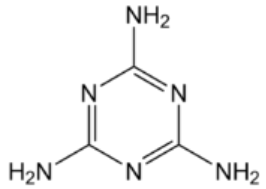
| | | | | contamination at the level of a premix plant and ultimately impacting the safety of the pet food product |
| | ***Melamine***<br>  | *Melamine* is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. Is widely used in plastics and adhesives.<br>Several frauds during the past years to simulate a higher level of protein of some materials (the normal check of the protein level is done through a test measuring nitrogen content; the addition of melamine increases the nitrogen content of the material and therefore its apparent protein content) | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk<br>Occurrence also linked to residues of packaging (soft plastic). |
| | ***Peroxides / Free Fatty Acids (FFA)*** | *Peroxides* and *FFA* are the result of oxidation or hydrolysis of grade oils and fats. This may provoke vomiting of cats and dogs. | Applicable | Quality and storage conditions of raw materials (oils, fats, etc.) needs to be taken into account. Raw materials and finished products need to be stabilized. |
| | ***Biogenic amines (incl. Histamine)*** | *Biogenic amines* are basic nitrogenous compounds formed mainly by decarboxylation of | Applicable | Quality of raw material may impact on the occurrence of the hazard.<br>May also occur during the |

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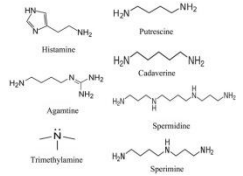
| |  | amino acids or by amination and transamination of aldehydes and ketones. High amount of biogenic amines may be an indication of material spoilage.<br>*Histamine* is naturally high in some fish species (e.g. tuna, mackerel, sardine…) and may have undesirable or harmful effect on dogs and/or cats (e.g. allergies). | | production process (standing time, temperature).<br><br>E.g. in fish meal |
| | ***Pesticides***<br><br>  | *Pesticides* are is something that prevents, destroys, or controls a harmful organism ('pest') or disease, or protects plants or plant products during production, storage and transport.<br>The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematicides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides. | Applicable | May occur at level of incoming materials as well as during production process via residues of sanitizing operations.<br>The sanitizing or pest control must be monitored by control measurements |
| | ***Lubricants*** | US FDA defines 3 types of lubricants: | Applicable | Food lubricants are mostly used in pet food production. In case it is not, |

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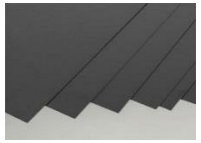
| |  | - H1: lubricants that could have incidental food contact<br>- H2: lubricants with no possibility of contacting food<br>- H3: soluble oils | | contamination may occur in finished pet food. |
| **Physical** | ***Glass***<br>  | The presence of *glass* may origin from raw materials, factories environment (e.g. lab equipment, lightings…), primary packs or manpower (e.g. glasses, watches…) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food |
| | ***Hard plastic***<br>  | The presence of *hard plastic* may origin from raw materials (e.g. handling bins, weasand clips…), factories equipment (e.g. belts scrapers, elevators, protections…) or manpower (pens, identification badges…) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of hard plastic in pet food. |
| | ***Metal***<br>  | The presence of *metal* may origin from raw materials, factories equipment, engineering works (e.g. welding, screws and bolds…) or manpower. PRPs and CCPs are key to prevent occurrence of glass in pet food. | Applicable | Raw materials contamination PRPs and CCPs are key to prevent occurrence of metal in pet food |

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| | ***Wood***<br>  | The presence of *wood* may origin from raw materials, factories or engineering works. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of wood in pet food. |
| | ***Soft plastic & non-woven fabric***<br>  | The presence of *soft plastic & non-woven fabric* may origin Raw materials (protection of frozen meat pallets, bags of dry materials, etc.) | Applicable | Raw materials contamination PRPs and CCPs are key to prevent occurrence of soft plastic & non-woven fabric in pet food. |
| | ***Bones***<br>  | The presence of *bones* origins from raw materials (processed animal proteins or cereals harvested in land with bones residues) | Not applicable | / |
| | ***Stones***<br>  | The presence of *stones* origins from raw materials such as vegetables, animal stomachs or from factories (e.g. floors) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of stones in pet food. |
| | ***Pests***<br>  | The presence of *pests* origins from either raw materials or factories environment. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of pests in pet food. |
| | ***Workers' accessories*** | Workers' accessories such as | Applicable | PRPs are key to prevent occurrence |

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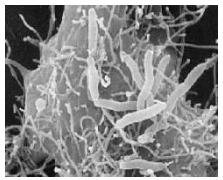
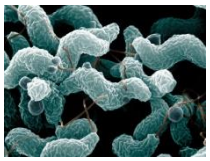
| | | jewels, ties, scarfs, glasses, watches may end up in pet food. PRPs are key to prevent occurrence of foreign materials in finished products. | | of foreign materials in finished products. |
| | ***Mud, soil***<br>  | The presence of *mud and soil may* origin from either raw materials or factories environment. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of soil in pet food.<br>Some biological hazards can be an indicator for soil contamination<br><br>E.g. Truck wheels during raw materials unloading |
| | ***Rubber***<br>  | The presence of *rubber* may origin from either raw materials or factories environment. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of rubber in pet food.<br><br>E.g. Parts of packaging lines |

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

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

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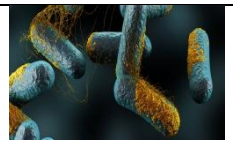
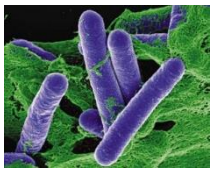
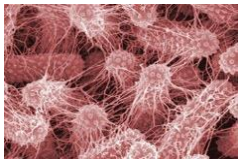
| |  | frequently in the intestines of many animals and is present in soil and areas contaminated by human or animal feces | | |
| | ***Clostridium botulinum***  | *Clostridium botulinum* is an anaerobic rod-shaped bacterium, i.e. it lives and grows in low oxygen conditions. The spore has a hard protective coating and is able to survive for years. C. botulinum is responsible for a disease called botulism. Clostridium botulinum is found in soil and untreated water throughout the world. | Applicable | Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. Depending on the process, *Clostridium botulinum* may remain in the product, because of anaerob conditions (folio). If *Clostridium botulinum* was in the product, the toxin remains. Sterilisation process is meant to destroy this bacterium and spore, not the toxin. |
| | ***Enterobacteriaceae***  | The *Enterobacteriaceae* are a large family of Gram-negative bacteria. They are not spore-forming. Many members of this family are a normal part of the gut flora found in the intestines of humans and other animals, while others are found in water or soil, or are parasites on a variety of different animals and plants. | Applicable | Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard. |
| | ***Listeria monocytogenes*** | *Listeria monocytogenes* is a Gram-positive bacterium Listeria is found in soil, plants and water. Animals, including cattle, sheep and goats, can also carry the bacteria. | Not applicable | Non-spore-forming and not thermo resistant which make it insignificant for semi- moist pet food. |

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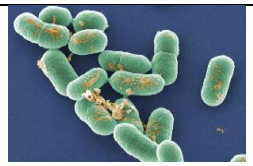
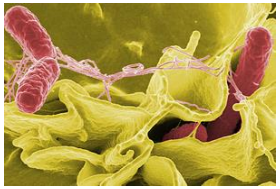
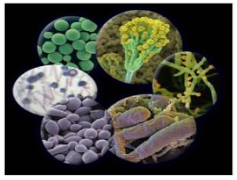
| |  | Cooking at temperatures higher than 65 °C kills the bacteria. | | |
| | ***Pathogenic E.coli***<br>  | *Escherichia coli* is a gram-negative, tentatively anaerobic, rod-shaped bacterium of the genus Escherichia that is commonly found in the lower intestine of warm-blooded organisms (endotherms) | Applicable | Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard. |
| | ***Salmonella***<br>  | *Salmonella* is a gram-negative bacteria of the Enterobacteriaceae family. Salmonella species are non-spore-forming | Applicable | Non-spore-forming and not thermo resistant which make it insignificant for wet pet food<br>Salmonella presence may be an indicator of occurrence of other microbiological risks.<br>Salmonella occurrence may happen after thermal treatment via packaging or personnel as well via droppings of animals in case buildings are not closed. |
| | ***Moulds and yeasts***<br>  | *Moulds* are fungus that grows in the form of multicellular filaments called hyphae. In contrast, fungi that can adopt a single-celled growth habit are called *yeasts*. | Applicable | Storage conditions of dry materials (cereals, vegetables…)<br>Heat treatment is required<br>Semi-moist pet food must be protected under anaerobic condition by nitrogen or similar |
| | ***Staphylococcus aureus*** | *Staphylococcus aureus* is a gram-positive coccal bacterium Produces several enterotoxins | Applicable | Spores are not thermo-resistant but the toxin is. |

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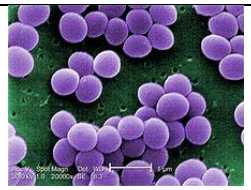
| |  | generally highly resistant to enzymatic degradation and heat. Bacterium exists in soil | | Staphylococci are living in warm blood animals. It indicates bad cleaning conditions<br><br>Adequate rules for product and personnel flows must be in place to avoid biological contamination |
| | ***Pests (rodents, insects,…)***<br><br>  | *Pests* are rodents or insects may carry pathogenic organisms which are source of contamination. | Applicable | Clean facilities and proper pest control policy must be in place. May also occur via raw materials. |
| **Chemical** | ***Biocides (cleaning substances)***<br><br>  | *Biocides* are any substance or mixture consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. This includes insecticides, insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibers and anti-fouling paints for the | Applicable | May occur at level of incoming materials as well as during production process via residues of sanitizing operations<br>Control measures after cleaning must be in place |

| | | | | |
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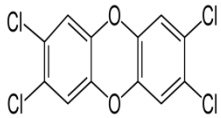
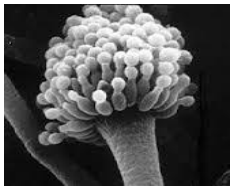
| | | protection of ship hulls. | | |
| | ***Carry over* of substances for non-target species** | *Carry over* is a transfer of any authorised substance or product from one production batch to the immediate subsequent batch destined to a different target specie. | Applicable | May occur during manufacturing process when different products are produced simultaneously or one after the other. |
| | ***Dioxins***<br>  | *Dioxins* and *dioxin-like compounds* (DLCs) are compounds that are highly toxic environmental persistent organic pollutants. | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk ( e.g. package by recycled material)<br><br>May also occur during production process (e.g. Crisis in Ireland back in 2008) |
| | ***Heavy metals***<br>  | *Heavy metals* are metals with a relatively high density, atomic weight or atomic number which presence may occur in pet food. Typical examples are lead, mercury and cadmium. | Applicable | Raw material contamination especially fisch |
| | ***Mycotoxins***<br>  | A *mycotoxin* is a toxic secondary metabolite produced by organisms of the fungus kingdom. The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops. One mold species may produce many different mycotoxins, and several species | Applicable | Raw material contamination or during transport and storage. Higher risk of contamination depending on the geographical origin of the incoming materials (weather conditions). The occurrence of the risk is linked to the quantity of cereals and vegetables used in the recipes. Itis not as sensitive in semi-moist pet |

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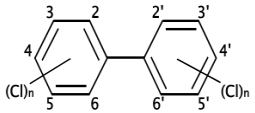
| | | may produce the same mycotoxin. | | food as in dry pet food. |
| | ***PCBs***<br>  <br> | A *polychlorinated biphenyl* (PCB) is an organic chlorine compound. PCBs cause cancer in animals and are probable human carcinogens. Because of PCBs' environmental toxicity and classification as a persistent organic pollutant, PCB production was banned by the United States Congress in 1979 and by the Stockholm Convention on Persistent Organic Pollutants in 2001. | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk<br>May also occur during production process, e.g.:<br>- Use of unappropriated combustion for heat treatment (e.g. bread meal)<br>- Residues of plastic used as folio, boxes etc. |
| | ***Toxins Veterinary drugs***<br>  | Hormones, growth regulators, antibiotics… used for feed animal treatments. | Applicable | The origin of animal by-products needs to be taken into account to ensure that no residues are found in the incoming materials.<br>Occurrence of toxins veterinary drugs may be the result of a cross-contamination at the level of a premix plant and ultimately impacting the safety of the pet food product |
| | ***Melamine*** | *Melamine* is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. Is widely used in plastics and adhesives.<br>Several frauds during the past years to simulate a higher level | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk<br>Occurrence also linked to residues of packaging (soft plastic). |

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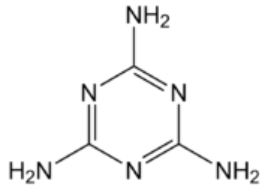
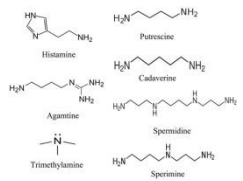
| |  | of protein of some materials (the normal check of the protein level is done through a test measuring nitrogen content; the addition of melamine increases the nitrogen content of the material and therefore its apparent protein content) | | |
| | ***Peroxides / Free Fatty Acids (FFA)*** | *Peroxides* and *FFA* are the result of oxidation of grade oils and fats. This may provoke vomiting of cats and dogs. | Applicable | Depends on the process, semi-moist pet food must be protected under anaerobic condition by nitrogen or similar<br>This process must be controlled |
| | ***Biogenic amines (incl. Histamine)***<br>  | *Biogenic amines* are basic nitrogenous compounds formed mainly by decarboxylation of amino acids or by amination and transamination of aldehydes and ketones. High amount of biogenic amines may be an indication of material spoilage.<br>*Histamine* is naturally high in some fish species (e.g. tuna, mackerel, sardine…) and may have undesirable or harmful effect on dogs and/or cats (e.g. allergies). | Applicable | Quality of raw material may impact on the occurrence of the hazard.<br>May also occur during the production process (standing time, temperature). |
| | ***Pesticides*** | *Pesticides* are is something that prevents, destroys, or controls a harmful organism ('pest') or disease, or protects plants or | Applicable | May occur at level of incoming materials as well as during production process via residues of sanitizing operations. |

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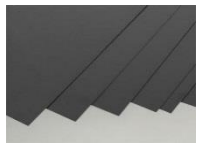
|---|---|---|---|---|
| |  | plant products during production, storage and transport.<br>The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematicides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides. | | The sanitizing or pest control must be monitored by control measurements |
| | ***Lubricants***<br>  | US FDA defines 3 types of lubricants:<br>- H1: lubricants that could have incidental food contact<br>- H2: lubricants with no possibility of contacting food<br>- H3: soluble oils | Applicable | Food lubricants are mostly used in pet food production. In case it is not, contamination may occur in finished pet food. |
| **Physical** | ***Glass***<br>  | The presence of *glass* may origin from raw materials, factories environment (e.g. lab equipment, lightings…), primary packs or manpower (e.g. glasses, watches…) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |
| | ***Hard plastic***<br>  | The presence of *hard plastic* may origin from raw materials (e.g. handling bins, weasand clips…), factories equipment (e.g. belts scrapers, elevators, protections…) or manpower (pens, identification badges…) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of hard plastic in pet food. |

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| | ***Metal***<br>  | The presence of *metal* may origin from raw materials, factories equipment, engineering works (e.g. welding, screws and bolds…) | Applicable | Raw materials contamination PRPs and CCPs are key to prevent occurrence of metal in pet food. |
| | ***Wood***<br>  | The presence of *wood* may origin from raw materials, factories or engineering works. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of wood in pet food. |
| | ***Soft plastic & non-woven fabric***<br>  | The presence of *soft plastic & non-woven fabric* may origin Raw materials (protection of frozen meat pallets, bags of dry materials, etc.) | Applicable | Raw materials contamination PRPs and CCPs are key to prevent occurrence of soft plastic in pet food. |
| | ***Bones***<br>  | The presence of *bones* origins from raw materials (processed animal proteins or cereals harvested in land with bones residues) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of bones in pet food. |
| | ***Stones***<br>  | The presence of *stones* origins from raw materials such as vegetables, animal stomachs or from factories (e.g. floors) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of stones in pet food. |
| | ***Pests*** | The presence of *pests* origins from either raw materials or | Applicable | Raw materials contamination PRPs are key to prevent occurrence |

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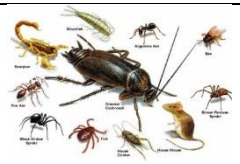
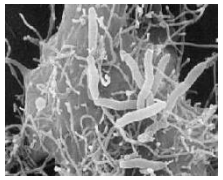
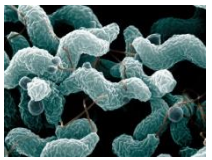
| |  | factories environment | | of pests in pet food. |
| | ***Workers' accessories*** | Workers' accessories such as jewels, ties, scarfs, glasses, watches may end up in pet food. PRPs are key to prevent occurrence of foreign materials in finished products. | Applicable | PRPs are key to prevent occurrence of foreign materials in finished products. |
| | ***Mud, soil***<br>  | The presence of *mud and soil may* origin from either raw materials or factories environment. | Applicable | Raw materials contamination<br>PRPs are key to prevent occurrence of soil in pet food.<br>Some biological hazards can be an indicator for soil contamination |
| | ***Rubber***<br>  | The presence of *rubber* may origin from either raw materials or factories environment. | Applicable | Raw materials contamination<br>PRPs are key to prevent occurrence of rubber in pet food. |

### 3.3.3. Table 3: List of hazards – Wet pet Food

| Nature of hazards | Hazards | Description | Wet pet food (≥60% moisture) | Comments |
|---|---|---|---|---|
| Biological | ***Aeromonas***<br>  | *Aeromonas* is a Gram-negative, non-spore-forming, tentatively anaerobic bacterium. This bacterium can be found in fresh or brackish water | Not applicable | No spore forming so no risk for wet pet food. |
| | ***Campylobacter***<br>  | *Campylobacter* is a Gram-negative, non-spore forming bacterium.<br>Campylobacter species are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs and sheep.<br>They live harmlessly in the gut but during slaughter and processing of farm animals, the contamination can spread from the gut to other parts of the animal. | Applicable | Raw material contamination.<br>Risk of occurrence may increase with standing time and temperature within the factory. |
| | ***Clostridium perfrigens*** | *Clostridium perfringens* is a Gram-positive, rod-shaped, anaerobic, spore-forming.<br>C. perfringens is found | Applicable | Raw material contamination.<br>Risk of occurrence may increase with standing time and temperature within the factory |

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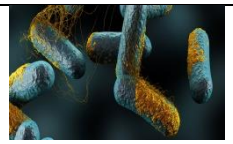
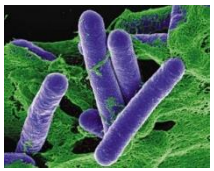
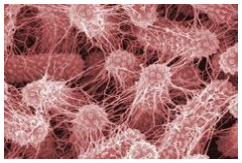
| |  | frequently in the intestines of many animals and is present in soil and areas contaminated by human or animal feces | | |
| | ***Clostridium botulinum***  | *Clostridium botulinum* is an anaerobic rod-shaped bacterium, i.e. it lives and grows in low oxygen conditions. The spore has a hard protective coating and is able to survive for years. C. botulinum is responsible for a disease called botulism. Clostridium botulinum is found in soil and untreated water throughout the world. | Applicable | Raw material contamination. Risk of occurrence may increase with standing time and temperature within the factory. Sterilisation process is meant to destroy this bacterium and spore. |
| | ***Enterobacteriaceae***  | The *Enterobacteriaceae* are a large family of Gram-negative bacteria. They are not spore-forming. Many members of this family are a normal part of the gut flora found in the intestines of humans and other animals, while others are found in water or soil, or are parasites on a variety of different animals and plants. | Applicable | Applicable for wet pet food only to determine hygiene levels. |
| | ***Listeria monocytogenes*** | *Listeria monocytogenes* is a Gram-positive bacterium Listeria is found in soil, plants and water. Animals, including cattle, sheep and goats, can also carry the bacteria. | Not applicable | Non-spore-forming and not thermo resistant which make it insignificant for wet pet food. |

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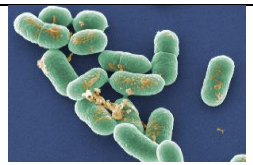
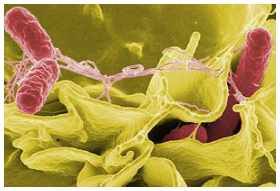
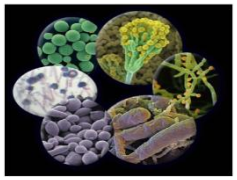
|---|---|---|---|---|
| |  | Cooking at temperatures higher than 65 °C kills the bacteria. | | |
| | ***Pathogenic E.coli***<br>  | *Escherichia coli* is a gram-negative, tentatively anaerobic, rod-shaped bacterium of the genus Escherichia that is commonly found in the lower intestine of warm-blooded organisms (endotherms) | Applicable | Occurrence from raw material contamination and linked to cleanliness of factory and personnel are key to prevent occurrence of this hazard. |
| | ***Salmonella***<br>  | *Salmonella* is a gram-negative bacteria of the Enterobacteriaceae family. Salmonella species are non-spore-forming | Not applicable | Non-spore-forming and not thermo resistant which make it insignificant for wet pet food. |
| | ***Moulds and yeasts***<br>  | *Moulds* are fungus that grows in the form of multicellular filaments called hyphae. In contrast, fungi that can adopt a single-celled growth habit are called *yeasts*. | Applicable | Storage conditions of dry materials (cereals, vegetables…) |
| | ***Staphylococcus aureus*** | *Staphylococcus aureus* is a gram-positive coccal bacterium Produces several enterotoxins generally highly resistant to enzymatic degradation and heat. | Applicable | Spores are not thermo-resistant but the toxin is.<br>Staphylococci are living in warm blood animals. It indicates bad cleaning conditions |

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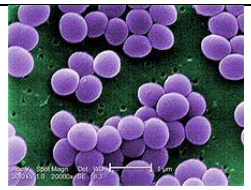
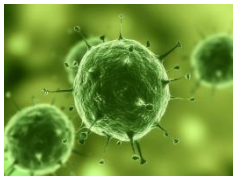
| |  | | | Adequate rules for product and personnel flows must be in place to avoid biological contamination |
| | ***Pests (rodents, insects,…)***<br>  | *Pests* are rodents or insects may carry pathogenic organisms which are source of contamination. | Applicable | Clean facilities and proper pest control policy in place.<br>May also occur via raw materials. |
| **Chemical** | ***Biocides (cleaning substances)***<br>  | *Biocides* are any substance or mixture consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. This includes insecticides, insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibers and anti-fouling paints for the protection of ship hulls. | Applicable | May occur at level of incoming materials as well as during production process via residues of sanitizing operations |
| | ***Carry over of substances for*** | *Carry over* is a transfer of any | Applicable | May occur during manufacturing |

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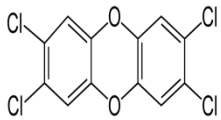
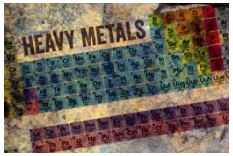
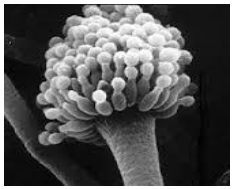
| | ***non-target species*** | authorised substance or product from one production batch to the immediate subsequent batch destined to a different target specie. | | process when different products are produced simultaneously or one after the other. |
| | ***Dioxins***<br>  | *Dioxins* and *dioxin-like compounds* (DLCs) are compounds that are highly toxic environmental persistent organic pollutants. | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk. May also occur during production process (e.g. Crisis in Ireland back in 2008) |
| | ***Heavy metals***<br>  | *Heavy metals* are metals with a relatively high density, atomic weight or atomic number which presence may occur in pet food. Typical examples are lead, mercury and cadmium. | Applicable | Raw material contamination as well as during the production process (leakage or deficient machinery). |
| | ***Mycotoxins***<br>  | A *mycotoxin* is a toxic secondary metabolite produced by organisms of the fungus kingdom. The term 'mycotoxin' is usually reserved for the toxic chemical products produced by fungi that readily colonize crops. One mold species may produce many different mycotoxins, and several species may produce the same mycotoxin. | Applicable | Raw material contamination or during transport and storage. Higher risk of contamination depending on the geographical origin of the incoming materials (weather conditions). The occurrence of the risk is linked to the quantity of cereals and vegetables used in the recipes. Itis not as sensitive in wet pet food as in dry pet food. |
| | ***PCBs*** | A *polychlorinated biphenyl* | Applicable | The origin of raw materials used for |

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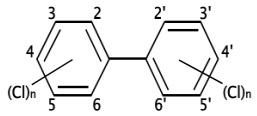
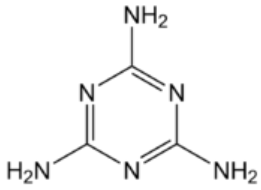
| |  | (PCB) is an organic chlorine compound. PCBs cause cancer in animals and are probable human carcinogens. Because of PCBs' environmental toxicity and classification as a persistent organic pollutant, PCB production was banned by the United States Congress in 1979 and by the Stockholm Convention on Persistent Organic Pollutants in 2001. | | the production of the pet food product needs to be taken into account to evaluate the level of risk<br>May also occur during production process, e.g.:<br>- Use of unappropriated combustion for heat treatment (e.g. bread meal)<br>- Residues of plastic used as folio, boxes etc. |
| | ***Toxins Veterinary drugs***<br>  | Hormones, growth regulators, antibiotics… used for feed animal treatments. | Applicable | The origin of animal by-products needs to be taken into account to ensure that no residues are found in the incoming materials.<br>Occurrence of toxins veterinary drugs may be the result of a cross-contamination at the level of a premix plant and ultimately impacting the safety of the pet food product. |
| | ***Melamine***<br>  | *Melamine* is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. Is widely used in plastics and adhesives.<br>Several frauds during the past years to simulate a higher level of protein of some materials (the normal check of the protein level is done through a test measuring nitrogen | Applicable | The origin of raw materials used for the production of the pet food product needs to be taken into account to evaluate the level of risk<br>Occurrence also linked to residues of packaging (soft plastic). |

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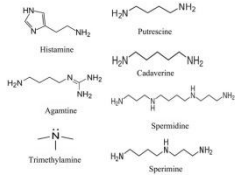
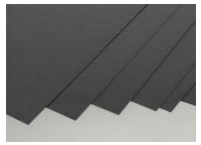
| | | content; the addition of melamine increases the nitrogen content of the material and therefore its apparent protein content) | | |
| | ***Peroxides / Free Fatty Acids (FFA)*** | *Peroxides* and *FFA* are the result of oxidation of grade oils and fats. This may provoke vomiting of cats and dogs. | Not applicable | Relevant only to dry pet food. |
| | ***Biogenic amines (incl. Histamine)***<br>  <br> | *Biogenic amines* are basic nitrogenous compounds formed mainly by decarboxylation of amino acids or by amination and transamination of aldehydes and ketones. High amount of biogenic amines may be an indication of material spoilage.<br>*Histamine* is naturally high in some fish species (e.g. tuna, mackerel, sardine…) and may have undesirable or harmful effect on dogs and/or cats (e.g. allergies). | Applicable | Quality of raw material may impact on the occurrence of the hazard. May also occur during the production process (standing time, temperature). |
| | ***Pesticides***<br>  | *Pesticides* are is something that prevents, destroys, or controls a harmful organism ('pest') or disease, or protects plants or plant products during production, storage and transport.<br>The term includes, amongst others: herbicides, fungicides, | Applicable | May occur at level of incoming materials as well as during production process via residues of sanitizing operations. |

| | | | | |
|---|---|---|---|---|
| | | insecticides, acaricides, nematicides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides. | | |
| | ***Lubricants***  | US FDA defines 3 types of lubricants:<br>- H1: lubricants that could have incidental food contact<br>- H2: lubricants with no possibility of contacting food<br>- H3: soluble oils | Applicable | Food lubricants are mostly used in pet food production. In case it is not, contamination may occur in finished pet food. |
| **Physical** | ***Glass***  | The presence of *glass* may origin from raw materials, factories environment (e.g. lab equipment, lightings…), primary packs or manpower (e.g. glasses, watches…) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |
| | ***Hard plastic***  | The presence of *hard plastic* may origin from raw materials (e.g. handling bins, weasand clips…), factories equipment (e.g. belts scrapers, elevators, protections…) or manpower (pens, identification badges…) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |
| | ***Metal***  | The presence of *metal* may origin from raw materials, factories equipment, engineering works (e.g. welding, screws and bolds…) or | Applicable | Raw materials contamination PRPs and CCPs are key to prevent occurrence of metal in pet food. |

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| | | manpower. | | |
| | ***Wood***  | The presence of *wood* may origin from raw materials, factories or engineering works. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |
| | ***Soft plastic & non-woven fabric***  | The presence of *soft plastic & non-woven fabric* may origin Raw materials (protection of frozen meat pallets, bags of dry materials, etc.) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |
| | ***Bones***  | The presence of *bones* origins from raw materials (processed animal proteins or cereals harvested in land with bones residues) | Applicable | Raw materials contamination. Factories cross-contamination May occur in case of wrong settings of the process steps of meat size reduction, or by cross-contamination in meat handling devices |
| | ***Stones***  | The presence of *stones* origins from raw materials such as vegetables, animal stomachs or from factories (e.g. floors) | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |
| | ***Pests*** | The presence of *pests* origins from either raw materials or factories environment. | Applicable | Raw materials contamination PRPs are key to prevent occurrence of glass in pet food. |

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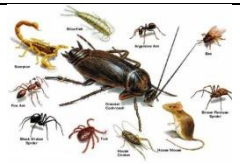
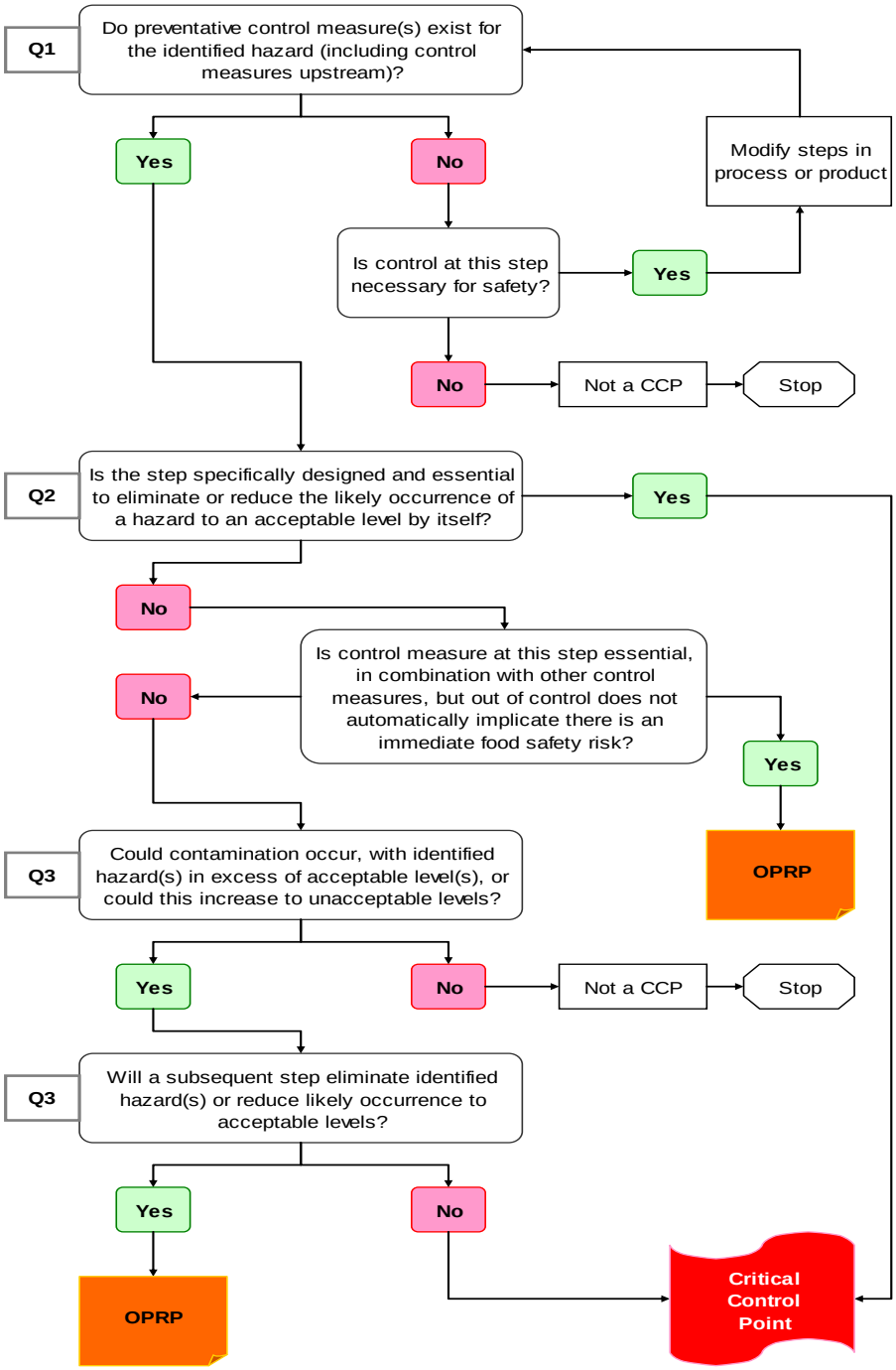
| |  | | | |
| | ***Workers' accessories*** | Workers' accessories such as jewels, ties, scarfs, glasses, watches may end up in pet food. | Applicable | PRPs are key to prevent occurrence of foreign materials in finished products. |
| | ***Mud, soil***<br>  | The presence of *mud and soil may* origin from either raw materials or factories environment. | Applicable | Raw materials contamination<br>PRPs are key to prevent occurrence of glass in pet food. |
| | ***Rubber***<br>  | The presence of *rubber* may origin from either raw materials or factories environment. | Applicable | Raw materials contamination<br>PRPs are key to prevent occurrence of glass in pet food. |

## Example of a decision-tree to identify CCPs and OPRPs



# ANNEX I. EUROPEAN PET FOOD LEGISLATION

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

**Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making up by weight or by volume of certain pre-packaged products**
The pre-packages may bear the so called "e mark" constituting a guarantee that they meet the weight and measures requirements of this Directive, including tolerances for packaging up to 10kg (annex 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.

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

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

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

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

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

- Feed materials may only be put into circulation in the EC if they are sound genuine and of merchantable quality.
- List of undesirable substances and the tolerated maximum levels in feed materials and feedingstuffs.
- Dilution and mixing with other consignments of feed materials or feedingstuffs is banned.

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

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

**Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**

- The Regulation applies to all stages of the production, processing and distribution of food and feed.
- It applies to feed produced for, or fed to, food producing animals, not directly to pet food. The Regulation's principles on safety, traceability, self-responsibilities and definitions must be observed by pet food manufacturers.
- Via Regulation 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).

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

- Animal and public health rules for the collection, transport, storage handling, processing and use or disposal of animal by-products, to prevent these products from presenting a risk to animal or public health.
- Approval of pet food plants including the requirements, which must be fulfilled by the plants.
- Specific health requirements for feed materials, processed animal proteins and pet food with regards to feed material origin (Category 3), heat treatment, prevention of re-contamination, packaging and microbiological testing.
- Health requirements and health certificates for import of animal by-products including feed materials, processed animal proteins and pet food from 3rd countries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 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.

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

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

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

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

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

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

**Directive 82/475 on the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals**
Lists and defines the 19 categories of feed materials that may be used in pet food and labelled as such on finished pet food products.

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

**European Register of feed additives**

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

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

# ANNEX II. PRACTICAL EXAMPLES OF CCPS AND OPRPS

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

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

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

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

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

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

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

| | | |
|---|---|---|
| | Chlorine) | 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 | Contamination or deterioration | Visual control |

| | | |
|---|---|---|
| package | due to loss of packaging integrity | |

**Table 4: Specific examples of CCPs and OPRPs for Chews**

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

**Table 5: Specific CCPs and OPRPs for small pets**

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

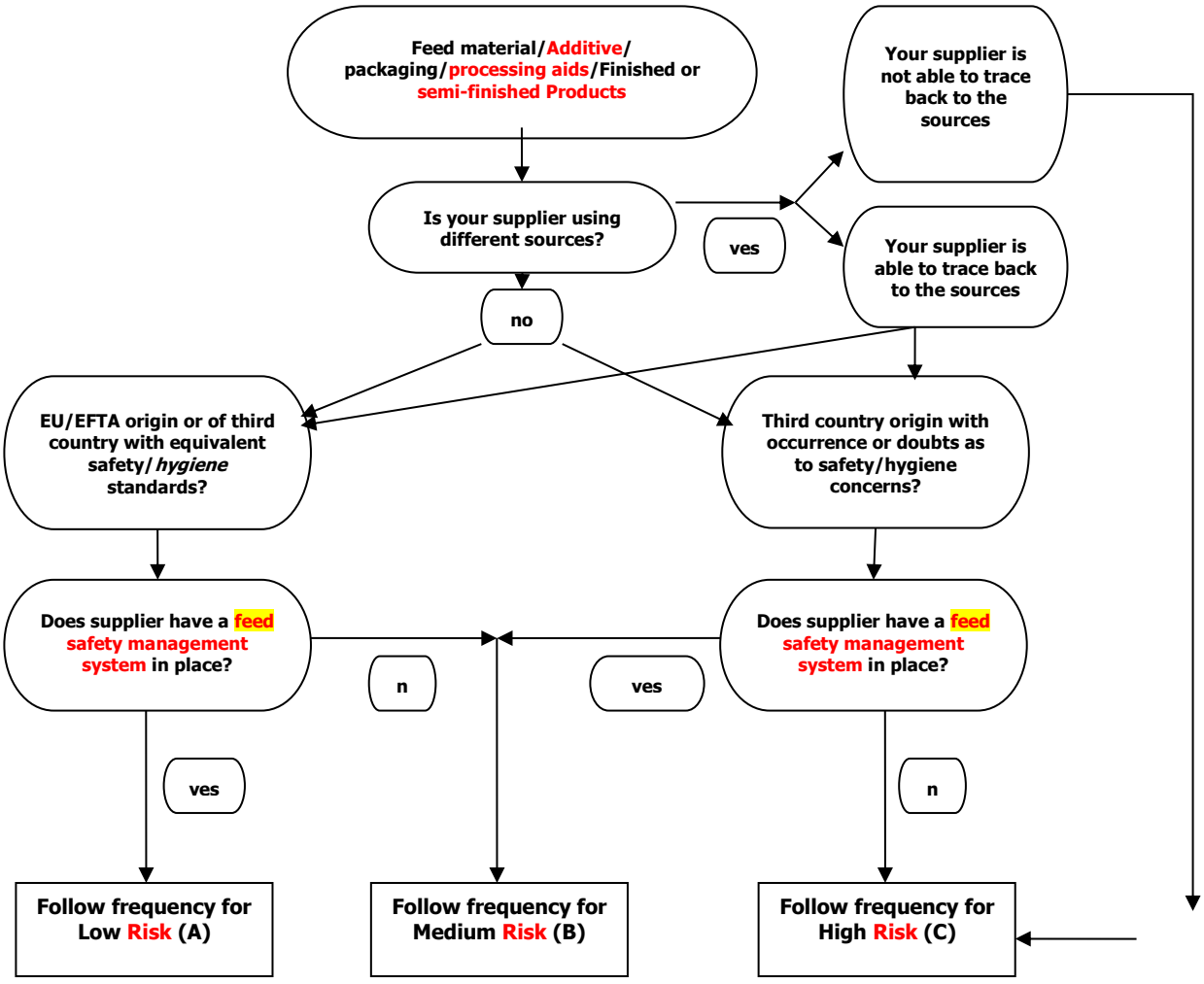
| Critical Control Point/OPRP depending on your HACCP | Hazard to be controlled | Typical Control Method |
|---|---|---|
| Transport / storage | Contamination or deterioration (e.g. humidity) | Assurance and inspection programme |
| Feed materials conform spec. | Incorrect or contaminated feed materials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

| | | |
|---|---|---|
| Storage of product | Microbial or mould growth | Aw/Warehouse assurance program |
| Handling of primary package | Contamination or deterioration due to loss of packaging integrity | Visual control, personnel training |

# ANNEX III. ASSESSMENT OF SUPPLIERS FOR THE PURPOSE OF CONTROLLING UNDESIRABLE SUBSTANCES AND CONTAMINANTS

This annex is describing an example on a way for management of vendors and their supplies. The proposed decision tree in section 1 shows how to determine the level of control needed and the level of frequency of checks to be done. The frequency must be established by the manufacturer on a case by case basis depending on the nature of the supply and the potential risk involved. The pet food operator needs to be able to show the feed safety risk is under control. Section 2 is an example of undesirable substances that need to be controlled. The list is not exhaustive and need to be adapted according the latest situation.

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



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

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

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

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

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

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

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

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