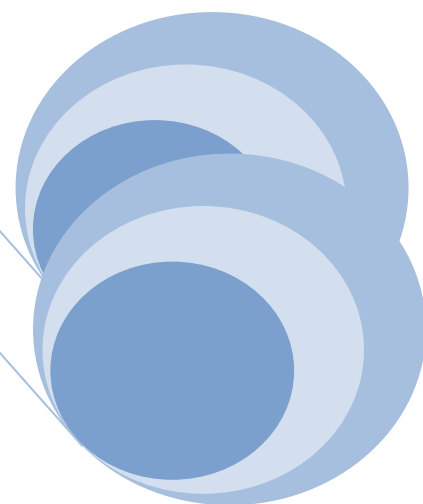


CN15: Conditions for approval of a plant involved in the production of processed petfood



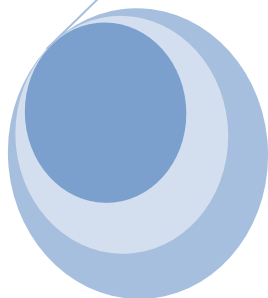
An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

CONDITIONS FOR APPROVAL OF A PLANT INVOLVED IN THE PRODUCTION OF PROCESSED PETFOOD



GOVERNING EU AND NATIONAL LEGISLATION:

The European Union (Animal By-Products) Regulation 2014 (S.I. No. 187 of 2014) and in accordance with Regulation (EC) No. 1069 of 2009 and Regulation (EU) No. 142 of 2011.



30th October 2014
Milk & Meat Hygiene/ABP/TSE Division

CN15: Conditions for approval of a plant involved in the production of processed petfood

CONDITIONS FOR APPROVAL OF A PLANT INVOLVED IN THE PRODUCTION OF PROCESSED PETFOOD

<u>CONTENTS</u>	<u>PAGE</u>
Glossary of terms	i
<u>Section 1: General Information/Requirements</u>	1-3
1.1 General Information and Requirements	1
1.2 Hazard Analysis and Critical Control Points (HACCP)	1-3
<u>Section 2: Biosecurity, Plant Structure, Hygiene and Transport</u>	4-8
2.1 Perimeter	4
2.2 Buildings/Structural	4
2.3 Plant Hygiene	4
2.4 Personnel and Workflows	5
2.5 Pests and Birds	5
2.6 ABP Transport and Signage	5-7
2.7 Plant Waste Disposal	8
<u>Section 3: Intake</u>	9-11
3.1 Raw Material Intake Procedures	9
3.2 Documentation	10&11
<u>Section 4: Processing/Handling</u>	12
4.1 Processing/Handling Requirements	12
4.2 Equipment	12
4.3 Cross-Contamination/By-Pass	12
<u>Section 5: Storage, Dispatch and Traceability/Recall</u>	13-14
5.1 Dispatch Procedures	13
5.2 Documentation	13&14
Contact Details	14

CN15: Conditions for approval of a plant involved in the production of processed petfood

GLOSSARY OF TERMS

A

‘**Animal By-Products**’ (ABP) means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen.

B

‘**Batch**’ means 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;

C

‘**Catering Waste**’ means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens

‘**Competent Authority**’ means the central authority of a Member State competent to ensure compliance with the requirements of EU ABP Regulations or any authority to which that competence has been delegated; it also includes, where appropriate, the corresponding authority of a third country;

D

‘**DAFM**’ means the Department of Agriculture, Food and the Marine;

‘**Derived products**’ means products obtained from one or more treatments, transformations or steps of processing of animal by-products;

E

‘**Establishment**’ or ‘**plant**’ means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel;

‘**EU**’ means the European Union.

F

‘**Feed Material**’ means 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;

O

‘**Operator**’ means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users.

R

‘**Raw petfood**’ means petfood containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing.

CN15: Conditions for approval of a plant involved in the production of processed petfood

SECTION 1

GENERAL INFORMATION AND REQUIREMENTS

1.1 GENERAL INFORMATION AND REQUIREMENTS

- A plant involved in the production of processed petfood (Animal By-Product (ABP)) must be approved and the approval must be in date. (EU Regulation 1069/2009, Article 24 (e))
- The operator must comply with all relevant requirements listed in the European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014) and EU Legislation (Regulation (EC) No. 1069/2009 and Regulation (EU) No.142/2011).
- Licenses and authorisations required to operate must be valid from all relevant licensing authorities while the plant is operational.
- The plant operator must notify DAFM immediately if significant changes are proposed to plant activities.
- The operator must notify DAFM immediately if the plant is no longer to be used for handling ABP. The plant must be decommissioned at this time and prior to use for any other activity. The operator will organise the decommissioning of the plant and clean up of the site and buildings as well as safe disposal of all equipment in a reasonable time period, under the direction of DAFM.
- The operator must provide data and statistics to DAFM as and when required and in whichever format requested.

1.2 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

- The plant must design, document and implement a HACCP plan incorporating all the following elements:
 - a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - b) identify the critical control points (CCPs) at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
 - c) establish critical limits at CCPs which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;
 - d) establish and implement effective monitoring procedures at CCPs;
 - e) establish corrective action when monitoring indicates that a CCP is not under control;

CN15: Conditions for approval of a plant involved in the production of processed petfood

- f) establish procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;
- g) establish documents and records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out in points (a) to (f) above.

This HACCP plan should also describe and document:

- clear responsibilities for all previous points and actions;
- the HACCP team and frequency of routine HACCP review;
- HACCP training;
- detailed process flow diagrams;
- detailed product descriptions and end-usages, including labelling of product.

The HACCP should be underpinned by a good set of pre-requisite programme procedures (for example hygiene, maintenance, traceability, calibration, final product testing).

When any modification is made to a product, process or any stage of production, processing, storage or distribution, operators shall review their procedures and make the necessary changes.

- A plan for Microbiological testing of final product (whether designated a CCP or not) must be documented in a Standard Operating Procedure (SOP) by the plant.

This operating procedure must be provided to the authorised officer who should agree it.

The operating procedure must incorporate the following elements: -

- definition of a batch. A batch is taken as a volumetric measurement. It will not suffice for a batch to be defined in general terms as a week's production or any given period of time. A batch should be the final product deriving from raw material processed during a specific process cycle.
- the prescribed frequency at which testing will take place.
- documented sampling apparatus and sample taking procedure.
- documented laboratory testing procedure and the laboratory to be employed to carry out said test. The testing procedure must be one that is internationally accredited by an accreditation body (e.g. INAB accredited in Ireland). Where plants are using their own on-site laboratory verification of testing at this on-site laboratory must take place by comparison with an external ISO-accredited independent laboratory.
- defined pre-determined corrective actions in the event of test results being non-compliant.

CN15: Conditions for approval of a plant involved in the production of processed petfood

Legislation:

'Microbiological standards for derived products

The following microbiological standards shall apply to derived products:

Samples of the final products taken during or on withdrawal from storage at the processing plant must comply with the following standards:

Salmonella: absence in 25 g: $n = 5$, $c = 0$, $m = 0$, $M = 0$

Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 300$ in 1 g

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m ;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M , the sample still being considered acceptable if the bacterial count of the other samples is m or less.

However, the microbiological standards set out in this Chapter shall not apply to rendered fats and fish oil from the processing of animal by-products, when the processed animal protein, which is obtained during the same processing, is subject to sampling to ensure compliance with those standards.'

- The records of tests and associated results must be suitably organised, retained on site and available to DAFM authorised officers.

CN15: Conditions for approval of a plant involved in the production of processed petfood

SECTION 2

BIOSECURITY, PLANT STRUCTURE, HYGIENE AND TRANSPORT

2.1 PERIMETER

- The premises must be located so that it is adequately separated from public highways, slaughterhouses and other appropriate premises sufficient to prevent cross-contamination of food and feed for humans and animals respectively. Animals must not be allowed access to the plant.

2.2 BUILDINGS/STRUCTURAL

- There must be a sufficiently large covered space to receive, handle and store the ABP. All ABP must be under cover.
- All buildings must be maintained, clean and in good condition and any necessary repairs must be made on a regular basis.
- The floors must be smooth and sloped to facilitate the drainage of liquids. The inner walls must be smooth, clean and well maintained.
- The layout of plants must ensure the total separation of Category 3 material from all other materials from reception until dispatch.
- The plant must be designed and personnel must work so as to assure adequate separation of the handling of materials for different end-usage destinations.
- There must be adequate separation between the area of the plant where incoming material for handling is unloaded and the areas set aside for the handling and the storage of products.
- Suitable office facilities where an examination of records can take place must be provided on site.

2.3 PLANT HYGIENE

- The operator must ensure that a hygiene plan has been designed and implemented effectively for all areas of the plant.
- All handling and storage locations and equipment must be emptied and cleaned regularly to the extent necessary to ensure hygienic practice.

CN15: Conditions for approval of a plant involved in the production of processed petfood

2.4 PERSONNEL AND WORKFLOWS

- Management of the plant must implement effective procedures and training plans for all operatives employed or subcontracted, ensuring to focus the procedures and training on:
 - safe handling of ABP and derived products;
 - supervision of processing, storage and transport temperature controls;
 - ensuring the acquisition and correct completion of documentation so as to contribute to safe intake of ABP, safe dispatch of ABP to suitable safe end-usage and safe dispatch of ABP 'waste' to suitable, legal disposal;Examples of documentation would include: -
 - Health certificates and associated ancillary documentation
 - Commercial documentation and proof of arrival at destination for documentation going with outgoing consignments.
- Operatives must use suitable dedicated protective clothing when handling ABP, which must be removed/cleaned/disinfected or discarded before leaving the plant.
- Footbaths/bootwashes must be provided at all entrances and exits to the plant.
- There must be access to adequate facilities for personal hygiene including lavatories, changing rooms and washbasins for staff. The washing facilities must be equipped with hot water, soap and paper towels.

2.5 PESTS AND BIRDS

- The operator must have a documented rodent control program in place which includes the following:
 - a bait map;
 - service schedule for bait points;
 - service records for bait points.

2.6 ABP TRANSPORT AND SIGNAGE

- Operators transporting ABP to the plant or from the plant must be registered ABP hauliers and listed on the DAFM's Animal By-Products transport register.
- The operator must maintain receptacle registers for each ABP haulier used (each haulier must provide each ABP plant they service with a copy of the receptacle register) which should contain the following information:
 - container number;
 - receptacle chassis number;
 - authorised ABP or derived product category;
 - registered owner;
 - date of listing/commission;
 - date of delisting/decommission;
 - date of cleaning and disinfection as indicated on cleaning certificate at time of delisting.

CN15: Conditions for approval of a plant involved in the production of processed petfood

- ABP transport vehicles must be designed so as to prevent any accidental discharge of organic material or liquids to the environment.
- The operator must have a system for cleaning and disinfecting the vehicles or re-useable containers or receptacles in which ABP are transported.
- Transport vehicles or containers must be dedicated to the carriage of a single Category of ABP or derived (final) product. Raw and processed product should not be transported in the same vehicle or container unless transport takes place in sealed packaging in both instances (preventing cross-contamination). Transport vehicles and containers must be permanently and prominently marked on both sides appropriately, as follows:

Raw ABP or Waste (Category 3 ABP)

- Haulier registration code¹ and receptacle number;
- The Category of ABP as well as the applicable ancillary wording

Example:

“CATEGORY 3 MATERIAL Not For Human Consumption”

- The labelling and the presentation of feed shall not mislead the user, in particular:
 - as to the intended use or characteristics of the feed, in particular, the nature, method of manufacture or production, properties, composition, quantity, durability, species or categories of animals for which it is intended;
 - by attributing to the feed effects or characteristics that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feeds possess such characteristics;
- The person responsible for the labelling shall ensure the presence and substantive accuracy of the labelling particulars. The person responsible for the labelling shall be the feed business operator who first places feed on the market or, where applicable, the feed business operator under whose name or business name the feed is marketed.
- A feed material or compound feed shall not be placed on the market unless the the following particulars are indicated by labelling:
 - a) the type of feed: ‘feed material’, ‘complete feed’ or ‘complementary feed’
 - for ‘complete feed’, the designation ‘complete milk replacer feed’ may be used, if appropriate,
 - for ‘complementary feed’, the following designations may be used if appropriate: ‘mineral feed’ or ‘complementary milk replacer feed’,
 - for pets other than cats and dogs, ‘complete feed’ or ‘complementary feed’ may be replaced by ‘compound feed’
 - b) the name or business name and the address of the feed business operator responsible for the labelling;
 - c) if available, the establishment approval number of the person responsible for the labelling
 - d) the batch or lot reference number;

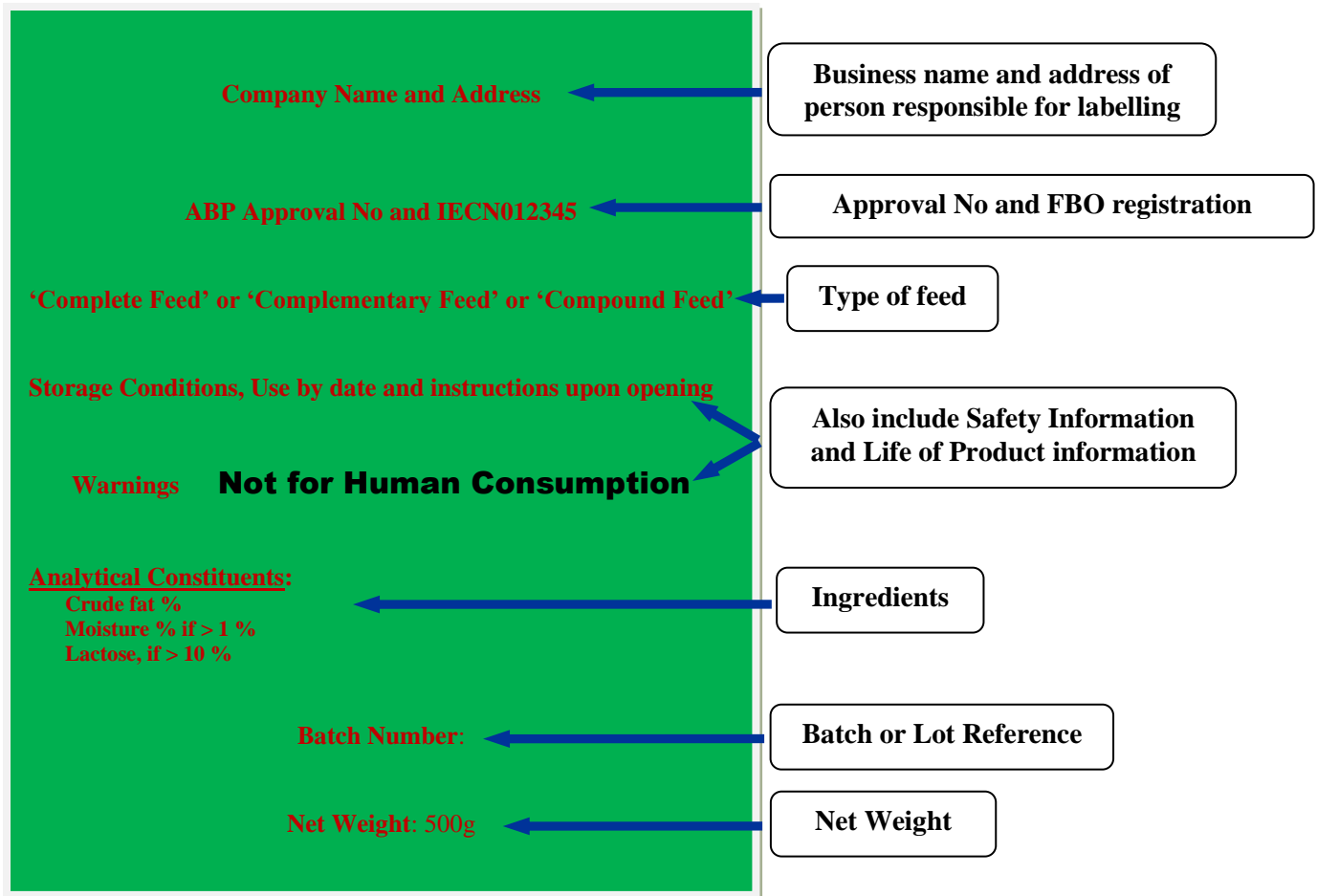
¹ The haulier must be officially registered with the Department of Agriculture, Food and the Marine.

CN15: Conditions for approval of a plant involved in the production of processed petfood

- e) the net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;
- f) the list of feed additives preceded by the heading ‘additives’.
- g) Safety information

Example:

Text in Red is required under feedingstuffs legislation.



- Plant operators must retain documentation on file to justify and support assertions, nutritional claims or labelling instructions.

This justification should include good support for claims in relation to minimum durability of product at different storage conditions, i.e. support for use by dates for example.

Research in relation to allergens or ingredients that may pose risks to humans or animals should also be documented and retained.

CN15: Conditions for approval of a plant involved in the production of processed petfood

2.7 PLANT WASTE DISPOSAL

- All waste ABP from the plant must be disposed of appropriately in compliance with national and EU legislation and in a way that mitigates risk. Traceability of waste disposal must be ensured.
- The operator must ensure to maintain and implement measures to prohibit the disposal of ABP, intermediate or derived products via the waste water stream. This may be achieved by the use of drain traps or screens with apertures with a filter pore or a mesh size of no more than 6 mm. Waste water that has passed through the screen is no longer regarded as ABP. However, the operator has a responsibility to ensure that waste water is treated in accordance with relevant Community environmental legislation. See Trader Notice 02/2011 which can be found on the DAFM website by using the following link:
<http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/animalbyproducts-tradernotices/>

CN15: Conditions for approval of a plant involved in the production of processed petfood

SECTION 3

INTAKE

3.1 RAW MATERIAL INTAKE PROCEDURES

- Only the raw materials listed in the conditions attached to the approval may be accepted into the plant.
- Processed Animal Protein (PAP) of mammalian origin where it is exclusively destined for use in petfood may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, provided that it is:
 - transported in dedicated containers that are not used for the transport of ABP or feedingstuffs for farmed animals, and
 - consigned directly from a processing plant for Category 3 material to the petfood plant or to an approved storage plant, from where it is directly consigned to a petfood plant.
- Management must organise for documentary and visual checks on raw material consignments to verify that only raw material allowed in this approval and which are safe will be accepted into the plant.
- The transport of ABP destined for the production of feed material or raw petfood must take place at an appropriate temperature, in the case of ABP from meat and meat products which have been destined for purposes other than human consumption, at a maximum of 7 °C, (unless the premises is approved as a collection centre and the ABP are exclusively used for feeding purposes in accordance with Chapter I of Annex II of 142/2011) in order to avoid any risk to animal or public health, and unless processing will take place within 24 hours.

Operators must communicate with suppliers ensuring in contracts and implemented procedures, including intake checks, that the cold-chain at the supplier premises and during transport has been maintained.

- Should Category 3 material at any stage become contaminated with Category 1 material or adulterated or contaminated with material that may be hazardous to humans or animals then it should not be accepted into the plant i.e. all of that material must be treated as Category 1 for the purposes disposal.

CN15: Conditions for approval of a plant involved in the production of processed petfood

3.2 DOCUMENTATION

- All Category 3 material delivered to the plant must be accompanied by a commercial document which meets the requirements as laid down in Annex VIII Chapter III of Regulation (EU) No. 142/2011, and, when required by the legislation, a health certificate.

Commercial documents must specify:

- the name and address of the consignor and approval number of the plant (If applicable);
- the name and address of the consignee and plant approval number (if applicable);
- the name and address of the carrier (haulier) and the registration number of the vehicle;
- the quantity/weight of the material;
- the date of dispatch;
- the container number (if applicable);
- the seal number (if applicable);
- a description of the material;
- signature of the consignor;
- signature of carrier (haulier).

Four copies of the commercial document must be produced.

Relevant Trader Notices can be found on the DAFM website by using the following link:

<http://www.agriculture.gov.ie/agri-foodindustry/animalbyproducts/animalbyproducts-tradernotices/>

A separate commercial document must be completed for each batch of material collected in the case of mixed loads. The consignor should send the original plus two copies with the ABP and retain the final copy. The carrier retains one copy and hands the original plus a copy to the receiver. The receiver should keep the original, sign and return the copy to the producer as proof of arrival of the consignment.

- The operator must keep an up to date intake register, completed appropriately, in chronological order and should include:
 - a description of the material including species of animal(s) and quantities;
 - dates of intake;
 - a batch reference or consignment number if appropriate;
 - a health certificate or commercial document reference number;
 - the name and address and country of the premises of origin (and approval number if applicable);
 - the name and address of the carrier/haulier and the receptacle registration number (if applicable);
 - date of notification of the District Veterinary Officer of intake of material (if relevant);

CN15: Conditions for approval of a plant involved in the production of processed petfood

- Weights of consignments of incoming material (preferably using a plant's own weighbridge).
- The operator must establish a system to notify the Competent Authority (District Veterinary Officer) when imported² ABP/derived products are received on site.
- All records must be accessible to DAFM and must be kept for a minimum of 3 years.

² Imported products are products received from non-EU countries.

CN15: Conditions for approval of a plant involved in the production of processed petfood

SECTION 4

PROCESSING/HANDLING

4.1 PROCESSING/HANDLING REQUIREMENTS

- Procedures on site should ensure the safe handling and temporary storage of ABP. ABP should be stored in temperature conditions that should be appropriate both in terms of mitigating public and animal health risks and preventing odours.
- All the time during storage the Category 3 material must be handled and stored separately from other goods and in such a way as to prevent the spread of disease. In the case of mixed loads, Category 3 material must be dispatched for lawful disposal within a reasonable timeframe.
- The operator must not engage in activities other than the acceptance, collection, sorting, treatment, temporary storage and dispatching of the Category 3 ABP specified in the plants approval.
- (a) Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.
(b) Processed petfood other than canned petfood must:
 - (i) be subjected to a heat treatment of at least 90 °C throughout the substance of the final product;
 - (ii) be subjected to a heat treatment to at least 90 °C of the ingredients of animal origin; or
 - (iii) be produced as regards feed material of animal origin exclusively using:
 - ABP or derived products from meat or meat products which have been subject to a heat treatment of at least 90 °C throughout their substance;
 - the following derived products which have been produced and transported in accordance with the requirements of EU legislation: milk and milk-based products, gelatine, hydrolysed protein, egg products, collagen, blood products referred to in Section 2 of Chapter II of Annex X, processed animal protein including fishmeal, rendered fat, fish oils, dicalcium phosphate, tricalcium phosphate or flavouring innards.

4.2 EQUIPMENT

- The operator must ensure that all measuring devices including weighbridges are calibrated and confirmed to be working effectively at least once every 12 months.
- If any significant changes to equipment or buildings are intended, the operator should contact the local District Veterinary Office to describe the changes. These changes must be sanctioned by an authorised officer prior to taking place.

4.3 CROSS-CONTAMINATION/BY-PASS

- All necessary measures must be taken to prevent contamination and the spreading of diseases communicable to humans or animals, throughout the production chain.

CN15: Conditions for approval of a plant involved in the production of processed petfood

SECTION 5

STORAGE, DISPATCH AND TRACEABILITY/RECALL

5.1 DISPATCH PROCEDURES

- The operator must ensure that ABP or products manufactured or derived from ABP, dispatched from the plant, are traceable and must be disposed of safely and in compliance with National and EU legislation. The prescribed end-usages are set out in the conditions attached to the Approval.
- ABP suspected or discovered not to comply with the legislation or the specific plant approval requirements may not leave the plant unless destined for disposal.

5.2 DOCUMENTATION

- Only the final destinations or usages listed in the conditions attached to the approval may be accepted into the plant. The operator must ensure that ABP consignments, or consignments of products manufactured or derived from ABP, dispatched from the plant are traceable and disposed of safely.
- The operator must keep an up to date dispatch register, completed appropriately, in chronological order and should include:
 - a description of the ABP (including waste), intermediate products or derived products dispatched (including quantities);
 - dates of dispatch;
 - a batch reference or consignment number if appropriate;
 - a health certificate or commercial document reference number;
 - the name and address and country of the premises of dispatch (and approval number if applicable);
 - the name and address of the carrier/haulier and the receptacle registration number (if applicable);
 - date of notification of the District Veterinary Office of dispatch (if relevant, e.g. for exportation);
 - Weights of consignments of incoming material (preferably using a plant's own weighbridge).
- The system of documentation must be sufficient so that raw material consignments from suppliers can be tracked to the specific process cycle where they receive heat treatment and from there to end-product consignments (with batch reference numbers) dispatched to customers.
- Copies of all health certificates issued must be retained. Health certificates may only be drawn up and signed by DAFM officials.
- The operator must retain proof of destination for all ABP consignments or consignments of products manufactured or derived from ABPs dispatched from the plant. This proof of destination would typically be the signed or stamped copy of the commercial document returned by the customer (consignee) or notification of arrival on the TRACES system.

CN15: Conditions for approval of a plant involved in the production of processed petfood

- All records must be accessible to DAFM and must be kept for a minimum of 3 years.
- The operator must implement a system of sampling and testing to check Category 3 material being dispatched to a raw petfood plant, as indicated below. This system must be pre-approved by a DAFM authorised officer prior to dispatching any material to a raw petfood plant:

Random samples must be taken from category 3 material during storage (before dispatch) to verify compliance with the following standards:

Salmonella: absence in 25 g, $n = 5$, $c = 0$, $m = 0$, $M = 0$.

Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 300$ in 1 g

Where: n = number of samples to be tested; m = threshold value for the number of bacteria; the result shall be considered satisfactory if the number of bacteria in all samples does not exceed m ; M = maximum value for the number of bacteria; the result shall be considered unsatisfactory if the number of bacteria in one or more samples is M or more; and c = number of samples the bacterial count of which may be between m and M , the sample shall still be considered acceptable if the bacterial count of the other samples is m or less.

- Operators must implement procedures to ensure continuity of the cold-chain during transport for all Category 3 material destined for pet-food production.

CONTACT DETAILS

For Further Information contact:

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