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Ministria e Bujqësisë, Pylltarisë dhe Zhvillimit Rural
Ministarstvo Poljoprivrede, Šumarstva i Ruralnog Razvoja/Ministry of Agriculture, Forestry and Rural Development

Minister of the Ministry of Agriculture, Forestry and Rural Development,

Pursuant to article 18 point (c) of the Law No. 2004/21 On Veterinary (Official Gazette, No.18/01 November 2007), article 4 paragraph 1 sub-paragraph 1.11), Article 11 paragraph 1 under paragraph 1.3 of Law No. 08/L-117 on the Government of the Republic of Kosovo (Official Gazette of the Republic of Kosovo / No. 34 / 18 November 2022), Annex 1: point 11. of the Regulation (GRK)-NO. 14/2023 on the Administrative Fields and Responsibilities of the Prime Minister Office and the Ministries (16.08.2023) as well as article 38, paragraph 6 of the Rules and Procedure of the Government No. 09/2011 (Official Gazette, No. 15, 12.09.2011),

Issues:

**ADMINISTRATIVE INSTRUCTION (MAFRD) - NO. 15/ 2023 IMPLEMENTING
ADMINISTRATIVE INSTRUCTION (MAFRD) 05/2022 LAYING DOWN HEALTH RULES FOR
ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREOF NOT INTENDED FOR
HUMAN CONSUMPTION**

CHAPTER I
GENERAL PROVISIONS

SUBCHAPTER I
PURPOSE, SCOPE AND DEFINITIONS

Article 1
Purpose

1.This Administrative Instruction lays down implementing measures:

1.1. for the public and animal health rules for animal by products and products derived thereof not intended for human consumption and

1.2. concerning certain samples and items exempt from veterinary checks at border inspection posts.

2. This Administrative Instruction is in accordance with the Commission Regulation (EC) No 142/2011 Laying down health rules as regards animal by-products and derived products not intended for human

consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, as last amended by Commission Regulation (EU) 2020/797 of 17 June 2020.

Article 2

Scope

The provisions of this Administrative Instruction are mandatory for all business operators dealing with animal by products and derived products throughout the territory of the Republic of Kosovo.

Article 3

Definitions

1. For the purpose of this Administrative Instruction, the following definitions shall apply:

1.1. fur animals- means animals kept or reared for the production of fur and not used for human consumption;

1.2. blood- means fresh whole blood;

1.3. Feed material- means feed materials, as defined in specific legislation in force on the placing on the market and use of feed, 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;

1.4. blood products means- derived products from blood or fractions of blood, excluding blood meal; they include dried/frozen/liquid plasma, dried whole blood, dried/frozen/liquid red cells or fractions thereof and mixtures;

1.5. processed animal protein” means animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex VIII of this Administrative Instruction.

1.5.1. including blood meal and fishmeal so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen;

1.6. Blood meal - means processed animal protein derived from the heat treatment of blood or fractions of blood in accordance with Section 1 of Chapter II of Annex VIII of this Administrative Instruction;

1.7. Fishmeal” means processed animal protein derived from aquatic animals except sea mammals, including farmed aquatic invertebrates, including those covered by specific legislation on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, and starfish of the species *Asterias rubens* which are harvested in a mollusc

production area, or oil from the processing of fish for human consumption, which an operator has destined for purposes other than human consumption;

1.8. Rendered fats means either fats derived from the processing of:

1.8.1. Animal by-products; or

1.8.2. Products for human consumption, which an operator has destined for purposes other than human consumption;

1.9. Fish oil means - oil derived from the processing of aquatic animals except sea mammals, including farmed aquatic invertebrates, including those covered by specific legislation on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, and starfish of the species *Asterias rubens* which are harvested in a mollusc production area, or oil from the processing of fish for human consumption, which an operator has destined for purposes other than human consumption;

1.10. Apiculture by-products-means honey, beeswax, royal jelly, propolis or pollen not intended for human consumption;

1.11. Collagen- means protein-based products derived from hides, skins, bones and tendons of animals;

1.12. Gelatine - means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals;

1.13. Greaves-means the protein-containing residue of rendering, after partial separation of fat and water;

1.14. Hydrolysed proteins -means polypeptides, peptides and aminoacids, and mixtures thereof, obtained by the hydrolysis of animal by-products;

1.15. White water- means a mixture of milk, milk-based products or products derived thereof with water which is collected during the rinsing of dairy equipment including containers used for dairy products, prior to their cleaning and disinfection;

1.16. Canned petfood- means heat-processed petfood contained within a hermetically sealed container;

1.17. Dogchews- means products for pet animals to chew, produced from untanned hides and skins of ungulates or from other material of animal origin;

1.18. Flavouring innards- means a liquid or dehydrated derived product of animal origin used to enhance the palatability values of petfood;

1.19. Petfood- means feed, other than material referred to in Article 26, paragraph 2 of this Administrative Instruction, for use as feed for pet animals, and dogchews consisting of animal by-products or derived products which:

1.19.1. Contain Category 3 material, other than material referred to in Article 10, paragraph 1, subparagraphs 1.14, 1.15 and 1.16 of the Administrative Instruction (MAFRD) - No.05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption, and

1.19.2. May contain imported Category 1 material comprising of animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 2, paragraph 2 and 3 of Administrative instruction (MAFRD) - NO.26/2005 on Measures for the monitoring certain substances and their residues in live animals and in products of animal origin of concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists in live animals and animal products.

1.20. Processed petfood- means petfood, other than raw petfood, which has been processed in accordance with paragraph 3 of Chapter II of Annex XI of this Administrative Instruction;

1.21. Raw petfood- means petfood containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing;

1.22. Catering waste- means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;

1.23. Digestion residues- means residues resulting from the transformation of animal by-products in a biogas plant;

1.24. Digestive tract content - means the content of the digestive tract of mammals and ratites;

1.25. Fat derivatives - means derived products from rendered fats, which, as regards rendered fats of Category 1 or Category 2 material, have been processed in accordance with Chapter XI of Annex XI of this Administrative Instruction;

1.26. Guano - means a natural product which has been collected from the excrements of bats or wild sea birds and which is not mineralised;

1.27. Meat-and-bone meal - means animal protein derived from the processing of Category 1 or Category 2 materials in accordance with one of the processing methods set out in Chapter III of Annex II of this Administrative Instruction;

1.28. Treated hides and skins - means derived products from untreated hides and skins, other than dogchews, that have been;

1.28.1.dried;

1.28.2.dry-salted or wet-salted for a period of at least 14 days prior to dispatch;

1.28.3.salted for a period of at least seven days in sea salt with the addition of 2 % of sodium carbonate;

1.28.4.dried for a period of at least 42 days at a temperature of at least 20 °C; or

- 1.28.5.subject to a preservation process other than tanning;
- 1.29. untreated hides and skins- means all cutaneous and subcutaneous tissues that have not undergone any treatment, other than cutting, chilling or freezing;
- 1.30. untreated feathers and parts of feathers- means feathers and parts of feathers, other than feathers or parts of feathers, which have been treated:
- 1.30.1. with a steam current; or
 - 1.30.2.by another method that ensures that no unacceptable risks remain;
- 1.31. untreated wool- means wool, other than wool which has:
- 1.31.1. undergone factory washing;
 - 1.31.2.been obtained from tanning;
 - 1.31.3. been treated by another method that ensures that no unacceptable risks remain;
 - 1.31.4. been produced from animals other than those of the porcine species, and has undergone factory-washing which consisting of the immersion of the wool in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
 - 1.31.5.been produced from animals other than those of the porcine species, is intended for being dispatched directly to a plant producing derived products from wool for the textile industry and has undergone at least one of the following treatments:
 - 1.31.6. chemical depilation by means of slaked lime or sodium sulphide;
 - 1.31.7. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
 - 1.31.8.industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60 - 70 °C;
 - 1.31.9.storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;
- 1.32. untreated hair` means hair, other than hair which has:
- 1.32.1. undergone factory washing;
 - 1.32.2. been obtained from tanning;
 - 1.32.3. been treated by another method that ensures that no unacceptable risks remain;

1.33.untreated pig bristles” means pig bristles, other than pig bristles which have:

1.33.1. undergone factory washing;

1.33.2.been obtained from tanning; or

1.33.3.been treated by another method that ensures that no unacceptable risks remain;

1.34. display item- means animal by-products or derived products intended for exhibitions or artistic activities;

1.35. intermediate product” means a derived product:

1.35.1.which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products as follows:

1.35.2. as material in a manufacturing process or in the final production of a finished product;

1.35.3. in validation or verification during a manufacturing process; or

1.35.4. in quality control of a finished product;

1.35.5. whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in subparagraph 1.35.1. of this paragraph;

1.35.6. which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products;

1.36. laboratory reagent-means a packaged product, ready for use, containing animal by-products or derived products and intended as such or in combination with substances of non-animal origin for specific laboratory use as a reagent or reagent product, calibrator or control material to detect, measure, examine or produce other substances;

1.37.product used for in vitro diagnosis- means a packaged product, ready for use, containing a blood product or another animal by-product, and used as a reagent, reagent product, calibrator, kit or any other system, whether used alone or in combination, intended to be used in vitro for the examination of samples of human or animal origin, solely or principally with a view to the diagnosis of a physiological state, state of health, disease or genetic abnormality or to determine safety and compatibility with reagents; it does not include donated organs or blood;

1.38. Research and diagnostic samples-means animal by-products and derived products intended for the following purposes: examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities;

1.39.trade samples- means animal by-products or derived products intended for particular studies or analyses authorised by the competent authority in accordance with Article 17, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment;

1.40 co-incineration means the recovery or disposal of animal by-products or derived products, if they are waste, in a co-incineration plant;

1.41 combustion-means a process involving the oxidisation of fuel in order to use the energy value of the animal by-products or derived products, if they are not waste;

1.42 incineration- means the disposal of animal by-products or derived products as waste, in an incineration plant, as defined in specific legislation on the incineration of waste;

1.43 incineration and co-incineration residues- means any residues as defined in specific legislation on the incineration of waste, which are generated by incineration or co-incineration plants treating animal by-products or derived products;

1.44.colour-coding-means the systematic use of colours as set out in paragraph 1, subparagraph 1.3 of Chapter II of Annex VI of this Administrative Instruction for displaying information as provided for in this Administrative Instruction on the surface or on part of the surface of a packaging, container or vehicle, or on a label or symbol;

1.45. intermediate operations-means the operations, other than storage, referred to in Article 20, paragraph 1, subparagraph 1.2 of this Administrative Instruction;

1.46.Tanning-means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents;

1.47. taxidermy-means the art of preparing, stuffing and mounting the skins of animals with lifelike effect, so that no unacceptable risks to public and animal health may be transmitted through the mounted skin;

1.48.trade-means trade of products between of the Republic of Kosovo and/ other countries;

1.49. Processing methods-means the methods listed in Chapters III and IV of Annex II of this Administrative Instruction;

1.50. 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;

1.51. Hermetically sealed container- means a container that is designed and intended to be secure against the entry of micro-organisms;

1.52. Biogas plant- means a plant in which animal by-products or derived products are at least part of the material which is submitted to biological degradation under anaerobic conditions;

1.53. Collection centres- means premises other than processing plants in which the animal by-products referred to in Article 18, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption are collected with the intention to be used for feeding to the animals referred to in the same article;

1.54. Composting plant- means a plant in which animal by-products or derived products are at least part of the material which is submitted to biological degradation under aerobic conditions;

1.55. Co-incineration plant- means any stationary or mobile plant whose main purpose is the generation of energy or the production of material products as defined by legislation in force;

1.56. Incineration plant- means any stationary or mobile technical unit and equipment dedicated to the thermal treatment of waste as defined in specific legislation on the incineration of waste;

1.57. Petfood plant- means premises or facilities for the production of petfood or flavouring innards, as referred to in Article 24, paragraph 1, subparagraph 1.5 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption;

1.58. Processing plant- means premises or facilities for the processing of animal by-products as referred to in Article 24, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption

1.59. Processing plant- means premises or facilities for the processing of animal by-products as referred to in Article 24, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption, in which animal by-products are processed in accordance with Annex II and/or Annex VIII of this Administrative Instruction.

1.60. Growing media- means materials, including potting soil, other than soil in situ, in which plants or mushrooms are grown and which is used independently from soil in situ;

1.61 Process hygiene criterion- means a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with general requirements for the safety of feed;

1.62.Competent authority-means the Food and Veterinary Agency.

1.63Administrative Instruction (MBPZHR) -NO.05/2022 Laying down Health Rules for Animal By-products and Derived Products that are not Intended for Human Consumption (henceforth in the entire text of this administrative instruction Administrative Instruction will be used (MAFRD)-NO.05/2022).

Article 4

End point in the manufacturing chain for certain derived products

1.The derived products may be placed on the market, other than imported, without restrictions, as provided in Article 5, paragraph 2 of Administrative Instruction (MAFRD) - No. 05/2022, as follows:

1.1.biodiesel which fulfils the requirements for the disposal and use of derived products set out in paragraph 2, subparagraph 2.2 of Section 3 of Chapter IV of Annex II of this Administrative Instruction;

1.1.processed petfood which fulfils the specific requirements for processed petfood set out in paragraph 7, subparagraph 7.1 of Chapter II of Annex XI of this Administrative Instruction;

1.2.dogchews which fulfil the specific requirements for dogchews set out in paragraph 7, subparagraph 7.2 of Chapter II of Annex XI of this Administrative Instruction;

1.3.hides and skins of ungulates which fulfil the specific requirements for the end point for those products set out in point B of Chapter VIII of Annex XI of this Administrative Instruction;

1.5.wool and hair, which fulfil the specific requirements for the end point for those products set out in point B of Chapter VII of Annex XI of this Administrative Instruction;

1.6. feathers and down, which fulfil the specific requirements for the end point for those products set out in point C of Chapter VII of Annex XI of this Administrative Instruction;

1.7.fur which fulfils the special requirements for the end point for that product set out in Chapter VIII of Annex XI of this Administrative Instruction;

1.8. fish oil for the production of medicinal products which fulfils the special requirements for the end point for that product set out in Chapter XIII of Annex XI of this Administrative Instruction;

1.9. gasoline and fuels which fulfil the specific requirements for products from the multi-step catalytic process for the production of renewable fuels set out in paragraph 2, subparagraph 2.3 of Section 3 of Chapter IV of Annex II of this Administrative Instruction;

1.10. oleochemical products derived from rendered fats and which fulfils the requirements set out in Chapter XI of Annex XI of this Administrative Instruction;

1.11. renewable diesel, renewable jet fuel, renewable propane and renewable gasoline which fulfil the specific requirements for products from the multi-step catalytic hydro-treatment for the production of

renewable fuels set out in paragraph 2, subparagraph 2.6 of Section 3 of Chapter IV of Annex II of this Administrative Instruction.

Article 5

Serious transmissible diseases

The diseases listed by the WHOA in Article 1.2.3 of the Terrestrial Animal Health Code, and in Chapter 1.3 of the Aquatic Animal Health Code, shall be regarded as serious transmissible diseases for the purposes of general animal health restrictions, as provided for in Article 6, paragraph 1, subparagraph 1.2.2 of Administrative Instruction (MAFRD) - No. 05/2022.

CHAPTER II

DISPOSAL AND USE OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS

RESTRICTIONS ON THE USE OF ANIMAL BY-PRODUCTS

Article 6

Feeding of farmed animals with herbage

1. Operators shall comply with the restrictions on the feeding of farmed animals with herbage from land to which certain organic fertilisers or soil improvers have been applied.

2. The following conditions shall apply to the feeding of farmed animals with herbage from land, either by direct access of the animals to that land or by using cut herbage as feed, provided that organic fertilisers or soil improvers have been applied to that land:

2.1. the waiting period of at least 21 days referred to in Article 11, paragraph 1, subparagraph 1.3 of Administrative Instruction (MAFRD) - No. 05/2022;

2.2. only organic fertilisers and soil improvers have been used which comply with Article 32, paragraphs 1 and 4 of Administrative Instruction (MAFRD) - No. 05/2022 and with Chapter II of Annex IX of this Administrative Instruction.

3. Conditions from paragraph 2 of this Article shall not apply, provided only organic fertilisers or soil improvers have been applied to land:

3.1. manure and guano;

3.2. digestive tract content, milk, milk-based products, milk-derived products, colostrum and colostrum products, which the competent authority does not consider to present a risk for the spread of any serious animal disease.

Article 7

Disposal by incineration, disposal or recovery by co-incineration and use as a fuel for combustion

1. The competent authority shall ensure that incineration and co-incineration of animal by-products and derived products shall only take place:

1.1.in incineration plants and co-incineration plants which have been granted a permit in accordance with the legislation on the incineration of waste in force; or

1.2.for plants not required to have a permit under legislation on the incineration of waste in force, in incineration and co-incineration plants which have been approved by the competent authority to carry out disposal by incineration, or disposal or recovery of animal by-products or derived products, if they are waste, by co-incineration, in accordance with Article 24, paragraph 1, subparagraphs 1.2 and 1.3 of Administrative Instruction (MAFRD) - No. 05/2022.

2.The competent authority shall only approve incineration plants and co-incineration plants as referred to in subparagraph 1.2 of this Article, in accordance with Article 24, paragraph 1, subparagraphs 1.2 and 1.3 of Administrative Instruction (MAFRD) - No. 05/2022 if they comply with the requirements set out in Annex I of this Administrative Instruction.

3.Operators of incineration plants and co-incineration plants shall comply with the general requirements for incineration and co-incineration set out in Chapter I of Annex I of this Administrative Instruction.

4.Operators of high-capacity incineration and co-incineration plants shall comply with the requirements of Chapter II of Annex I of this Administrative Instruction.

5.Operators of low-capacity incineration and co-incineration plants shall comply with the requirements of Chapter III of Annex I of this Administrative Instruction.

6.Operators shall ensure that combustion plants other than those referred to in Section 2 of Chapter IV of Annex II of this Administrative Instruction, under their control in which animal by-products or derived products are used as a fuel, comply with the general conditions and specific requirements set out in Chapters IV and V of Annex I of this Administrative Instruction, respectively and are approved by the competent authority in accordance with Article 24, paragraph 1, subparagraph 1.4 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption.

7.The competent authority shall only approve combustion plants referred to in paragraph 6 to this Article for the use of animal by-products and derived products as fuel for combustion, provided that:

7.1.the combustion plants fall within the scope of Chapter V of Annex I of this Administrative Instruction;

7.2.the combustion plants comply with all the relevant general conditions and specific requirements set out in Chapters IV and V of Annex I of this Administrative Instruction;

7.3. administrative procedures are in place to ensure that the requirements for the approval of the combustion plants are checked annually

8. For the use of manure of farmed animals or meat-and-bone meal as a fuel for combustion as set out in Chapter V of Annex I of this Administrative Instruction, the following rules shall apply in addition to those referred to in paragraph 7 of this Article:

8.1.the application for approval that is submitted by the operator to the competent authority in accordance with Article 24, paragraph 1, subparagraph 1.4 of Administrative Instruction (MAFRD) - No. 05/2022 must contain evidence certified by the competent authority or by a professional organisation authorised by the competent authority, that the combustion plant in which the manure of farmed animals or meat-and-bone meal is used as a fuel meets the requirements laid down in point B, paragraph 3 for manure, and point D in case of meat-and-bone meal as well as the requirements set out for both fuels in point B, paragraph 4 and 5 of Chapter V of Annex I to this Administrative Instruction, without prejudice to the possibility for the competent authorities to grant a derogation from compliance with certain provisions in accordance with point C, paragraph 5 of Chapter V of Annex I;

8.2. the procedure for approval provided for in Article 44 of the Administrative Instruction (MAFRD) - No. 05/2022 shall not be completed until at least two consecutive checks, one of them unannounced, have been carried out by the competent authority or by a professional organisation authorised by that authority, during the first six months of the operating of the combustion plant, including the necessary temperature and emission measurements. After the results of those checks showed compliance with the requirements set out in points B, paragraph 3, 4 and 5 for manure, and point D for meat-and-bone meal and, where applicable, with point C, paragraph 4 or point D, paragraph 5 of Chapter V of Annex I to this Administrative Instruction, full approval can be granted.

8.3. the combustion of meat-and-bone meal in combustion plants referred to in points A, B and C of Chapter V of Annex I to this Administrative Instruction shall not be authorised.

Article 8

Landfilling of certain Category 1 and 3 materials

1. By way of derogation from Article 12 and Article 14, paragraph 14, subparagraph 1.3 of Administrative Instruction (MAFRD) - No. 05/2022, the competent authority may authorise the disposal of the following Category 1 and 3 materials in an authorised landfill:

1.1.imported petfood or petfood produced from imported materials, from Category 1 material referred to in Article 8, paragraph 1, subparagraph 1.3 of Administrative Instruction (MAFRD) - No. 05/2022.

1.2.Category 3 material referred to in Article 10, paragraph 1, subparagraphs 1.6 and 1.7 of Administrative Instruction (MAFRD) - No. 05/2022 provided that:

1.2.1. such materials have not been in contact with any of the animal by-products referred to in Articles 8, 9 and Article 10, paragraph 1, subparagraphs 1.1 - 1.5, 1.8 - 1.16 of Administrative Instruction(MAFRD) - No. 05/2022 ;

1.2.2. at the time when they are destined for disposal, the materials:

1.2.2.1.referred to in Article 10, paragraph 1, subparagraph 1.6 of that Administrative Instruction have undergone processing as provided in the Regulation on hygiene of foodstuffs, and

1.2.2.2. referred to in Article 10, paragraph 1, subparagraph 1.7 of that Administrative Instruction have been processed in accordance with Chapter II of Annex VIII of this Administrative Instruction or in accordance with the specific requirements for petfood set out in Chapter II of Annex XI of this Administrative Instruction; and

1.2.2.3. the disposal of such materials does not pose a risk to public or animal health.

Article 9

Requirements for processing plants and other establishments

1. Operators shall ensure that processing plants and other establishments under their control comply with the following requirements set out in Chapter I of Annex II of this Administrative Instruction:

- 1.1. the general conditions for processing set out in Section 1;
- 1.2. the requirements for wastewater treatment set out in Section 2;
- 1.3. the specific requirements for the processing of Category 1 and 2 materials set out in Section 3;
- 1.4. the specific requirements for the processing of Category 3 materials set out in Section 4.

2. The competent authority shall only approve processing plants and other establishments, if they comply with the conditions laid down in Chapter I of Annex II of this Administrative Instruction.

Article 10

Hygiene and processing requirements for processing plants and other establishments

1. Operators shall ensure that establishments and plants under their control comply with the requirements set out in Annex II of this Administrative Instruction:

- 1.1. the hygiene and processing requirements set out in Chapter II;
- 1.2. the standard processing methods set out in Chapter III, provided such methods are used in the establishment or plant;
- 1.3. the alternative processing methods set out in Chapter IV, provided such methods are used in the establishment or plant.

Article 11

Requirements regarding the transformation of animal by-products and derived products into biogas and composting

1. Operators shall ensure that establishments and plants under their control comply with the following requirements for the transformation of animal by-products and derived products into biogas or for composting set out in Annex III of this Administrative Instruction:

- 1.1. the requirements applicable to biogas and composting plants set out in Chapter I;
- 1.2. the hygiene requirements applicable to biogas and composting plants set out in Chapter II;
- 1.3. the standard transformation parameters set out in Section 1 of Chapter III;

- 1.4. the standards for digestion residues and compost set out in Section 3 of Chapter III.
2. The competent authority shall only approve biogas and composting plants, if they comply with the requirements laid down in Annex III of this Administrative Instruction.
3. The competent authority may authorise the use of alternative transformation parameters for biogas and composting plants subject to the requirements set out in Section 2 of Chapter III of Annex III of this Administrative Instruction.

CHAPTER III

DEROGATIONS FROM CERTAIN PROVISIONS OF THE ADMINISTRATIVE INSTRUCTION (MAFRD) - NO. 05/2022 LAYING DOWN HEALTH RULES FOR ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREOF NOT INTENDED FOR HUMAN CONSUMPTION

Article 12

Special rules on research and diagnostic samples

1. The competent authority may authorise the transport, use and disposal of research and diagnostic samples under conditions which ensure the control of the risks to public and animal health. The competent authority shall in particular ensure that operators comply with the requirements of Chapter I of Annex IV of this Administrative Instruction.
2. Operators shall comply with the special rules on research and diagnostic samples set out in Chapter I of Annex IV of this Administrative Instruction.

Article 13

Special rules on trade samples and display items

1. The competent authority may authorise the transport, use and disposal of trade samples and display items under conditions which ensure the control of the risks to public and animal health. The competent authority shall in particular ensure that operators comply with the requirements of paragraph 2, 3 and 4 of Section 1 of Chapter I of Annex IV of this Administrative Instruction.
2. Operators shall comply with the special rules on trade samples and display items set out in Section 2 of Chapter I of Annex IV of this Administrative Instruction.

Article 14

Special feeding rules

1. Operators may feed Category 2 material to the following animals, provided that such material comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, subject to compliance with the general requirements laid down in Section 1 of Chapter II of Annex IV of this Administrative Instruction and any other conditions that may be laid down by the competent authority:

- 1.1. zoo animals;

- 1.2. fur animals;
- 1.3. dogs from recognised kennels or packs of hounds;
- 1.4. dogs and cats in shelters;
- 1.5. maggots and worms for fishing bait;
- 1.6. circus animals.

2. Operators may feed Category 3 material to the following animals subject to compliance with the general requirements laid down in Section 1 of Chapter II of Annex IV of this Administrative Instruction and any other condition that may be laid down by the competent authority:

- 2.1. zoo animals;
- 2.2. fur animals;
- 2.3. dogs from recognised kennels or packs of hounds;
- 2.4. dogs and cats in shelters;
- 2.5. maggots and worms for fishing bait;
- 2.6. circus animals.

Article 15

Feeding of certain species in and outside feeding stations and in zoos

1. The competent authority may authorise the use of Category 1 material consisting of entire bodies or parts of dead animals containing specified risk material for the feeding:

- 1.1. in feeding stations, to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity, subject to compliance with the conditions set out in Section 2 of Chapter II of Annex IV of this Administrative Instruction;
- 1.2. outside feeding stations, if appropriate without prior collection of the dead animals, to wild animals referred to paragraph 1, subparagraph 1.1 of Section 2 of Chapter II of Annex IV of this Administrative Instruction, subject to compliance with the conditions set out in Section 3 of that Chapter.

2. The competent authority may authorise the use of Category 1 material consisting of entire bodies or parts of dead animals containing specified risk materials and the use of material derived from zoo animals for the feeding of zoo animals subject to compliance with the conditions set out in Section 4 of Chapter II of Annex IV of this Administrative Instruction.

Article 16

Special rules on collection and disposal

1.If the competent authority authorises the disposal of animal by-products by way of the derogation provided for in Article 19, paragraph 1, subparagraph 1.1, 1.2, 1.3, 1.5 and 1.6 of Administrative Instruction (MAFRD) - No. 05/2022, the disposal shall comply with the following special rules set out in Chapter III of Annex IV of this Administrative Instruction:

1.1.the special disposal rules for animal by-products set out in Section 1, Chapter III, Annex IV of this administrative instruction;

1.2.the rules for the burning and burial of animal by-products in remote areas set out in Section 2, Chapter III, annex IV of this administrative instruction;

1.3.the rules for the burning and burial of bees and apiculture by-products set out in Section 3, Chapter III, Annex IV of this administrative instruction.

2.By way of derogation from Article 14 of Administrative Instruction (MAFRD) - No. 05/2022, competent authority may authorise the collection, transport and disposal of small quantities of Category 3 materials as referred to in Article 10, paragraph 1, subparagraph 1.6 of that Administrative Instruction by means referred to in Article 19, paragraph 1, subparagraph 1.4 of that Administrative Instruction, subject to compliance with the requirements for disposal by other means set out in Chapter IV of Annex IV of this Administrative Instruction.

CHAPTER IV AUTHORISATIONS OF ALTERNATIVE METHODS

Article 17

Standard format for applications for authorisation of alternative methods

1. Applications for authorisation of alternative methods of use or disposal of animal by-products or derived products, as referred to in Article 20, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 shall be submitted by interested parties in accordance with the requirements of the standard format for applications for alternative methods set out in Annex V of this Administrative Instruction.

2.Competent authority will set up rules for authorization of alternative method.

CHAPTER V COLLECTION,TRANSPORT, IDENTIFICATIONAND TRACEABILITY

Article 18

Requirements regarding commercial documents and health certificates, identification, the collection and transport of animal by-products and traceability

1.Operators shall ensure that animal by-products and derived products:

1.1.comply with the requirements for collection, transport and identification set out in Chapters I and II of Annex VI of this Administrative Instruction;

1.2. are accompanied during transport by commercial documents or health certificates in accordance with the requirements set out in Chapter III of Annex VI of this Administrative Instruction.

2. Operators consigning, transporting or receiving animal by-products or derived products shall keep records of consignments and related commercial documents or health certificates in accordance with the requirements set out in Chapter IV of Annex VI of this Administrative Instruction.

3. Operators shall comply with the requirements for the marking of certain derived products set out in Chapter V of Annex VI of this Administrative Instruction.

CHAPTER VI

REGISTRATION AND APPROVAL OF ESTABLISHMENTS AND PLANTS

Article 19

Requirements regarding the approval of one or more establishments and plants handling animal by-products on the same site

The competent authority may grant approval to more than one establishment or plant handling animal by-products on the same site, provided that the transmission of risks to public and animal health between the establishments or plants is excluded by their layout and the handling of animal by-products and derived products within the establishments or plants.

Article 20

Requirements concerning certain approved establishments and plants handling animal by-products and derived products

1. Operators shall ensure that establishments and plants under their control which have been approved by the competent authority, comply with the requirements set out in the following Chapters of Annex VII of this Administrative Instruction where they carry out one or more of the following activities referred to Article 24, paragraph 1 of the Administrative Instruction (MAFRD) - No. 05/2022:

1.1. chapter I, where they manufacture petfood as referred to in Article 24, paragraph 1, subparagraph 1.5 of this Administrative Instruction;

1.2. chapter II, where they store animal by-products as referred to in Article 24, paragraph 1, subparagraph 1.9 of Administrative Instruction 05/2022 and where they handle animal by-products after their collection, by way of the following operations referred to in Article 24, paragraph 1, subparagraph 1.8 of this Administrative Instruction:

1.2.1 sorting;

1.2.2 cutting;

1.2.3 chilling;

1.2.4 freezing;

1.2.5 salting;

- 1.2.6 preservation by other processes;
- 1.2.7 removal of hides and skins or removal of specified risk material;
- 1.2.8 operations involving the handling of animal by - products which are carried out in compliance with by he requirements of the respective legislation into force;
- 1.2.9 hygienisation/pasteurisation of animal by-products destined for transformation into biogas/composting, prior to such transformation or composting in another establishment or plant in accordance with Annex III of this Administrative Instruction;
- 1.2.10 sieving;
- 1.2.11 phase transition processes of Category 3 materials, such as:
 - 1.2.11.1. blood thermocoagulation,
 - 1.2.11.2. blood centrifugation,
 - 1.2.11.3. hydrolyzing of hooves, pig bristles, feathers and hair destined for processing with processing methods set out in this Administrative Instruction;
- 1.3 chapter III, where they store derived products for certain intended purposes as referred to in Article 24, paragraph 1, subparagraph 1.10 of Administrative Instruction (MAFRD) - No. 05/2022;
- 1.4 chapter V, where they store on the farm animal by-products as referred to in subparagraph 1.8 or 1.9 of Article 24, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022;
- 1.5. where the operations referred to sub subparagraphs 1.2.1 to 1.2.7 and 1.2.11 of this Article take place on the site of the approved establishment or plant referred to in Article 26, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 generating those materials, the competent authority may authorise the operation without registration in accordance with Article 23 of this Administrative Instruction or approval in accordance with Article 24, paragraph 1, subparagraph 1.8 of this Administrative Instruction, provided that the animal by-products are stored, transported and disposed of or used as unprocessed animal by-products in accordance with Administrative Instruction (MAFRD) - No. 05/2022.

Article 21

Requirements concerning certain registered establishments and plants handling animal by-products and derived products

- 1. Registered plants or establishments or other registered operators shall handle animal by-products and derived products under the conditions set out in Chapter II of Annex VII of this Administrative Instruction.
- 2. Registered operators transporting animal by-products or derived products, other than between premises of the same operator, shall in particular comply with the conditions set out in paragraph 2 of Chapter IV of Annex VII of this Administrative Instruction.

3.Paragraphs 1 and 2 of this Article shall not apply to:

3.1.approved operators who are transporting animal by - products or derived products as an ancillary activity;

3.2. operators who have been registered for transport activities in accordance with specific legislation on feed hygiene.

4.The competent authority may exempt the following operators from the obligation to notify, referred to in Article 23, paragraph 1, subparagraph 1.1. of Administrative Instruction (MAFRD) - No. 05/2022 if;

4.1.operators handling or generating game trophies or other preparations referred to in Chapter VI of Annex XI of this Administrative Instruction for private or non-commercial purposes;

4.2.operators handling or disposing research and diagnostic samples for educational purposes;

4.3.operators transporting dry untreated wool and hair, provided they are securely enclosed in packaging, and directly dispatched to a plant producing derived products for uses outside the feed chain or to a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents;

4.4.operators using small quantities of Categories 2 and 3 materials referred to in Articles 9 and 10 of Administrative Instruction (MAFRD) - No. 05/2022 or of products derived therefrom, for the purpose of direct supply of the products within the region to the final user, on the local market or to local retail establishments, if the competent authority does not consider such activity to present a risk of spreading any serious transmissible disease to humans or animals, this point shall not apply where those materials are used as feed for farmed animals other than fur animals;

4.5.users of organic fertilisers or soil improvers at premises where farmed animals are not kept;

4.6.operators handling and distributing organic fertilisers or soil improvers exclusively in ready-to-sell retail packaging of not more than 50 kg in weight for uses outside the feed and food chain.

Article 22

Lists of establishments, plants and operators

1.The competent authority shall ensure that up-to-date lists of establishments, plants and operators, referred to in the Article 47, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 how :

1.1.are drawn up in accordance with the technical specifications published on the European Commission website;

1.2.might entered in TRACES system when requested by the European Commission.

2.The lists of establishments, plants and operators shall be published on the website of competent authority.

CHAPTER VII

PLACING ON THE MARKET

Article 23

Processing and placing on the market of animal by- products and derived products for feeding to farmed animals, excluding fur animals

1. Operators shall comply with the following requirements for the placing on the market, other than the import, of the animal by-products and derived products destined for feeding to farmed animals excluding fur animals, as provided for in Article 31, paragraph 2 of the Administrative Instruction (MAFRD) - No. 05/2022 set out in Annex VIII of this Administrative Instruction:

- 1.1 the general requirements for the processing and the placing on the market set out in Chapter I;
- 1.2. the specific requirements for processed animal proteins and other derived products set out in Chapter II;
- 1.3. the requirements for certain fish feed and fishing baits set out in Chapter III.

2. The competent authority may authorise the placing on the market, other than the import, of milk, milk-based products and milk-derived products categorised as Category 3 material in accordance with Article 10, paragraph 1, subparagraphs 1.5, 1.6 and 1.8 of Administrative Instruction (MAFRD) - No. 05/2022 and which have not been processed in accordance with the general requirements set out in Part I of Section 4 of Chapter II of Annex VIII of this Administrative Instruction, provided that those materials comply with the requirements for the derogation for the placing on the market of milk processed in accordance with national standards set out in Part II of Section 4

Article 24

Placing on the market and use of organic fertilisers and soil improvers

1. Operators shall comply with the requirements for the placing on the market, other than the import, of organic fertilisers and soil improvers, and the use of such products, in particular their application to land, as provided for in Article 15, paragraph 1, subparagraph 1.9 and Article 32, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022, set out in Annex IX of this Administrative Instruction.

- 1.1. The placing on the market of the following is not subject to any animal health conditions:
- 1.2. guano from wild sea birds imported;
- 1.3. ready-to-sell growing media, other than that imported, with a content of less than:
 - 1.3.1 5 % in volume of derived products of Category 3 material or of Category 2 material other than processed manure;
 - 1.3.2 50 % in volume of processed manure.

2. When an organic fertiliser or a soil improver, which has been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein, is to be applied to land, the competent authority shall authorise one or more components which are to be mixed with those materials, in accordance with Article 32, paragraph 1, subparagraph 1.4 of Administrative Instruction (MAFRD) - No. 05/2022, according to the criteria set out in point 3 of Section 1 of Chapter II of Annex IX of this Administrative Instruction.

3. The competent authorities of the Republic of Kosovo as a country of origin and of a country of destination, which share a common border may authorise the dispatch of manure between farms located in border regions of those two countries subject to appropriate conditions for the control of any possible risks to public or animal health, such as obligations for the operators concerned to keep appropriate records, which are laid down in a bilateral agreement.

4. As provided for in Article 30, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022, the competent authority shall encourage, where necessary, the development, dissemination and use of national guides for good agricultural practice for the application of organic fertilisers and soil improvers to land.

Article 25

Intermediate products

1. Intermediate products, imported into or in transit through the Republic of Kosovo shall comply with the conditions controlling potential risks to public and animal health referred to in Annex X of this Administrative Instruction.

2. Intermediate products which have been transported to an establishment or plant referred to in point 3 of Annex X of this Administrative Instruction, may be handled without further restrictions under Administrative Instruction (MAFRD) - No. 05/2022 and under this Administrative Instruction, provided that:

2.1. the establishment or plant has adequate facilities for the receipt of the intermediate products, which prevent the transmission of diseases communicable to humans or animals;

2.2. the intermediate products do not pose any risk of transmission of diseases communicable to humans or animals, due to their purification or to other treatments to which the animal by-products in the intermediate product have been submitted, due to the concentration of animal by-products in the intermediate product or due to adequate bio-security measures for the handling of the intermediate products;

2.3. the establishment or plant keeps records on the amount of materials received, their category, if applicable, and the establishment, plant or operator to whom they have supplied their products; and

2.4. unused intermediate products or other surplus materials from the establishment or plant, such as expired products, are disposed of in accordance with Administrative Instruction (MAFRD) - No. 05/2022.

3. The operator or owner of the establishment or plant of destination of intermediate products or his representative shall use and/or dispatch the intermediate products exclusively for mixing, wrapping, gathering, packaging or further labeling according to the definition of intermediate products under subparagraph 1.35 of Article 3 of this Administrative Instruction.

Article 26

Petfood and other derived products

1.The use of Category 1 material referred to in Article 8, paragraph 1, subparagraph 1.1, 1.2, and 1.5 of Administrative Instruction (MAFRD) - No. 05/2022 for the manufacture of derived products which are intended to be ingested by or applied to humans or animals, other than for derived products referred to in Articles 33 and 36 of this Administrative Instruction shall be prohibited.

2.Where an animal by-product or a derived product may be used for feeding to farmed animals or for other purposes referred to in Article 36, paragraph 1, subparagraph 1.1 of the Administrative Instruction (MAFRD) - No. 05/2022, shall be placed on the market, other than imported, in accordance with the specific requirements for processed animal protein and other derived products set out in Chapter II of Annex VIII of this Administrative Instruction, provided that Annex XI of this Administrative Instruction does not set out any specific requirements for such products.

3.Operators shall comply with the requirements for the placing on the market, other than the import, of petfood, as referred to in Article 40 of the Administrative Instruction (MAFRD) - No. 05/2022 set out in Chapters I and II of Annex XI of this Administrative Instruction.

4.Operators shall comply with the requirements for the placing on the market, other than the import, of derived products, as referred to in Article 40 of Administrative Instruction (MAFRD) - No. 05/2022 set out in Chapter I and Chapters III to XII of Annex XI of this Administrative Instruction.

CHAPTER VIII

IMPORT, TRANSIT AND EXPORT

Article 27

Import, transit and export of animal by-products and of derived products

1.The importation into and the transit through the Republic of Kosovo of the following animal by-products shall be prohibited:

1.1. unprocessed manure;

1.2. wool and hair which has been factory-washed or which has been treated by another method which ensures that no unacceptable risks remain;

1.3. untreated feathers and parts of feathers and down;

1.4.beeswax in the form of honeycomb.

2.The importation into and the transit through the Republic of Kosovo of the following shall not be subject to any animal health conditions:

2.1.wool and hair which has been factory-washed or which has been treated by another method which ensures that no unacceptable risks remain;

2.2.furs which have been dried at an ambient temperature of 18°C for a period of at least two days at a humidity of 55 %;

2.3.wool and hair produced from animals other than those of the porcine species, which has been treated by factory-washing which consisting of the immersion of the wool and hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide;

2.4.wool and hair produced from animals other than those of the porcine species, which is dispatched directly to a plant producing derived products from wool and hair for the textile industry and has been treated by at least one of the following methods:

2.4.1.chemical depilation by means of slaked lime or sodium sulphide,

2.4.2.fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours,

2.4.3.industrial scouring which consists of the immersion of wool and hair in a water-soluble detergent held at 60 - 70 °C,

2.4.4.storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;

2.5.wool and hair that is dry and securely enclosed in packaging, produced from animals other than those of the porcine species, which is intended for dispatch to a plant producing derived products from wool and hair for the textile industry and meets all of the following requirements:

2.5.1.it was produced at least 21 days before the date of entry into the Republic of Kosovo kept in a country or region thereof which is;

2.5.2.EU country or other country from which imports to EU of fresh meat of ruminants is authorized.

2.6.free of foot-and-mouth disease, and, in the case of wool and hair from sheep and goats, of sheep pox and goat pox in accordance with the legislation in force;

2.7.it is accompanied by a importers' declaration as required in accordance with paragraph 1, subparagraph 1.37 of Annex XIII of this Administrative Instruction;

2.8.it was presented by the operator to the border inspection posts where it passed with satisfactory result the documentary check.

3. Operators shall comply with the following specific requirements for the importation into and the transit through the Republic of Kosovo of certain animal by-products and derived products, as referred to in Articles 41, paragraph 3 and Article 42 of the Administrative Instruction (MAFRD) - No. 05/2022 set out in Annex XII of this Administrative Instruction.

4.the specific requirements for the import and transit of Category 3 material and derived products for uses in the feed chain, other than for petfood or feed to fur animals, set out in Chapter I of that Annex XII;

5.the specific requirements for the import and transit of animal by-products and derived products for uses outside the feed chain for farmed animals, set out in Chapter II of that Annex XII;

6.the specific requirements for animal by-products and derived products originating from, and returning to, the Republic of Kosovo following a refusal of entry by a other country, set out in Chapter VI of that Annex XII.

7.The rules set out in Chapter V of Annex XII shall apply to exports from the Republic of Kosovo of the derived products specified therein.

Article 28

Placing on the market, including importation, and export of certain Category 1 materials

1.The competent authority may authorise the placing on the market, including the importation, and the export of hides and skins derived from animals which have been submitted to an illegal treatment as defined in specific legislation concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists and of ruminant intestines with or without content and of bones and bone products containing vertebral column and skull, subject to compliance with the following requirements:

1.1.those materials must not be Category 1 materials derived from any of the following animals:

1.1.1. animals suspected to be infected with TSE disease in accordance with the legislation in force;

1.1.2. animals in which the presence of TSE has been officially confirmed;

1.1.3. animals killed in the context of measures for the eradication of TSE;

1.2 these materials must not be intended for any of the following uses:

1.2.1 feeding;

1.2.2 application to land from which farmed animals are fed;

1.3.the manufacture of:

1.3.1. cosmetic products as defined in specific legislation on cosmetic products in force;

1.3.2.active implantable medical devices as defined by the legislation in force;

1.3.3.medical devices as defined as defined by the legislation in force;

1.3.4.in vitro diagnostic medical devices as defined by the legislation in force;

1.3.5.veterinary medicinal products as defined by the legislation in force;

1.3.5.medicinal products as defined by the legislation in force;

1.4. The materials must be imported with a label and must comply with the specific requirements for certain movements of animal by-products set out in Section 1 of Chapter IV of Annex XII of this Administrative Instruction;

1.5. the materials must be imported in accordance with certification requirements laid down by legislation in force;

1.6. the materials originating from Republic of Kosovo and returning to Republic of Kosovo following a refusal of entry by another country, must comply with the specific requirements set out in Chapter VI of Annex XII of this Administrative Instruction.

Article 29

Importation and transit of research and diagnostic samples

1.The competent authority may authorise the importation and the transit of research and diagnostic samples, comprising derived products or animal by-products, including the animal by-products referred to in Article 25, paragraph 1 of this Administrative Instruction in accordance with conditions which ensure the control of risks to public and animal health. Such conditions shall include at least the following:

1.1. the introduction of the consignment must have been authorised in advance by the competent authority; and

1.2. the consignment must be sent directly from the point of entry into the Republic of Kosovo to the authorised user.

2.Operators handling research samples or diagnostic samples shall comply with the special requirements for disposal of research and diagnostic samples set out in Section 1 of Chapter III of Annex XII of this Administrative Instruction.

Article 30

Importation and transit of trade samples and display items

1.The competent authority may authorise the importation and the transit of trade samples in accordance with the special rules set out in paragraph 1 of Section 2 of Chapter III of Annex XII of this Administrative Instruction.

2.Operators handling trade samples shall comply with the special rules for handling and disposal of trade samples set out in paragraph 2 and 3 of Section 2 of Chapter III of Annex XII of this Administrative Instruction.

3.The competent authority may authorise the importation and the transit of display items in accordance with the special rules for display items set out in Section 3 of Chapter III of Annex XII of this Administrative Instruction.

4. Operators handling display items shall comply with the conditions for packaging, handling and disposal of display items set out in Section 3 of Chapter III of Annex XII of this Administrative Instruction.

Article 31

Lists of establishments and plants of other countries

1. Import into Republic of Kosovo is allowed only from:

1.1. EU listed registered or approved establishments;

1.2. Other third countries registered and approved establishments authorized to export into EU;

1.3. Other countries registered and approved establishments listed on the basis of bilateral agreement between Republic of Kosovo and that country.

Article 32

Models of health certificates and declarations for importation and transit

1. Consignments of animal by-products and derived products for importation into or transit through the Republic of Kosovo shall be accompanied by EU model health certificates laid down in Annex XII of this administrative instruction, at the point of entry into the Republic of Kosovo where the veterinary checks take place.

2. The list of certificates and related notes are laid down in Annex XIII of this Administrative Instruction.

3. For the models of certificates listed in appendix XIII will be obtained from the European Commission system TRACES

4. By way of derogation from the paragraph 1 to this Article, animal by-products and derived products originating from, and returning to the Republic of Kosovo following a refusal of entry by another country, must comply with the specific requirements set out in Chapter VI of Annex XII of this Administrative Instruction.

CHAPTER IX

OFFICIAL CONTROLS

Article 33

Official controls

1. The competent authority shall take the necessary measures to control the entire chain of collection, transport, use and disposal of animal by-products and derived products, as referred to in Article 4, paragraph 2 of Administrative Instruction (MAFRD) - No. 05/2022. Those measures shall be carried out in accordance with the principles for official controls laid down by legislation in force on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

2.The official controls referred to in paragraph 1 to this Article shall include checks on the keeping of records and other documents required by the rules laid down in this administrative instruction.

3.The competent authority shall carry out the following official controls, as referred to in Article 45, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/ in accordance with the requirements set out in Annex XIV in this Administrative Instruction:

3.1.official controls in processing plants as set out in Chapter I;

3.2. official controls of other activities which involve the handling of animal by-products, and derived products as set out in Sections 1 to 9 of Chapter II.

4.The competent authority shall carry out checks on seals which are applied to consignments of animal by-products or derived products.

5.When the competent authority applies a seal to such consignment which is transported to a place of destination, it must inform the competent authority of the place of destination.

6.The competent authority shall decide upon the application by an operator concerning the acceptance or refusal of certain Category 1, Category 2 material and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials, within 20 calendar days from the date of receipt of such application provided that it has been submitted in at least in Albanian and Serbian as official languages of the Republic of Kosovo.

Article 34

Reapproval of plants and establishments after the grant of a temporary approval

1.Where a plant or establishment approved for the processing of Category 3 material is subsequently granted temporary approval for the processing of Category 1 or Category 2 material, in accordance with Article 24, paragraph 2, subparagraph 2.2, sub subparagraph 2.2.2 of the Administrative Instruction (MAFRD) - No. 05/2022 it shall be prohibited from recommencing the processing of Category 3 material, without first obtaining the approval of the competent authority to recommence processing of Category 3 material in accordance with Article 44 of this Administrative Instruction.

2.Where a plant or establishment approved for the processing of Category 2 material is subsequently granted temporary approval for the processing of Category 1 material, in accordance with Article 24, paragraph 2, subparagraph 2.2, sub subparagraph 2.2.2 of the Administrative Instruction (MAFRD) - No. 05/2022 it shall be prohibited from recommencing the processing of Category 2 material, without first obtaining the approval of the competent authority to recommence processing of Category 2 material in accordance with Article 44 of Administrative Instruction (MAFRD) - No. 05/2022.

CHAPTER X FINAL PROVISIONS

Article 35

Restrictions on the placing on the market of certain animal by-products and derived products for reasons of public and animal health

1.The competent authority shall not prohibit or restrict the placing on the market of the following animal by-products and derived products for public health or animal health reasons other than the rules laid down in the legislation of the Republic of Kosovo, and in particular those laid down in the Administrative Instruction (MAFRD) - No. 05/2022:

1.1.processed animal protein and other derived products referred to in Chapter II of Annex X of this Administrative Instruction;

1.2.petfood and certain other derived products referred to in Annex XIII of this Administrative Instruction;

1.3.animal by-products and the derived products imported into or in transit through the Republic of Kosovo as referred to in Annex XIV of this Administrative Instruction.

Article 36

1. An integral part of this Administrative Instruction are the Annexes as follows:

1.1.Annex I: Disposal and recovery;

1.2.Annex II :Procesing;

1.3.Annex III:Transformation of the ABP and derived products into biogas, compost;

1.4.Annex IV: Special rules on research, feeding, collection and disposal;

1.5. Annex V:Standard format for application for alternative methods;

1.6.Annex VI : Collection, transport and traceability;

1.7. Annex VII: Requirements applicable to certain approved and registered establishments;

1.8.Annex VIII:Feeding materials;

1.9.Annex IX:Organic fertilisers and soil improvers;

1.10.Annex X:Intermediary products;

1.11.Annex XI: Animal feed for domestic materials and other derivative products;

1.12.annex XII:Import, export and transit;

1.13.Annex XIII: Models of the Health Certificates and

1.14.annex XIV: Official Controls.

Article 37
Entry into force

This administrative instruction enters into force seven (7) days after the publication in the Official Gazzete of the Republic of Kosovo.

The Minister of the Ministry of Agriculture, Forestry and Rural Development



ANNEX I

DISPOSAL, RECOVERY AND USE AS A FUEL

CHAPTER I

GENERAL REQUIREMENTS FOR INCINERATION AND CO-INCINERATION

Section 1

General conditions

1. Operators of incineration and co-incineration plants referred to in Article 7, paragraph 1, subparagraph 1.2 of this Administrative Instruction shall ensure that the following hygiene conditions are met in the plants under their control:

1.1. Animal by-products and derived products must be disposed of as soon as possible after arrival, in accordance with conditions laid down by the competent authority. They shall be stored properly until disposal, in accordance with conditions laid down by the competent authority.

1.2. Plants must have appropriate arrangements for the cleaning and disinfection of containers and vehicles in place, in particular in a designated area from which wastewater is disposed of in accordance with legislation in force, to avoid risks of contamination.

1.3. Plants must be located on a well-drained hardstanding material.

1.4. Plants must have appropriate arrangements for protection against pests, such as insects, rodents and birds. A documented pest control programme must be used for that purpose.

1.5. Staff must have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins, if necessary to prevent risks of contamination;

1.6. Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning;

1.7. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.

2. The operator of an incineration or co-incineration plant shall take all necessary precautions concerning the reception of animal by-products or derived products to prevent, or limit as far as practicable, direct risks to human or animal health.

3. Animals must not have access to the plants, animal by-products and derived products that are awaiting incineration or co-incineration or to ash resulting from the incineration or co-incineration of animal by-products.

4. If the incineration or co-incineration plant is located on a livestock holding:

4.1. there must be total physical separation between the incineration or co-incineration equipment and the livestock and their feed and bedding, with fencing where necessary;

- 4.2. equipment must be dedicated entirely to the operation of the incinerator and not used elsewhere on the holding or, alternatively, cleaned and disinfected before such use;
- 4.3. personnel working in the plant must change their outer clothing and footwear before handling livestock or livestock feed.
5. The storage of animal by-products and derived products that are awaiting incineration or co-incineration and of ashes must be in covered, correctly identified and, if appropriate, leak proof containers.
6. Incompletely incinerated animal by-products must be re-incinerated or disposed of by other means, other than by disposal in an authorised landfill, in accordance with Articles 12, 13 and 14, as referred in the Administrative Instruction (MAFRD) - No. 05/2022.

Section 2

Operating conditions

Incineration or co-incineration plants shall be designed, equipped, built and operated in such a way that the gas resulting from the process is raised in a controlled and homogeneous fashion, even under the most unfavourable conditions, to a temperature of 850 °C for at least 2 seconds or to a temperature of 1 100 °C for 0.2 seconds, as measured near the inner wall or at another representative point of the chamber where the incineration or the co-incineration is carried out, as authorised by the competent authority.

Section 3

Incineration and co-incineration residues

1. Incineration and co-incineration residues shall be minimised in their amount and harmfulness. Such residues must be recovered, where appropriate, directly in the plant or outside it in accordance with relevant legislation in force or disposed of in an authorised landfill.
2. Transport and intermediate storage of dry residues, including dust, shall take place in such a way as to prevent dispersal in the environment, such as in closed containers.

Section 4

Measurement of temperature and of other parameter

1. Techniques shall be used to monitor the parameters and conditions relevant to the incineration or co-incineration process.
2. The approval issued by the competent authority, or conditions attached to it, shall lay down temperature measurement requirements.
3. The functioning of any automated monitoring equipment shall be subject to control and to an annual surveillance test.
4. Temperature measurement results shall be recorded and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions laid down in this Administrative Instruction in accordance with procedures to be decided upon by the competent authority.

Section 5

Abnormal operating

In the case of a breakdown, or abnormal operating conditions of an incineration plant or a co-incineration plant, the operator shall reduce or close down operations as soon as practicable until normal operations can be resumed.

CHAPTER II

HIGH-CAPACITY INCINERATION AND CO-INCINERATION PLANTS

Section 1

Specific operating conditions

1. Incineration or co-incineration plants treating only animal by-products and derived products with a capacity of more than 50 kg per hour (high-capacity plants) and which are not required to have a permit to operate in accordance with legislation on the incineration of waste shall comply with the following conditions:

1.1. The plants must be equipped for each line with at least one auxiliary burner. This burner shall be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 850 °C or 1 100 °C, as applicable. It must also be used during plant start-up and shut-down operations to ensure that the temperature of 850 °C or of 1 100 °C, as applicable, is maintained at all times during these operations and as long as unburned material is in the chamber where the incineration or co-incineration is carried out.

1.2. When animal by-products or derived products are introduced into the chamber where the incineration or co-incineration is carried out by a continuous process, the plant must operate an automatic system to prevent the introduction of animal by-products or derived products at start-up, until the temperature of 850 °C or of 1 100 °C, as applicable, has been reached, and whenever the temperature is not maintained.

1.3. The operator must operate the incineration plant in such manner that a level of incineration is achieved such that the slag and bottom ashes total organic carbon content is less than 3 % or their loss on ignition is less than 5 % of the dry weight of the material. If necessary, appropriate techniques of pre-treatment shall be used.

Section 2

Water discharges

1. Sites of high capacity plants, including associated storage areas for animal by-products, shall be designed in such a way as to prevent unauthorised and accidental release of any polluting substances into soil, surface water and groundwater.

2. Storage capacity shall be provided for contaminated rainwater run-off from the plant site or for contaminated water arising from spillage or firefighting operations.

3. If necessary the operator shall, ensure that such rainwater and such water can be tested and treated before discharge, when necessary.

CHAPTER III

LOW-CAPACITY INCINERATION AND CO-INCINERATION PLANTS

1. Incineration and co-incineration plants treating only animal by-products and derived products with a maximum capacity of less than 50 kg of animal by-products per hour or per batch (low-capacity plants) and which are not required to have a permit to operate in accordance with specific legislation on the incineration of waste shall:

1.1. only be used for the disposal of:

1.1.1. dead pet animals referred to in Article 8, paragraph 1, subparagraph 1.1 sub-subparagraph 1.1.3 of the Administrative Instruction (MAFRD) - No. 05/2022.

1.1.2. Category 1 materials referred to in Article 8, paragraph 1, subparagraph 1.2, 1.5 and 1.6, Category 2 materials referred to in Article 9 or Category 3 materials referred to in Article 10 to this the Administrative Instruction and

1.1.3. when Category 1 materials referred to in Article 8, paragraph 1, subparagraph 1.2 of the Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption are introduced into the low - capacity plant, be equipped with an auxiliary burner;

1.1.4. operate in such way that the animal by-products are completely reduced to ash.

CHAPTER IV

GENERAL REQUIREMENTS FOR THE USE OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS AS A FUEL

Section 1

General requirements regarding the combustion of animal by-products and derived products as a fuel

1. Operators of combustion plants referred to in Article 7, paragraph 6 of this Administrative Instruction shall ensure that the following conditions are met in the combustion plants under their control:

1.1. Animal by-products and derived products intended to be used as a fuel must be utilised for that purpose as soon as possible or safely stored until used.

1.2. The combustion plants must have in place appropriate measures to ensure that cleaning and disinfection of containers and vehicles are carried out in a designated area of their premises from which the wastewater can be collected and disposed of in accordance with legislation in force, to avoid risks of contamination of the environment.

2. By way of derogation from the requirements set out in the subparagraph 1.1 of this Section containers and vehicles used for the transport of rendered fats may be cleaned and disinfected at the plant of loading or at any other plant approved or registered under Administrative Instruction (MAFRD) - No. 05/2022 as:

2.1. the combustion plants must be located on a well-drained hard standing.

2.2. the combustion plants must have appropriate measures in place for the protection against pests. A documented pest control programme must be used for that purpose;

2.3. staff must have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins, if necessary, to prevent risks of contamination of equipment for handling of farmed animals or their feedstuffs;

2.4. cleaning and disinfection procedures, must be established and documented for all parts of the combustion plant. Suitable equipment and cleaning agents must be provided for cleaning.

2.5. hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and retained for a period of at least two years;

2.6. where rendered fats are used as a fuel for combustion in stationary internal combustion engines located within approved or registered food or feed processing plants, the processing of food or feed on the same site must take place under strict conditions of separation.

3. Operators of the combustion plants shall take all necessary precautions concerning the reception of animal by-products or derived products to prevent or limit as far as practicable, risks to human or animal health and the environment.

4. Animals must not have access to the combustion plant or to the animal by-products and derived products awaiting combustion or the ash resulting from the combustion.

5. Where the combustion plant is located on a holding keeping animals of food producing species:

5.1. there must be total physical separation between the combustion equipment and the animals including their feed and bedding;

5.2. equipment must be dedicated entirely to the operation of the combustion plant and not used elsewhere on the holding unless it had been effectively cleaned and disinfected before such use;

5.3. personnel working in the combustion plant must change their outer clothing and footwear and take personal hygiene measures before handling animals on this or any other holding or their feed or bedding material.

6. The animal by-products and derived products that are awaiting combustion as a fuel and the combustion residues must be stored in a closed and covered dedicated area, or in covered and leak-proof containers.

7. The combustion of animal by-products or derived products shall be carried out under conditions which prevent cross-contamination of feed for animals.

Section 2

Operating conditions of combustion plants

1. Combustion plants must be designed, built, equipped and operated in such a way that even under the most unfavourable conditions the animal by-products and derived products are treated for at least for 2 seconds at a temperature of 850 °C or for at least 0,2 seconds at a temperature of 1 100 °C.
2. The gas resulting from the process is raised in a controlled and homogeneous fashion for 2 seconds to a temperature of 850 °C or for 0,2 seconds to a temperature of 1 100 °C.
3. The temperature must be measured near the inner wall or at another representative point of the combustion chamber, as authorised by the competent authority.
4. Automated techniques shall be used to monitor the parameters and conditions relevant to the combustion process.
5. Temperature measurement results shall be recorded automatically and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions referred to in paragraph 1 and 2 of this Section in accordance with procedures to be decided upon by the relevant authority.
6. The operator of a combustion plant shall ensure that the fuel is combusted in such a way that the total organic carbon content of the slags and bottom ashes is less than 3 % or their loss on ignition is less than 5 % of the dry weight of the material.

Section 3

Combustion residues

1. Combustion residues shall be minimised in their amount and harmfulness. Such residues must be recovered, or where it is not appropriate, disposed of or used in accordance with relevant legislation.
2. The transport and intermediate storage of dry residues, including dust, shall take place in closed containers or in another way which prevents dispersal into the environment.

Section 4

Breakdown or abnormal operating conditions

1. The combustion plant shall be equipped with facilities which automatically shut down operations in the case of a breakdown or abnormal operating conditions until normal operations can be resumed.
2. Incompletely combusted animal by-products and derived products must be combusted again or disposed in an authorised landfill. by means referred to in Articles 12, 13 and 14 of the Administrative Instruction (MAFRD) - No. 05/2022.

CHAPTER V

TYPES OF PLANTS AND FUELS THAT MAY BE USED FOR COMBUSTION AND SPECIFIC REQUIREMENTS FOR PARTICULAR TYPES OF PLANTS

A. Stationary internal combustion engines

1. Starting material:

For this process, a fat fraction derived from animal by-products of all categories may be used provided it meets the following conditions:

1.1. unless fish oil or rendered fat is used which has been produced in accordance with legislation in force, respectively, the fat fraction derived from animal by-products must first be processed using:

1.1.1 in the case of a fat fraction of Category 1 and 2 materials, any of the processing methods 1 to 5 as set out in Chapter III of Annex II of this Administrative Instruction. Where this fat is moved by a closed conveyer system, which may not be by-passed, and provided such a system has been authorised by the competent authority, from the processing plant for immediate direct combustion the permanent marking with glyceroltriheptanoate (GTH) referred to in paragraph 1 of Chapter V of Annex VI of this Administrative Instruction shall not be required;

1.1.2 in the case of a fat fraction of Category 3 material, any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex II of this Administrative Instruction;

1.1.3. in the case of the materials derived from fish, any of the processing methods 1 to 7 as set out in Chapter III of Annex II of this Administrative Instruction;

1.1.4. the fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed.

2. Methodology:

Combustion of animal fat as a fuel in a stationary internal combustion engine shall be carried out as follows:

2.1. the fat fractions referred to in paragraph 1, subparagraph 1.1 and 1.2 of this point A must be combusted:

2.1.1. under the conditions laid down in Section 2, paragraph 1 of Chapter IV of this Annex; or

2.1.2. using process parameters achieving an equivalent outcome as the conditions under subparagraph 2.1 of this paragraph and which are authorised by the competent authority;

2.2. the combustion of material of animal origin other than animal fat must not be permitted;

2.3. the animal fat derived from Category 1 or Category 2 combusted in premises approved or registered in accordance with legislation in force laying down specific rules on hygiene of food of animal origin,

specific legislation on feed hygiene, or in public places must have been processed with processing method 1 as set out in Chapter III of Annex II of this Administrative Instruction;

3. The combustion of animal fat must be carried out in accordance with legislation in force for the protection of the environment, in particular, with reference to the standards and requirements of that legislation and the requirements regarding best available techniques for the control and monitoring of emissions.

Operating conditions:

By way of derogation from the requirements set out in the paragraph 2 of Section 2 of Chapter IV of this Annex, requirements based on other process parameters, which ensure an equivalent environmental outcome may be authorised by the competent authority responsible for environmental issues.

B. On-farm combustion plants in which poultry manure is used as a fuel

1. Type of plant:

On-farm combustion plant with a total rated thermal input not exceeding 5 MW.

2. Starting material and scope:

Exclusively unprocessed poultry manure, as referred to in Article 9, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022, to be used as a fuel for combustion in accordance with the requirements set out in paragraph 3 to 5 of this point B. The combustion of other animal by-products or derived products and of manure of other species or generated outside the holding shall not be allowed for use as a fuel in on-farm combustion plants referred to in paragraph 1 of this point B.

3. Specific requirements for poultry manure used as a fuel for combustion:

3.1. the manure shall be stored securely in a closed storage area to minimise the need for further handling and to prevent cross contamination with other areas on a holding keeping animals of food producing species.

3.2. the on-farm combustion plant must be equipped with:

3.2.1. an automatic fuel management system to place the fuel directly in the combustion chamber without further handling;

3.2.2. an auxiliary burner which must be used during start-up and shut-down operations to ensure that the temperature requirements set out in Section 2, paragraph 2 of Chapter IV of this Annex are met at all times during those operations and as long as unburned material is in the combustion chamber.

4. emission limit values and monitoring requirements:

4.1. the emissions of sulphur dioxide, nitrogen oxides (namely the sum of nitrogen monoxide and nitrogen dioxide, expressed as nitrogen dioxide) and particulate matter shall not exceed the following

emission limit values, expressed in mg/Nm³ at a temperature of 273,15 K, a pressure of 101,3 kPa and an oxygen content of 11 per cent, after correction for the water vapour content of the waste gases:

Pollutant	Emission limit value in mg/Nm ³
Sulphur dioxide	50
Nitrogen oxides (as NO ₂)	200
Particulate matter	10

4.1.1 the operator of the on-farm combustion plant shall carry out at least annual measurements of sulphur dioxide, nitrogen oxides and particulate matter.

As an alternative to the measurements referred to in the first subparagraph, other procedures, verified and approved by the competent authority, may be used to determine the emissions of sulphur dioxide.

Monitoring shall be carried out by or on behalf of the operator in accordance with CEN standards. Where CEN standards are not available, ISO, national or other international standards which ensure the provision of data of an equivalent scientific quality shall apply.

4.1.2.all results shall be recorded, processed and presented in such a way as to enable the competent authority to verify compliance with the emission limit values.

4.1.3.for on-farm combustion plants applying secondary abatement equipment in order to meet the emission limit values, the effective operation of that equipment shall be monitored continuously and the results thereof recorded;

4.1.4 in the event of non-compliance with the emission limit values referred to in subparagraph 4.1 of this paragraph or where an on-farm combustion plant does not meet the requirements of paragraph 1 of Section 2 of Chapter IV of this Annex, operators shall immediately inform the competent authority and take the measures necessary to ensure that compliance is restored within the shortest possible time. Where compliance cannot be restored, the competent authority shall suspend the operation of the plant and withdraw its approval.

5.Changes of operation and breakdowns:

5.1.The operator shall notify the competent authority of any planned change of the on-farm combustion plant which would affect its emissions at least one month before the date on which the change takes place.

5.2.The operator shall take the necessary measures to ensure that the periods of start-up and shut-down of the on-farm combustion plant and of any malfunctions are kept as short as possible. In the case of a malfunction or a breakdown of secondary abatement equipment, the operator shall immediately inform the competent authority.

C. Combustion plants in which manure of farmed animals other than poultry manure set out in point B is used as a fuel for combustion

1. Type of plant:

Combustion plants with a total rated thermal input not exceeding 50 MW.

2.Starting material:

Exclusively manure of farmed animals other than poultry manure set out in point B of this Chapter, to be used as a fuel for combustion in accordance with the requirements set out in paragraph 3 of this point C. The combustion of other animal by-products or derived products shall not be allowed for use as a fuel in combustion plants referred to in paragraph 1 of this point C. Manure of farmed animals other than poultry manure set out in point B of this Chapter generated outside the holding should not come in contact with farmed animals.

3. Methodology:

Combustion plants in which manure of farmed animals other than poultry manure set out in point B of this Chapter is used as a fuel shall comply with requirements set out in points B, paragraph 3, 4 and 5.

D. Combustion plants in which meat-and-bone meal is used as a fuel for combustion

1.Type of plant:

Combustion plants with a total rated thermal input not exceeding 50 MW.

2.Starting material:

Meat-and-bone meal of Category 1 and Category 2 materials, to be used as a fuel for combustion in accordance with the requirements set out in paragraph 3 of this point D, alone or in a mixture of meat-and-bone meal, rendered fat and manure.

3.Specific requirements for meat-and-bone meal used as a fuel for combustion:

3.1.meat-and-bone meal shall be stored in the combustion plant securely in a closed storage protected from access of animals and shall not be sent to another destination unless authorised by the competent authority in case of breakdown or abnormal operating conditions;

3.2.the combustion plant must be equipped with:

3.2.1.an automatic or continuous fuel management system to place the fuel directly in the combustion chamber without further handling;

3.2.2. an auxiliary burner which must be used during start-up and shut - down operations to ensure that the temperature requirements set out in Section 2, paragraph 2 of Chapter IV of this Annex are met at all times during those operations and as long as unburned material is in the combustion chamber.

4.Methodology:

Combustion plants in which meat-and-bone meal of Category 1 or Category 2 materials is used as a fuel shall comply with the general requirements set out in Chapter IV of this Annex and the specific requirements set out in point B, paragraph 4 and 5 of this Chapter.

ANNEX II PROCESSING

CHAPTER I REQUIREMENTS FOR PROCESSING PLANTS AND CERTAIN OTHER PLANTS AND ESTABLISHMENTS

Section 1

General conditions

1.Processing plants shall meet the following requirements, for processing by pressure sterilisation or in accordance with the processing methods referred to in Article 15, paragraph 1, subparagraph of Administrative Instruction (MAFRD) - No. 05/2022:

1.1.Processing plants must not be situated on the same site as slaughterhouses or other establishments which have been approved or registered in accordance with legislation in force laying down specific rules on hygiene of food of animal origin, unless the risks to public and animal health resulting from the processing of animal by-products, which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:

1.1.1.the processing plant must be physically separated from the slaughterhouse or other establishment, where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse or other establishment;

1.2.the following must be installed and operated in the processing plant:

1.2.1.a conveyer system which links the processing plant to the slaughterhouse or other establishment and which may not be by-passed,

1.2.2.separate entrances, reception bays, equipment and exits for both the processing plant and the slaughterhouse or establishment;

1.2.3.measures must be taken to prevent the spreading of risks through the operation of personnel which is employed in the processing plant and in the slaughterhouse or other establishment;

1.2.4.unauthorised persons and animals must not have access to the processing plant;

1.3.by way of derogation from sub-subparagraph 1.1.1 to 1.1.4 of this subparagraph, in the case of processing plants processing Category 3 material, the competent authority may authorise other conditions instead of those set out in those sub-subparagraphs, aimed at mitigating the risks to public and animal health, including the risks arising from the processing of Category 3 material, which originates from off-site establishments approved or registered in accordance with legislation in force on hygiene of foodstuff or by specific rules on hygiene of food of animal origin.

- 1.4.the processing plant must have a clean and unclean sector, adequately separated. The unclean sector must have a covered place to receive animal by-products and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids;
- 1.5.the processing plant must have adequate facilities including lavatories, changing rooms and washbasins for staff;
- 1.6.the processing plant must have sufficient production capacity for hot water and steam for the processing of animal by-products;
- 1.7.the unclean sector must, if appropriate, contain equipment to reduce the size of animal by-products and equipment for loading the crushed animal by-products into the processing unit;
- 1.8.where heat treatment is required, all installations must be equipped with:
 - 1.8.1 measuring equipment to monitor temperature against time and, if applicable for the processing method used, pressure at critical points;
 - 1.8.2recording devices to record continuously the results of these measurements in a way so that they remain accessible for the purpose of checks and official controls;
 - 1.8.3. an adequate safety system to prevent insufficient heating;
- 1.9..To prevent recontamination of the derived product by the introduction of animal by-products, there must be a clear separation between the area of the plant where incoming material for processing is unloaded and the areas set aside for the processing of that product and the storage of the derived product.
- 2.The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the means of transport, other than ships, in which they are transported.
- 3.Adequate facilities must be provided for the disinfecting of vehicle wheels and the other parts of the vehicle, as appropriate, on leaving the unclean sector of the processing plant.
- 4.All processing plants must have a waste-water disposal system meeting the requirements set out by the competent authority in accordance with legislation in force.
- 5.The processing plant must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority on the basis of an assessment of the capacity of the laboratory to carry out those analyses, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority, to assess the capacity of the laboratory to carry out those analyses.
- 6.If on the basis of a risk assessment, the volume of products treated requires the regular or permanent presence of the competent authority, the processing plants must have an adequately equipped lockable room for the exclusive use of the inspection service.

Section 2

Wastewater treatment

1.Processing plants processing Category 1 material and other premises where specified risk material is removed, slaughterhouses and processing plants processing Category 2 material shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of wastewater.

2.The equipment used in the pre-treatment process from paragraph 1 of this Section shall consist of drain traps or screens with apertures with a filter pore or a mesh size of no more than 6 mm in the downstream end of the process or equivalent systems that ensure that the solid particles in the wastewater passing through them are no more than 6 mm.

3.Wastewater from the premises as referred to in paragraph 1 of this Section must enter a pre-treatment process which shall ensure that all wastewater has been filtered through the process before being drained off the premises. No grinding, maceration or any other processing or application of pressure shall be carried out which could facilitate the passage of solid animal material through the pre-treatment process.

4.All animal material retained in the pre-treatment process in premises as referred to in paragraph 1 of this Section shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with the Administrative Instruction (MAFRD) - No. 05/2022.

5.Wastewater having passed the pre-treatment process in premises referred to in paragraph 1 of this Section and wastewater from other premises handling or processing animal by-products shall be treated in accordance with legislation in force, without restrictions in accordance with this Administrative Instruction.

6.In addition to the requirements laid down in paragraph 5 of this Section, the competent authority may oblige operators to treat wastewater originating in the unclean sector of processing plants and in plants or establishments carrying out intermediate operations with Category 1 material or Category 2 material or storing Category 1 material or Category 2 material, in accordance with conditions which ensure that risks from pathogens are mitigated.

7.Without prejudice to paragraph 1 to 6 of this Section, the disposal of animal by-products, including blood and milk, or derived products through the wastewater stream shall be prohibited. However, Category 3 material comprising of centrifuge or separator sludge may be disposed of through the wastewater stream, provided that it has been subject to one of the treatments for centrifuge or separator sludge set out in Part III of Section 4 of Chapter II of Annex VIII of this Administrative Instruction.

Section 3

Specific requirements for the processing of Category 1 and Category 2 materials

The layout of processing plants processing Category 1 and Category 2 materials must ensure the total separation of Category 1 material from Category 2 material from reception of the raw material until dispatch of the resulting derived product, unless a mixture of Category 1 material and Category 2 material is processed as Category 1 material.

Section 4

Specific requirements for the processing of Category 3 materials

1.The following requirements shall apply in addition to the general conditions set out in Section 1 of this Annex:

1.1.Processing plants processing Category 3 materials shall not be located at the same site as processing plants processing Category 1 or Category 2 materials, unless located in a completely separate building;

1.2.However, the competent authority may authorise the processing of Category 3 material on a site where handling or processing of Category 1 or Category 2 material takes place, if cross-contamination is prevented due to:

1.2.1.the layout of the premises, in particular the arrangements for the reception, and by way of the further handling of raw materials;

1.2.2.the layout and the management of the equipment used for processing, including the layout and the management of separate processing lines or of cleaning procedures which are excluding the propagation of any possible risks to public and animal health; and

1.2.3.the layout and the management of the areas for the temporary storage of the end products.

1.3.Processing plants processing Category 3 material shall have in place an installation to check the presence of foreign bodies, such as packaging material or metallic pieces, in the animal by-products or derived products, if they are processing materials which are destined for feeding. Such foreign bodies shall be removed before or during processing.

CHAPTER II

HYGIENE AND PROCESSING REQUIREMENT

Section 1

General hygiene requirements

In addition to the general hygiene requirements provided for in Article 25 of Administrative Instruction (MAFRD) - No. 05/2022, processing plants shall have a documented pest control programme in place for the implementation of the arrangements for protection against pests, such as insects, rodents and birds, referred to in Article 25, paragraph 1, subparagraph 1.3 of Administrative Instruction (MAFRD) - No. 05/2022.

Section 2

General processing requirements

1.Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept to show the date of calibration of gauges/recorders.

2.Material that may not have received the specified heat treatment, such as material discharged at start up or leakage from cookers, must be recirculated through the heat treatment or collected and reprocessed or disposed of in accordance with Administrative Instruction (MAFRD) - No. 05/2022.

Section 3

Processing methods for Category 1 and Category 2 material

Unless the competent authority requires the application of pressure sterilisation (method 1), Category 1 and Category 2 material shall be processed in accordance with processing methods 2, 3, 4 or 5 as referred to in Chapter III of this Annex.

Section 4 **Processing of Category 3 material**

1. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Chapter III of this Annex:

- 1.1. raw material particle size;
- 1.2. temperature achieved in the heat treatment process;
- 1.3. pressure, if applied to the raw material;
- 1.4. duration of the heat treatment process or feed rate to a continuous system. Minimum processing standards must be specified for each applicable critical control point.

2. In the case of chemical treatments which have been authorised by the competent authority as processing method 7 in accordance with point G of Chapter III of this Annex, the critical control points that determine the extent of the chemical treatments applied shall include the pH adjustment achieved.

3. Records shall be maintained for at least two years to show that the minimum process values for each critical control point are applied.

4. Category 3 material shall be processed in accordance with any of the processing methods 1 to 5 or processing method 7, or, in the case of material originating from aquatic animals, with any of the processing methods 1 to 7, as referred to in Chapter III to this Annex.

CHAPTER III **STANDARD PROCESSING METHODS**

A. Processing method 1 (pressure sterilisation)

Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

1. The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the

replacement of the air by steam ('saturated steam'); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.

2. The processing may be carried out in batch or continuous systems.

B. Processing method 2

Reduction

1. If the particle size of the animal by-products to be processed is more than 150 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

1. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 125 minutes, a core temperature greater than 110 °C is achieved for at least 120 minutes and a core temperature greater than 120 °C is achieved for at least 50 minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

2. The processing must be carried out in a batch system.

C. Processing method 3

Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

1. After reduction the animal by-products must be heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 95 minutes, a core temperature greater than 110 °C is achieved for at least 55 minutes and a core temperature greater than 120 °C is achieved for at least 13 minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

2. The processing may be carried out in batch or continuous systems.

D. Processing method 4

Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is

no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

1. After reduction the animal by-products must be placed in a vessel with added fat and heated in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 16 minutes, a core temperature greater than 110 °C is achieved for at least 13 minutes, a core temperature greater than 120 °C is achieved for at least eight (8) minutes and a core temperature greater than 130 °C is achieved for at least three (3) minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

2. The processing may be carried out in batch or continuous systems.

E. Processing method 5 Reduction

1. If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.

Time, temperature and pressure

1. After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated in a manner which ensures that a core temperature greater than 80 °C is achieved for at least 120 minutes and a core temperature greater than 100 °C is achieved for at least 60 minutes. The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

2. The processing may be carried out in batch or continuous systems.

F. Processing method 6 (for Category 3 animal by-products originating from aquatic animal or aquatic invertebrates only)

Reduction

1. The animal by-products must be reduced to a particle size which is no greater than:

1.1. 50 mm, in case of heat treatment in accordance with paragraph 2, subparagraph 2.1 of this point F;
or

1.2. 30 mm, in case of heat treatment in accordance with paragraph 2, subparagraph 2.2 of this point F.

2. They must then be mixed with formic acid to reduce and maintain the pH to 4,0 or lower. The mixture must be stored for at least 24 hours pending further treatment.

Time, temperature and pressure

3. After reduction, the mixture must be heated to:

3.1 a core temperature of at least 90 °C for at least 60 minutes; or

3.2 a core temperature of at least 70 °C for at least 60 minutes.

When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature.

4. The processing may be carried out in batch or continuous systems.

G. Processing method 7

1. Any processing method authorised by the competent authority where the following have been demonstrated by the operator to the authority:

1.1. the identification of relevant hazards in the starting material, in view of the origin of the material and of the potential risks in view of the animal health, where the method is to be used;

1.2. the capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health;

1.3. the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards:

1.3.1. samples of material taken directly after the treatment:

1.3.1.1. *Clostridium perfringens* absent in 1 g of the products.

1.3.1.2. samples of material taken during or upon withdrawal from storage:

1.3.1.3. *Salmonella*: absence in 25g: $n=5$, $c=0$, $m=0$, $M=0$ Enterobacteriaceae: $n=5$, $c=2$; $m=10$; $M=300$ in 1 g, where :

1.3.1.4. n = number of samples to be tested;

1.3.1.5 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 ;

1.3.1.6. 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

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

1.4. Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the operator and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored must include the particle size, and, as appropriate, the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

1.5. The competent authority shall permanently or temporarily suspend the application of processing methods referred to in paragraph 1 of this point G, if it obtains evidence that any of the circumstances specified in paragraph 1, subparagraph 1.1 or 1.2 of this point G have substantially changed.

1.6. The competent authority shall inform the competent authority of any other country upon request about the information at its disposal under points 1 and 2 in relation to an authorised processing method.

CHAPTER IV ALTERNATIVE PROCESSING METHODS

Section 1 General provisions

1. Materials resulting from the processing of Category 1 and 2 materials shall be permanently marked in accordance with the requirements for the marking of certain derived products set out in Chapter V of Annex VI to this Administrative Instruction..

2. However, such marking shall not be required for the following materials referred to in Section 2 of this Chapter:

2.1. biodiesel produced in accordance with point D;

2.2. hydrolysed materials referred to in point H;

2.3. mixtures of pig and poultry manure with quick lime produced in accordance with point I;

2.4. renewable fuels produced from rendered fats, which are derived from Category 1 and Category 2 materials, in accordance with point J and L.

Section 2 Processing standards

A. Alkaline hydrolysis proces

1. Strating material

For this process, animal by-products of all categories may be used.

2. Processing method

Alkaline hydrolysis shall be carried out according to the following processing standards:

2.1. either a sodium hydroxide (NaOH) or potassium hydroxide (KOH) solution (or a combination thereof) must be used in an amount that assures approximate molar equivalency to the weight, type and composition of the animal by-products to be digested.

2.2. in the case of high fat in the animal by-products that neutralises the base, the added base must be adjusted so that the molar equivalency referred to is achieved.

2.3. animal by-products must be placed in a steel alloy container. The measured amount of alkali must be added either in solid form or as a solution as referred to in subparagraph 2.1 to this paragraph.

2.4. the container must be closed and the animal by-products and alkali mixture must be heated to a core temperature of at least 150 °C and at a pressure (absolute) of at least 4 bars for at least:

2.4.1. three hours without interruption;

2.4.2. six hours without interruption in case of treatment of animal by-products referred to in Article 8, paragraph 1, subparagraph 1.1 sub-subparagraphs 1.1.1 and 1.1.2 of Administrative Instruction (MAFRD) - No. 05/2022.

2.4.3. however, materials derived from Category 1 materials comprising of animals killed in the context of TSE eradication measures which are either ruminants not requiring TSE testing or ruminants which have been tested with a negative result in accordance with legislation in force may be processed in accordance with paragraph 2, subparagraph 2.4 sub-subparagraph 2.1.1 of this point A; or

2.4.4. one hour without interruption in the case of animal by-products consisting of fish or of poultry materials..

2.5. the process must be carried out in a batch system and the material in the vessel must be constantly mixed in order to facilitate the digestion process until the tissues are dissolved and bones and teeth are softened; and

2.6. the animal by-products must be treated in such way that the requirements regarding time, temperature and pressure are achieved at the same time.

B. High pressure high temperature hydrolysis proces

1. Starting material

For this process, Category 2 and Category 3 materials may be used.

2. Processing method

High pressure high temperature hydrolysis shall be carried out according to the following processing standards:

2.1 The animal by-products must be heated to a core temperature of at least 180 °C for at least 40 minutes without interruption at a pressure (absolute) of at least 12 bar, heated by indirect steam application to the biolytic reactor;

2.2 The process must be carried out in a batch and the material in the vessel must be constantly mixed; and

2.3 The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time.

C.High pressure hydrolysis biogas proces

1.Starting material

For this process, animal by-products of all categories may be used.

2. Processing method

The high pressure hydrolysis biogas process shall be carried out according to the following processing standards:

1.1. The animal by-products must be first processed using processing method 1 (pressure sterilisation) as set out in Chapter III of this Annex in an approved processing plant;

1.2. Following the process referred to in subparagraph 2.1 of this paragraph, the defatted materials must be treated at a temperature of at least 220 °C for at least 20 minutes at a pressure (absolute) of at least 25 bar, heated in a two-step procedure, first by direct steam injection, secondly indirect in a coaxial heat exchanger;

1.3. The process must be carried out in a batch or continuous system and the material is constantly mixed;

1.4. The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time;

1.5. The resulting material must then be mixed with water and anaerobically fermented (biogas transformation) in a biogas reactor;

1.6. In the case of starting material of Category 1, the entire process must take place on the same site and in a closed system and the biogas produced during the process must be combusted rapidly in the same plant at a minimum of 900 °C followed by rapid chilling ('quenching').

D.Biodiesel production proces

1. Starting material

For this process, a fat fraction derived from animal by-products of all categories may be used.

2. Processing method

Biodiesel production shall be carried out according to the following processing standards:

2.1. Unless fish oil or rendered fat are used which have been produced in accordance with legislation in force laying down specific rules on hygiene of food of animal origin, respectively, the fat fraction derived from animal by-products must be first processed using:

2.2. in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III of this Annex; and

2.3. in the case of Category 3 materials, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III of this Annex;

3. The processed fat must then be processed further using one of the following methods:

3.1. a process whereby the processed fat must be separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight must be removed, and the processed fat must be subsequently submitted to esterification and transesterification. However, esterification is not required for processed fat derived from Category 3 material. For esterification the pH must be reduced to less than 1 by adding sulphuric acid (H_2SO_4) or an equivalent acid and the mixture must be heated to 72 °C for at least two hours during which it must be intensely mixed.

Transesterification must be carried out by increasing the pH to about 14 with potassium hydroxide or with an equivalent base at 35 °C to 50 °C for at least 15 minutes. Transesterification shall be carried out twice under the conditions described in this point using a new base solution. This process must be followed by refinement of the products including vacuum distillation at 150 °C, leading to biodiesel;

3.2. a process using equivalent process parameters authorised by the competent authority.

E. "Brookes" gasification process

1. Starting material

For this process, Category 2 and Category 3 material may be used

2. Processing method

Brookes' gasification shall be carried out according to the following processing standards:

2.1. The afterburner chamber must be warmed up using natural gas;

2.2. The animal by-products must be loaded into the primary chamber of the gasificator and the door must be closed.

3. The primary chamber must have no burners and must be heated instead by the transfer of heat by conduction from the afterburner, which must be underneath the primary chamber. The only air admitted to the primary chamber must be via three inlet valves mounted on the main door to enhance the efficiency of the process;

3.1.the animal by-products must be volatilised into complex hydrocarbons and the resultant gases must pass from the primary chamber via a narrow opening at the top of the back wall to the mixing and cracking zones, where they must be broken down into their constituent elements. Finally the gases must pass into the afterburner chamber where they must be burned in the flame of a natural gas fired burner in the presence of excess air;

3.2.each process unit must have two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber must be designed to give a minimum residence time of two seconds at a temperature of at least 950 °C under all conditions of combustion;

3.3.on leaving the secondary chamber the exhaust gases must pass through a barometric damper at the base of the stack, which cools and dilutes them with ambient air, maintaining a constant pressure in the primary and secondary chambers;

3.4.the process must be carried out over a 24-hour cycle, which includes loading, processing, cool down and ash removal. At the end of the cycle the residual ash must be removed from the primary chamber by a vacuum extraction system into enclosed bags and sealed before transporting;

3.5.the gasification of material other than animal by-products must not be permitted.

F. Combustion of animal fat in a thermal boiler proces

1.Starting material

For this process, a fat fraction derived from animal by-products of all categories may be used.

2. Processing method

Combustion of animal fat in a thermal boiler shall be carried out according to the following processing standards:

2.1.Unless fish oil or rendered fat are used which has been produced in accordance with legislation in force laying down specific rules of hygiene of food of animal origin, respectively, the fat fraction derived from animal by-products must first be processed using:

2.1.1. in the case of fat fraction of Category 1 and 2 materials which is intended to be combusted in another plant,

2.1.2. for the fat fraction from the processing of ruminants which have been tested with a negative result in accordance with legislation in force On the Control, Prevention and Eradication of TSEs in Kosovo and from the processing of animals, other than ruminants which require TSE testing, any of the processing methods 1 to 5 as set out in Chapter III of this Annex.

2.1.3. for the fat fraction from the processing of other ruminants, processing method 1 as referred in Chapter III of this Annex; and

2.1.4. in the case of Category 1 and 2 materials intended for combustion within the same plant and in the case of Category 3 material, any of the processing methods 1 to 5 or processing method 7; in the case the materials are derived from fish, processing methods 1 to 7 as set out in Chapter III of this Annex;

2.1.5. The fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed;

2.1.6. Following the process referred to in subparagraph 2.1 and 2.2 of this point F, the fat must be:

2.1.6.1.vaporised in a steam-raising boiler and combusted at a temperature of at least 1 100 °C for at least 0,2 seconds; or

2.1.6.2.processed using equivalent process parameters authorised by the competent authority;

2.1.7.The combustion of material of animal origin other than animal fat must not be permitted;

2.1.8.The combustion of the fat derived from Category 1 and Category 2 materials shall take place in the same plant where the fat is rendered with the aim of utilising the energy generated for the rendering processes. However, the competent authority may authorise the movement of that fat to other plants for combustion provided that:

2.1.8.1.the plant of destination is authorised for the combustion;

2.1.8.2.the processing of food or feed in an approved plant on the same premises takes place under strict conditions of separation;

2.1.8.3.The combustion must be carried out in accordance with legislation in force For the protection of the environment, in particular, with reference to the standards of this legislation regarding best available techniques for the control and monitoring of emissions.

G. Thermomechanical biofuel production proces

1.Starting material

For this process, manure and digestive tract content and Category 3 material may be used.

2.Processing method

Thermomechanical biofuel production shall be carried out according to the following processing standards:

2.1.the animal by-products must be loaded into a converter and subsequently treated at a temperature of 80 °C for a period of eight hours. During this period, the material must be constantly reduced in size using appropriate mechanical abrasion equipment.

2.2.the material must be subsequently treated at a temperature of 100 °C for at least two hours.

2.3.the particle size of the resulting material must not be larger than 20 millimetres;

2.4.the animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure set out in subparagraph 2.1 and 2.2 of this paragraph are achieved at the same time;

2.5.during the heat treatment of the material, evaporated water must be continually extracted from the air-space above the biofuel and must be passed through a stainless steel condenser. The condensate must be kept at a temperature of at least 70 °C for at least one hour before being discharged as wastewater;

2.6.after the heat treatment of the material, the resulting biofuel from the converter must then be discharged and automatically conveyed by a fully covered and interlocked conveyor to incineration or co-incineration on the same site;

2.7 the process must be carried out in a batch mode.

I. Lime treatment for pig and poultry manure

Starting materials

1.For this process, manure of pig and poultry origin, as referred to in Article 9, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022, may be used.

2.Processing method

2.1.the dry matter content of the manure must be determined by using the CEN EN 12880:2000 method 'Characterization of sludges. Determination of dry residue and water content'. For this process, the dry matter content must be between 15 % and 70 %.

2.2.the amount of lime which has to be added must be determined in such way that one of the combinations of time and temperature set out in subparagraph 2.6 of this paragraph is achieved.

2.3.the particle size of the animal by-products to be processed must be no greater than 12 mm. If necessary, the particles of the manure must be reduced in size in such a way that maximum particle size is achieved.

2.4.the manure must be mixed with quick lime (CaO) which has a medium to high reactivity of less than six minutes to achieve a 40 °C rise in temperature as per the criteria in the reactivity test 5.10 in the CEN EN 459-2:2002 method.

The mixing must be carried out with two mixers which are operating in line, with two screws per mixer.

Both mixers must:

2.4.1.have a screw diameter of 0,55 m and a screw length of 3,5 m;

2.4.2. operate with a power of 30 kW and a rotation speed of the screw of 156 rpm;

2.4.3. have a treatment capacity of 10 tonnes per hour. The mean blending duration must be approximately two minutes.

2.5. the mixture must be mixed for a period of at least six hours into a stockpile with a minimum size of two tonnes.

2.6. at monitoring points which must be introduced into the stockpile, continuous measurements must be carried out to demonstrate that the mixture in the stockpile reaches a pH of at least 12 during one of the following periods of time, during which period one of the corresponding following temperatures must be achieved:

2.6.1. 60 °C for 60 minutes; or

2.6.2. 70 °C for 30 minutes.

2.7. the process must be carried out in a batch mode.

2.8. a permanent written procedure based on the HACCP principles must be put in place.

2.8.1. operators may demonstrate to the competent authority, by way of a validation according to the following requirements, that a process using a mixing device which is different from the mixing device referred to in subparagraph 2.4 of paragraph 2 or using lime (CaOMgO) instead of quick lime is at least as efficient as the process set out in subparagraph 2.1 to 2.8 of this paragraph:

That validation must:

2.8.1.1. demonstrate that by using the different mixing device to that referred to in subparagraph 2.4 of this paragraph or the dolime, as applicable, a mixture with manure can be produced which achieves the parameters for pH, time and temperature referred to in subparagraph 2.6 of this paragraph;

2.8.1.2. be based on monitoring of time and temperature at the base, the middle and at the top of the stockpile, with a representative number of monitoring points (at least four monitoring points in the basal zone, which are located at a maximum of 10 cm above the base and at a maximum of 10 cm below the top, one monitoring point in the middle half way between base and the top of stockpile, and four monitoring points in the marginal zone at the top of the pile, which are located at a maximum of 10 cm below the surface and at a maximum of 10 cm below the top of the stockpile);

2.1.8.3. be carried out during two periods of at least 30 days, of which one must be in the cold season of the year at the geographical place where the mixing device is to be used.

J. Multi-step catalytic process for the production of renewable fuels.

1. Starting material

1.1. For this process, the following materials may be used:

1.1.1.rendered fats derived from Category 2 material, which have been processed using processing method 1 (pressure sterilisation);

1.1.2.fish oil or rendered fats derived from Category 3 material, which have been processed using:

1.1.2.1.any of the processing methods 1 to 5 or processing method 7; or

1.1.2.2.in the case of material derived from fish oil, any of the processing methods 1 to 7;

1.2.3.fish oil or rendered fat which have been produced in accordance with legislation in force laying down specific rules of hygiene of food of animal origin, respectively.

1.2.the use of rendered fats derived from Category 1 material for this process shall be prohibited

2. Processing method

2.1.the rendered fat must be submitted to a pre-treatment which consists of:

2.1.1 the bleaching of the centrifuged materials by passing them through a clay filter;

2.1.2.the removal of remaining insoluble impurities by filtration.

2.2.the pre-treated materials must be submitted to a multi-step catalytic process which consists of a hydro-deoxygenisation step, followed by an isomerisation step. The materials must be submitted to a pressure of at least 20 bars at a temperature of at least 250 °C for at least 20 minutes.

K. Ensilage of fish material

1. Starting materials

For this process, only the following by-products obtained from aquatic animals may be used:

1.1.Category 2 materials referred to in Article 9, paragraph 1, subparagraph 1.6 sub-subparagraph 1.6.1 and 1.6.3 of Administrative Instruction (MAFRD) - No. 05/2022;

1.2. Category 3 materials.

2. Processing method

2.1.The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.

2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.

L. Multiple-step catalytic hydro-treatment for the production of renewable fuels

1. Starting materials

1. For this process, only the following by-products obtained from aquatic animals may be used:

1.1. Category 2 materials referred to in Article 9, paragraph 1, subparagraph 1.6 sub-subparagraph 1.6.1 and 1.6.3 of Administrative Instruction (MAFRD) - No. 05/2022;

1.2. Category 3 materials.

2. Before authorisation is given, the operator's permanent written procedure referred to in Article 29, paragraph 1, subparagraph 1.1 to 1.3 of Administrative Instruction (MAFRD) - No. 05/2022 must be assessed by the competent authority.

2. Processing method

2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.

2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.

2.3. Before authorisation is given, the operator's permanent written procedure referred to in Article 29, paragraph 1 to 3 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption must be assessed by the competent authority.

Section 3 Disposal and use of derived products

1. Products derived from the processing of:

1.1 Category 1 material shall be:

1.1.1 disposed of in accordance with Article 12, paragraph 1, subparagraph 1.1 sub-subparagraph 1.1.1 and 1.1.2 of Administrative Instruction (MAFRD) - No. 05/2022;

1.1.2. disposed of by burial in an authorised landfill;

1.1.3. transformed into biogas. In such case the digestion residues must be disposed of in accordance with sub-subparagraph 1.1.1 or 1.1.2 of this subparagraph, except where the material results from processing in accordance with paragraph 2, subparagraph 2.1 or 2.2 of this Section where the residues can be used in accordance with the conditions set out in paragraph 2, subparagraph 2.1 or paragraph 2, subparagraph 2.2, sub-subparagraph 2.2.3 of this Section as appropriate; or

1.1.4. further processed into fat derivatives for uses other than feeding.

1.2 Category 2 or Category 3 material shall be:

1.2.1. disposed of as provided for in paragraph 1, subparagraph 1.1, sub-subparagraph 1.1.1 or 1.1.2, with or without prior processing as provided for in Article 13, paragraph 1, subparagraphs 1.1 and 1.2 and Article 14, paragraph 1, subparagraph 1.1 and 1.2 of Administrative Instruction (MAFRD) – No. 05/2022;

1.2.2. further processed into fat derivatives for uses other than feeding;

1.2.3. used as an organic fertilizer or soil improver; or

1.2.4. composted or transformed into biogas.

2. Materials resulting from processing in accordance with:

2.1. the alkaline hydrolysis process defined in point A of Section 2 of this Chapter may be transformed in a biogas plant and subsequently combusted rapidly at a minimum of 900°C, followed by rapid chilling ('quenching'); where material referred to in Article 8, paragraph 1, subparagraph 1.1 and 1.2 of Administrative Instruction (MAFRD) - No. 05/2022 has been used as starting material, the transformation into biogas shall take place on the same site as the processing and in a closed system;

2.2 the biodiesel production process may be:

2.2.1 in the case of biodiesel and of residues from the distillation of biodiesel, used as a fuel without restrictions under this Administrative Instruction;

2.2.2. in the case of potassium sulphate, used for direct application to land or for the production of derived products for application to land;

2.2.3.in the case of glycerine derived from Categories 1 and 2 material which has been processed in accordance with processing method 1 as set out in Chapter III of this Annex:

2.2.3.1.used for technical purposes,

2.2.3.2.transformed into biogas, in which case the digestion residues may be applied to land within the national territory, subject to the decision of the competent authority, or

2.2.3.3.used for denitrification in a waste water treatment plant, in which case the residues of the denitrification may be applied to land in accordance with legislation concerning urban waste-water treatment;

2.2.4.in the case of glycerine derived from Category 3 material:

2.2.4.1.used for technical purposes,

2.2.4.2.transformed into biogas, in which case the digestion residues may be applied to land, or

2.2.4.3.used for feeding, provided that the glycerine is not derived from Category 3 material referred to in Article 10, paragraph 1, subparagraph 1.14, 1.15, and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022 which animal by-products and products derived thereof not intended for human consumption.

2.3.the multi-step catalytic process for the production of renewable fuels may be:

2.3.1.in the case of gasoline and the other fuels resulting from the process, used as a fuel without restrictions under this Administrative Instruction ;

2.3.2.in the case of used clay from bleaching and sludge from the pre-treatment process referred to in point J, paragraph 2, subparagraph 2.1 of Section 2 of this Chapter:

2.3.2.1.disposed of by incineration or co-incineration,

2.3.2.2.transformed into biogas;

2.3.2.3.composted or used for the manufacture of derived products referred to in Article 36, paragraph 1, subparagraph 1.1., sub-subparagraph 1.1.1 of Administrative Instruction (MAFRD) - No. 05/2022;

2.4.the lime-treated mixture of pig and poultry manure may be applied to land as processed manure;

2.5.The final product derived from the ensilaging of fish material may:

2.5.1.for Category 2 materials, be used for purposes referred to in Article 13, paragraph 1, subparagraphs 1.1 to 1.4 and 1.7 to 1.9 of Administrative Instruction (MAFRD) - No. 05/2022 without further processing or as feed for animals referred to in Article 18 or Article 36, paragraph 1, subparagraph 1.1. sub-subparagraph 1.1.2 of that Administrative Instruction; or

2.5.2.for Category 3 materials, be used for purposes referred to in Article 14 of Administrative Instruction (MAFRD) - No. 05/2022;

2.6.the multiple-step catalytic hydro-treatment for the production of renewable fuels may be:

2.6.1.in the case of renewable diesel, renewable jet fuel, renewable propane and renewable gasoline resulting from the process, used as a fuel without restrictions under this Administrative Instruction ;

2.6.2.in the case of gum sludge and used bleaching clay from the pre-treatment process referred to in point L, paragraph 2, subparagraph 2.1 of Section 2 of this Chapter:

2.6.2.1.disposed of in accordance with Article 12, paragraph 1, subparagraph 1.1 or 1.2 of Administrative Instruction (MAFRD) - No. 05/2022,

2.6.2.2.disposed of by burial in an authorised landfill,

2.6.2.3.transformed into biogas, provided the digestion residues from the biogas transformation are disposed of by incineration, co-incineration or burial in an authorised landfill,

2.6.2.4.used for technical purposes referred to in Article 36, paragraph 1, subparagraph 1.1, subparagraph 1.1.1 of Administrative Instruction (MAFRD) - No. 05/2022.

2.7. Any waste other than animal by-products and derived products provided for in paragraph 2 of this Section, resulting from the processing of animal by-products in accordance with this Section, such as sludge, filter contents, ash and digestion residues, shall be disposed of in accordance with Administrative Instruction (MAFRD) - No. 05/2022 and with this Administrative Instruction.

ANNEX III

TRANSFORMATION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS INTO BIOGAS, COMPOSTING

CHAPTER I

REQUIREMENTS APPLICABLE TO PLANTS

Section 1

Biogas plants

1.A biogas plant must be equipped with a pasteurisation/hygienisation unit, which cannot be by-passed for the animal by-products or derived products introduced with a maximum particle size of 12 mm before entering the unit, with:

1.1.installations for monitoring that the temperature of 70 °C is reached during the time of one hour;

1.2.recording devices to record continuously the results of the monitoring measurements referred to in subparagraph 1.1 of this paragraph; and

1.3.an adequate system to prevent insufficient heating

2.By way of derogation from paragraph 1 of this Section, a pasteurisation /hygienisation unit shall not be mandatory for biogas plants that transform only:

2.1.Category 2 material that has been processed in accordance with processing method 1 as set out in Chapter III of Annex II of this Administrative Instruction;

2.2.Category 3 material that has been processed in accordance with any of the processing methods 1 to 5 or processing method 7, or in the case of material originating from aquatic animals, any of the processing methods 1 to 7, as set out in Chapter III of Annex II of this Administrative Instruction;

2.3.Category 3 material that has undergone pasteurisation/hygienisation in another approved plant;

2.4. animal by-products which may be applied as raw material without processing in accordance with Article 13, paragraph 1, subparagraph 1.6 of Administrative Instruction (MAFRD) - No. 05/2022 and with this Administrative Instruction, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals;

2.5.animal by-products which have been subject to the alkaline hydrolysis process set out in point A of Section 2 of Chapter IV of Annex II of this Administrative Instruction;

2.6.the following animal by-products, if authorised by the competent authority:

2.6.1.the animal by-products referred to in Article 10, paragraph 1, subparagraph 1.6 of Administrative Instruction (MAFRD) - No. 05/2022, which have undergone processing as defined by the legislation in force on hygiene of foodstuff at the time when they are destined for purposes other than human consumption;

2.6.2.the animal by-products referred to in Article 10, paragraph 1, subparagraph 1.7 of Administrative Instruction (MAFRD) - No. 05/2022 or

2.6.3.animal by-products which are transformed into biogas, where the digestion residues are subsequently composted or processed or disposed of in accordance with this Administrative Instruction.

3.If the biogas plant is located on or next to premises where farmed animals are kept and the biogas plant does not only use manure, milk or colostrum which accrues from those animals, the plant shall be located at a distance from the area where such animals are kept.

4.That distance shall be determined in a manner which ensures that there is no unacceptable risk for the transmission of a disease communicable to humans or animals from the biogas plant.

5.In all cases, there must be total physical separation between that biogas plant and the animals and their feed and bedding, with fencing where necessary.

6. Each biogas plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority, be accredited according to internationally recognized standards or be subject to regular controls by the competent authority.

Section 2

Composting plants

1. A composting plant must be equipped with a closed composting reactor or closed area, which cannot be by-passed for the animal by-products or derived products introduced into the plant, and it must be equipped with the following:

1.1. installations for monitoring temperature against time;

1.2. recording devices to record, where appropriate continuously, the results of the monitoring measurements referred to in subparagraph 1.1 of this paragraph;

1.3. an adequate safety system to prevent insufficient heating;

2. By way of derogation from paragraph 1 of this Section, other types of composting systems may be allowed provided they:

2.1. are managed in such a way that all the material in the system achieves the required time and temperature parameters, including, where appropriate, continuous monitoring of the parameters; or

2.2. transform only materials referred to in paragraph 2 of Section 1 of this Chapter; and comply with all relevant requirements of this administrative instruction.

3. If the composting plant is located on or next to premises where farmed animals are kept and the composting plant does not only use manure, milk or colostrum which accrues from those animals, the composting plant shall be located at a distance from the area where animals are kept.

4. That distance shall be determined in a manner which ensures that there is no unacceptable risk for the transmission of a disease communicable to humans or animals from the composting plant.

5. In all cases, there must be total physical separation between that composting plant and the animals and their feed and bedding, with fencing where necessary.

6. Each composting plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority.

CHAPTER II

HYGIENE REQUIREMENTS APPLICABLE TO BIOGAS AND COMPOSTING PLANTS

1. Animal by-products must be transformed as soon as possible after arrival at the biogas or composting plant. They must be stored properly until treated.

2. Containers, receptacles and vehicles used for transporting untreated material must be cleaned and disinfected in a designated area. That area must be situated or designed so as to prevent risk of contamination of treated products.
3. Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest-control programme must be used for that purpose.
4. Cleaning procedures must be documented and established for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
5. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented.
6. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.
7. Digestion residues and compost must be handled and stored at the biogas or composting plant in such way as to prevent recontamination

CHAPTER III

TRANSFORMATION PARAMETERS

Section 1

Standard transformation parameters

1. Category 3 material which is used as raw material in a biogas plant equipped with a pasteurisation/hygienisation unit must be submitted to the following minimum requirements:
 - 1.1. maximum particle size before entering the unit: 12 mm;
 - 1.2. minimum temperature in all material in the unit: 70 °C; and
 - 1.3. minimum time in the unit without interruption: 60 minutes.
2. However, milk, milk-based products, milk-derived products, colostrum and colostrum products may be used without pasteurisation/hygienisation as raw material in a biogas plant, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals.
3. The minimum requirements set out in subparagraphs 1.2 and 1.3 of paragraph 1 of this Section shall also apply to Category 2 material which is introduced into a biogas plant without prior processing in accordance with Article 13, paragraph 1, subparagraph 1.5, sub-subparagraph 1.5.2 of Administrative Instruction (MAFRD) - No. 05/2022.
4. Category 3 material which is used as raw material in a composting plant must be submitted to the following minimum requirements:
 - 4.1. maximum particle size before entering the composting reactor: 12 mm;

4.2.minimum temperature in all material in the reactor: 70 °C; and

4.3.minimum time without interruption: 60 minutes.

5.The minimum requirements set out in subparagraph 4.2 and 4.3 of paragraph 4 of this Article shall also apply to Category 2 material which is composted without prior processing in accordance with Article 13, paragraph 1, subparagraph 1.5, sub-subparagraph 1.5.2 of Administrative Instruction (MAFRD) - No. 05/2022.

Section 2

Alternative transformation parameters for biogas and composting plant

1.The competent authority may authorise the use of parameters other than the parameters set out in paragraph 1 of Section 1 of Chapter I of this Annex and other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with the following requirements:

1.1. Identification and analysis of possible hazards, including the impact of input material, based on a full description of the transformation conditions and parameters;

1.2.A risk assessment, which evaluates how the specific transformation conditions referred to in subparagraph 1.1 of this paragraph are achieved in practice under normal and atypical situations;

1.3.Validation of the intended process by measuring the reduction of viability/infectivity of:

1.3.1.endogenous indicator organisms during the process, where the indicator is:

1.3.1.1.consistently present in the raw material in high numbers;

1.3.1.2.not less heat resistant to the lethal aspects of the transformation process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

1.3.1.3.relatively easy to quantify and to identify and to confirm; or

1.3.1.4.a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.

1.4.The validation of the intended process referred to in subparagraph 1.3 of this paragraph must demonstrate that the process achieves the following overall risk reduction:

1.4.1.for thermal and chemical processes by:

1.4.1.1.a reduction of 5 log 10 of *Enterococcus faecalis* or *Salmonella* Senftenberg (775W, H2S negative),

1.4.1.2. reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 log10, whenever they are identified as a relevant hazard; and

as regards chemical processes also by:

1.4.1.3. a reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log10) of viable stages;

1.5. Designing a complete control programme including procedures for monitoring the functioning of the process referred to in subparagraph 1.3 of this paragraph;

1.6. Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant. Details on the relevant process parameters used in a biogas or composting plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant. Records must be made available by the operator to the competent authority on request. Information relating to a process authorised under this point must be made available to the European Commission on request.

1.7. By way of derogation from paragraph 1 of this Section, pending the adoption of rules as referred to in Article 15, paragraph 2, subparagraph 2.1, sub-subparagraph 2.1.2 of Administrative Instruction (MAFRD) - No. 05/2022, the competent authority may authorise the use of specific requirements other than those laid down in this Chapter, provided that they guarantee an equivalent effect regarding the reduction of pathogens, for:

1.7.1. catering waste used as the only animal by-product in a biogas or composting plant; and

1.8 mixtures of catering waste with the following materials:

1.8.1. manure;

1.8.2. digestive tract content separated from the digestive tract;

1.8.3. milk;

1.8.4. milk-based products;

1.8.5. milk-derived products;

1.8.6. colostrum;

1.8.7. colostrum products;

1.8.8. eggs;

1.8.9. egg products;

1.8.10. animal by-products referred to in Article 10, paragraph 1, subparagraph 1.6 of Administrative Instruction (MAFRD) - No. 05/2022, which have undergone processing as defined by the legislation in force on hygiene of foodstuff;

1.8.11. mixture of animal by-products referred to in paragraph 2, subparagraph 2.2 of this Section with non-animal by-product materials.

1.9. Where the materials referred to in paragraph 2, subparagraph 2.2 of this Section or derived products referred to in Article 10, paragraph 1, subparagraph 1.7 of Administrative Instruction (MAFRD) - No. 05/2022 are the only starting material of animal origin being treated in a biogas or composting plant, the competent authority may authorise the use of specific requirements other than those specified in this Chapter provided that it:

1.9.1. considers that the digestion residues or compost are unprocessed material and obliges operators to handle them in accordance with Administrative Instruction (MAFRD) - No. 05/2022, with this Administrative Instruction or, in the case of compost or digestion residues derived from catering waste, to recover or dispose of in accordance with the environmental legislation.

1.9.2. considers that the digestion residues or compost are unprocessed material and obliges operators to handle them in accordance with, Administrative Instruction (MAFRD) - No. 05/2022 with this instruction or, in the case of compost or digestion residues derived from catering waste, to recover or dispose of in accordance with the environmental legislation

1.10. Operators may place on the market digestion residues and compost, which have been produced according to parameters which have been authorised by the competent authority:

1.10.1. in accordance with paragraph 1 of this Section;

1.10.2. in accordance with paragraphs 2 and 3 of this Section.

Section 3

Standards for digestion residues and compost

1. Representative samples of the digestion residues or compost taken during or;

1.1. immediately after transformation at the biogas plant or composting at the composting plant in order to monitor the process must comply with the following standards:

1.1.1. *Escherichia coli*: $n = 5$, $c = 1$, $m = 1\ 000$, $M = 5\ 000$ in 1 g; Or

1.1.2. *Enterococcaceae*: $n = 5$, $c = 1$, $m = 1\ 000$, $M = 5\ 000$ in 1 g; and

1.2. Representative samples of the digestion residues or compost taken during or on withdrawal from storage must comply with the following standards:

1.2.1. *Salmonella*: absence in 25 g: $n = 5$; $c = 0$; $m = 0$; $M = 0$

1.2.2. Where in the case of subparagraph 1.1 and 1.2 to this paragraph:

1.2.1.1.n = number of samples to be tested;

1.2.2.2. m = threshold value for the number of bacteria;

1.2.2.3. the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

1.2.2.4. M = maximum value for the number of bacteria;

1.2.2.5. the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

1.2.2.6. 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

1.3.Digestion residues or compost other than those referred to in paragraph 3, subparagraph 3.2 of Section 2 of this Chapter, which do not comply with the requirements set out in this Section, shall be resubmitted to transformation or composting, and in the case of Salmonella handled or disposed of in accordance with the instructions of the competent authority.

3. When animal by-products are transformed into biogas or composted together with materials which are not of animal origin, the competent authority may authorise operators to take representative samples after the pasteurisation referred to in paragraph 1, subparagraph 1.1 of Section 1 of Chapter I of this Annex or after composting referred to in paragraph 1 of Section 2 of Chapter I of this Annex, as applicable, and before the mixing with materials which are not of animal origin takes place, in order to monitor the efficiency of the transformation or composting of the animal by-products, as applicable.

ANNEX IV

SPECIAL RULES ON RESEARCH, FEEDING AND COLLECTION AND DISPOSAL

CHAPTER I

SPECIAL RULES ON SAMPLES FOR RESEARCH AND OTHER PURPOSES

Section 1

Research and diagnostic samples

1. Operators shall ensure that consignments of research and diagnostic samples are accompanied by a commercial document, which must specify:

1.1. the description of the material and the animal species of origin;

1.2. the category of the material;

1.3. the quantity of the material;

1.4. the place of origin and the place of dispatch of the material;

- 1.5. the name and the address of the consignor;
 - 1.6. the name and the address of the consignee and/or user.
2. Users that handle research and diagnostic samples shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.
3. Any subsequent use of research and diagnostic samples for purposes other than those referred to in paragraph 1, subparagraph 1.38 of Article 3 of this Administrative Instruction shall be prohibited.
4. Unless they are kept for reference purposes, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:
- 4.1. as waste by incineration or co-incineration;
 - 4.2. in case of the animal by-products or derived products referred to in Article 8 , paragraph 1, subparagraph 1.1, sub-subparagraph 1.1.4, Article 8, paragraph 1, subparagraph 1.3 and 1.4 and Article 9 and Article 10 of Administrative Instruction (MAFRD) - No. 05/2022 which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves and subsequent disposal as waste or wastewater in accordance with relevant legislation;
 - 4.3. by pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Administrative Instruction (MAFRD) - No. 05/2022.
5. Users that handle research and diagnostic samples shall keep a register of consignments of such samples. The register shall include the information referred to in paragraph 1 of this Section and the date and method of disposal of the samples and of any derived products.
6. By way of derogation from paragraph 1, 4 and 5 of this Section, the competent authority may accept the handling and disposal of research and diagnostic samples for educational purposes under other conditions which ensure that no unacceptable risks for public or animal health arise.

Section 2

Trade samples and display items

1. Trade samples and display items may only be transported, used and disposed of in accordance with paragraphs 1 to 4 and 6 of Section 1 of this Chapter.
2. Unless trade samples are kept for reference purposes, they shall be, after the particular studies or analyses have been concluded:
 - 2.1. redispached to the country of origin;
 - 2.2. dispatched to another country, if such dispatch has been authorised by the competent authority of that country of destination in advance; or

2.3. disposed of or used in accordance with Articles 12, 13 and 14 of Administrative Instruction (MAFRD) - No. 05/2022

3. After the exhibition or after the artistic activity has been concluded, display items shall be redispached to the country of origin, dispatched or disposed of, in accordance with paragraph 2 of this Section.

CHAPTER II SPECIAL FEEDING RULES

Section 1 General requirements

1. Categories 2 and 3 materials as referred to in Article 18, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 for human consumption may be fed to the animals referred to in paragraph 1, subparagraph 1.1, 1.2, 1.4, 1.6, 1.7, 1.8 of that Article subject to compliance with at least the following conditions, in addition to any conditions laid down by the competent authority in accordance with Article 18, paragraph 1 of that Administrative Instruction:

2. The animal by-products shall be transported to the users or to collection centres in accordance with Sections 1 and 3 of Chapter I of Annex VI of this Administrative Instruction.

3. Collection centres shall be registered by the competent authority, provided that:

3.1. they comply with the requirements for plants carrying out the intermediate operations set out in Chapter II of Annex VII of this Administrative Instruction; and

3.2. they have adequate facilities for destroying unused material, or send it to an approved processing plant or to an approved incineration or co-incineration plant in accordance with this Administrative Instruction.

4. Competent authority may authorise the use of a processing plant for Category 2 material as a collection centre.

5. Operators of collection centres supplying material, other than animal by-products originating from aquatic animals and from aquatic invertebrates, to final users must ensure that it undergoes one of the following treatments:

5.1. denaturing with a solution of a colouring agent; the solution must be of such a strength that the colouring on the stained material is clearly visible and does not disappear when the coloured materials are subject to freezing or chilling, and the whole surface of all pieces of material must have been covered with such solution either by immersing the material in, or spraying or otherwise applying the solution;

5.2. sterilisation by boiling or steaming under pressure until every piece of material is cooked throughout; or

5.3. any other handling or treatment authorised by the competent authority responsible for the operator.

Section 2

Feeding of certain species in feeding stations

1. The competent authority may authorise the use of Category 1 material referred to in Article 18, paragraph 2, subparagraph 2.2 of Administrative Instruction (MAFRD) - No. 05/2022 for the feeding of the endangered and protected species in feeding stations under the following conditions:

1.1. The material must be fed to:

1.1.1. one of the species of necrophagous birds in the territory of Republic of Kosovo;

1.1.2. one of the species of the order Carnivora which are listed in specific legislation on the conservation of natural habitats and of wild fauna and flora in special areas of conservation which have been set up under that specific legislation; or

1.1.3. one of the species of the orders Falconiformes or Strigiformes, which are listed in specific legislation on the conservation of wild birds, in special protection areas which have been set up under that specific legislation;

1.1.4. The competent authority has granted an authorisation to the operator responsible for the feeding station.

1.2 The competent authority shall grant such authorisations provided that:

1.2.1 the feeding is not used as an alternative way of disposal of specified risk materials or the disposal of fallen ruminant stock containing such material posing a TSE risk;

1.2.2 an appropriate surveillance system for TSEs as laid down by the legislation in force for Control, Prevention and Eradication of TSE's in Kosovo is in place involving regular laboratory testing of samples for TSE;

1.3 The competent authority must ensure coordination with any other competent authorities responsible for the supervision of the requirements laid down in the authorisation;

1.4 The competent authority must be satisfied, on the basis of an assessment of the specific situation of the species concerned and their habitat, that the conservation status of the species will be improved;

1.5 The authorisation granted by the competent authority must:

1.5.1 refer to and name the species actually concerned;

1.5.2 describe in detail the location of the feeding station in the geographical area where feeding shall take place; and

1.5.3 be immediately suspended in the case of:

1.5.3.1 a suspected or confirmed link to the spread of TSE until the risk can be excluded, or

1.5.3.2 non-compliance with any of the rules provided for in this Administrative Instruction.

1.6 The operator responsible for the feeding shall:

1.6.1 dedicate an area to the feeding that is enclosed and to which access is limited to animals of the species to be conserved, if appropriate by fences or by other means which correspond to the natural feeding patterns of those species;

1.6.2 ensure that eligible bodies of bovine animals and at least 4 % of eligible bodies of ovine and caprine animals intended to be used for feeding are tested prior to that use with a negative result, in the TSE monitoring programme carried out in accordance with to Administrative Instruction MA-No.34 / 2006 On the Control, Prevention and Eradication of TSEs in Kosovo; and

1.6.3 keep records at least of the number, nature, estimated weight and origin of the carcasses of the animals used for feeding, the date of the feeding, the location where feeding took place and if applicable, the results of the TSE tests.

Section 3

Feeding of wild animals outside feeding stations

1. The competent authority may authorise the use of Category 1 material comprising of entire bodies or parts of dead animals containing specified risk materials outside feeding stations, if appropriate without prior collection of the dead animals, for feeding to wild animals referred to in paragraph, subparagraph 1.1 of Section 2 of this Annex under the following conditions:

1.1 The competent authority must be satisfied, on the basis of an assessment of the specific situation of the species concerned and their habitat, that the conservation status of the species will be improved;

1.2 The competent authority must identify in the authorisation, holdings or herds within a geographically defined feeding zone under the following conditions:

1.2.1 The feeding zone must not extend to areas where intensive farming of animals takes place;

1.2.2 Farmed animals in holdings or herds in the feeding zone must be under the regular surveillance of an official veterinarian regarding the prevalence of TSE and of diseases transmissible to humans or animals;

1.2.3 Feeding must be immediately suspended in the case of:

1.2.3.1 a suspected or confirmed link to the spread of TSE in a holding or herd, until the risk can be excluded;

1.2.3.2 a suspected or confirmed outbreak of a serious disease transmissible to humans or animals in a holding or herd, until the risk can be excluded; or

1.2.3.3 non-compliance with any of the rules provided for in this Administrative Instruction;

1.3 The competent authority must specify in the authorisation:

1.3.1 appropriate measures to prevent the transmission of TSE and of transmissible diseases from the dead animals to humans or other animals, such as measures targeted at the feeding patterns of the species to be conserved, seasonal feeding restrictions, movement restrictions for farmed animals and other measures intended to control possible risks of transmission of a disease communicable to humans or animals, such as measures relating to species present in the feeding zone for the feeding of which the animal by-products are not used;

1.3.2 the responsibilities of persons or entities in the feeding zone who are assisting with the feeding or responsible for farmed animals, in relation to the measures referred to under sub-subparagraph 2.4.1 of this subparagraph;

1.3.3 the conditions for the imposition of penalties as referred to in Article 50 of Administrative Instruction (MAFRD) - No. 05/2022 which are applicable to infringements of measures referred to under sub-subparagraph 2.4.1 by the persons or entities referred to under sub-subparagraph 2.4.2 of this paragraph 2.

1.4 Where the feeding is carried out without the prior collection of the dead animals, an estimate of the likely mortality rate of farmed animals in the feeding zone and of the likely feeding requirements of the wild animals must be carried out, as a basis for the assessment of the potential risks of disease transmission.

Section 4

Feeding of zoo animals with Category 1 material

1. The competent authority may authorise the use of Category 1 material comprising of entire bodies or parts of dead animals containing specified risk materials and the use of material derived from zoo animals, for the feeding of zoo animals under the following conditions:

1.1 The competent authority must have granted an authorisation to the operator responsible for the feeding. The competent authority shall grant such authorisations provided that:

1.1.1 the feeding is not used as an alternative way of disposal of specified risk materials or disposal of fallen ruminant stock containing such material posing a TSE risk;

1.1.2 when Category 1 material comprising of entire bodies or parts of dead animals containing specified risk material, which originates from bovine animals is used, an appropriate surveillance system for TSEs as laid down by the legislation in force On the Control, Prevention and Eradication of TSEs in Kosovo is in place involving regular laboratory testing of samples for TSEs;

1.2 The authorisation granted by the competent authority must be immediately suspended in the case of:

1.2.1 a suspected or confirmed link to the spread of TSEs until the risk can be excluded; or

1.2.2 non-compliance with any of the rules provided for in this Administrative Instruction;

1.2.3 The operator responsible for the feeding shall:

1.2.3.1 store the material to be used for the feeding and carry out the feeding in an enclosed and fenced area to ensure that no carnivorous animal other than the zoo animals for which the authorisation has been granted have access to the material for the feeding;

1.2.3.2 ensure that ruminant animals intended to be used for feeding are included in the TSE monitoring programme carried out in accordance with the legislation in force On the Control, Prevention and Eradication of TSEs in Kosovo;

1.2.3.3 keep records at least of the number, nature, estimated weight and origin of the bodies of the animals used for feeding, the results of the TSE tests and the date of the feeding.

CHAPTER III

SPECIAL RULES ON COLLECTION AND DISPOSAL

Section 1

Special disposal rules for animal by-products

1. If the competent authority authorises the disposal of animal by-products on site in accordance with Article 19, paragraph 1, subparagraph 1.1, 1.2, 1.3, and 1.5 of Administrative Instruction (MAFRD) - No. 05/2022, such disposal may take place:

1.1 by burning or burial on the premises on which the animal by-products originate;

1.2 in an authorised landfill; or

1.3 by burning or burial at a site which minimises the risk to animal and public health and the environment, provided that the site is located within a range of distance sufficient to enable the competent authority to manage the prevention of the risk to animal and public health and the environment.

2. The burning of animal by-products on the sites referred to in Article 19, paragraph 1, subparagraph 1.2, 1.3 and 1.5 of Administrative Instruction (MAFRD) - No. 05/2022 must be carried out in such a way to ensure that they are burnt:

2.1 on a properly constructed pyre and the animal by-products reduced to ash;

2.2 without endangering human health;

2.3 without using processes or methods which could harm the environment, in particular when they could result in risks to water, air, soil and plants and animals or through noise or odours;

2.4 under conditions which ensure that any resulting ash is disposed of by burial in an authorised landfill.

3. The burial of animal by-products on the sites referred to in Article 19, paragraph 1, subparagraph 1.1, 1.2, 1.3 and 1.5 of Administrative Instruction (MAFRD) - No. 05/2022 must be carried out to ensure that they are buried:

3.1 in such a way that carnivorous or omnivorous animals cannot gain access to them;

3.2 in an authorised landfill or in another site without endangering human health and using processes or methods which do not harm the environment, in particular when they could result in risks to water, air, soil and plants and animals, or through noise or odours.

4. In the case of disposal in accordance with Article 19, paragraph 1, subparagraph 1.1, 1.2, 1.3 and 1.5 of Administrative Instruction (MAFRD) - No. 05/2022, the movement of the animal by-products from the place of origin to the place of disposal must be carried out under the following conditions:

4.1 the animal by-products are transported in secure, leak-proof containers or vehicles;

4.2 the loading and unloading of the animal by-products is supervised by the competent authority, if appropriate;

4.3 the vehicle wheels are disinfected upon leaving the site of origin;

4.4 containers and vehicles used for transporting animal by-products are thoroughly cleansed and disinfected after unloading of the animal by-products; and

4.5 adequate escorts for the vehicles, leak testing and double covering are provided, if appropriate.

Section 2

Burning and burial of animal by-products in remote areas

1. The maximum percentage as referred to in Article 19, paragraph 2 of Administrative Instruction (MAFRD) - No. 05/2022 shall not exceed the following:

1.1 10 % of the bovine population in the Republic of Kosovo;

1.2 25 % of the ovine and caprine population in the Republic of Kosovo;

1.3 10 % of the porcine population in the Republic of Kosovo; and

1.4 a percentage of the population of other species which is determined by the competent authority, on the basis of an assessment of the possible risks for public and animal health which arise from the disposal of animals of those species by burning or burial on site.

Section 3

Burning and burial of bees and apiculture by-products

In the case of bees and apiculture by-products, the competent authority may authorise the disposal by burning or burial on site, as referred to in Article 19, paragraph 1, subparagraph 1.6 of Administrative

Instruction (MAFRD) - No. 05/2022, provided that all necessary measures are taken to ensure that the burning or burial does not endanger animal or human health or the environment.

CHAPTER IV

DISPOSAL BY OTHER MEANS

1. By way of derogation from Article 14 of Administrative Instruction (MAFRD) - No. 05/2022, the competent authority may authorise the collection, transport and disposal of the Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.6 of that Administrative Instruction by means other than burning or burial on site provided that:

1.1. the materials do not exceed a volume of 20 kg per week from the establishment or plant where the materials are collected, regardless of the species of origin of the materials;

1.2. the materials are collected, transported and disposed of by means which prevent the transmission of unacceptable risks to public and animal health;

1.3. the competent authority carries out regular checks, including checks on the records kept by operators, in the establishments or plants where the materials are collected, to ensure compliance with the provisions of this Chapter.

ANNEX V

STANDARD FORMAT FOR APPLICATIONS FOR ALTERNATIVE METHODS

CHAPTER I

Language regime

1. Applications for authorisation of an alternative method of use or disposal of animal by-products or derived products as referred to in Article 20 of Administrative Instruction (MAFRD) - No. 05/2022 (applications) shall be submitted in one of the official languages of the Republic of Kosovo.

2. Interested parties that submit such applications in a language other than the official languages of the Republic of Kosovo shall validate the official translation of their application.

CHAPTER II

Content of application

1. Applications shall contain all the necessary information to allow Competent Authority to assess the safety of the proposed alternative method, and in particular describe:

1.1. the categories of animal by-products intended to be submitted to the method,

1.2. the entire process,

1.3. biological risks to human and animal health involved, and

1.4. the degree of risk reduction to be achieved by the process.

2. The requirements laid down in paragraph 1 of this chapter must:

2.1 indicate the applicable points in Articles 8, 9 and 10 of Administrative Instruction (MAFRD) - No. 05/ including the physical status of those materials and, if applicable, any pre-treatment to which those materials have been submitted and indicating any materials other than animal by-products which are to be used in the process;

2.2 include a HACCP protocol and a flow diagram which clearly indicates the individual steps of the process, identifies the parameters critical for the inactivation of relevant pathogens such as temperature, pressure, exposure time, adjustment of the pH value and particle size and is complemented by technical data sheets of the equipment used during the process;

2.3 identify and characterize biological hazards for human and animal health represented by the categories of animal by-products intended to be submitted to the method;

2.4 show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the waste water, at least to the degree achieved by the processing standards laid down in this Administrative Instruction for the same category of animal by-products. The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable.

3. Validated direct measurements as referred to in paragraph 2, subparagraph 2.4 of this Chapter shall mean:

3.1 measuring the reduction of viability/infectivity of:

3.1.1 endogenous indicator organisms during the process, where the indicator is:

3.1.1.1 consistently present in the raw material in high numbers;

3.1.1.2 not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor;

3.1.1.3 relatively easy to quantify, to identify and to confirm; or

3.1.1.4 using a well-characterised test organism or virus introduced in a suitable test body into the starting material. If several treatment steps are involved, an assessment must be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps;

3.1.1.5 reporting complete results by describing in detail the used methodology;

3.1.1.6 describing the nature of samples which have been analysed;

3.1.1.7 showing that the number of samples analysed is representative;

3.1.1.8 justifying the number of tests performed and the selection of measuring points;

3.1.1.9 indicating the sensitivity and the specificity of the detection methods used;

3.1.1.10 providing data on the repeatability and statistical variability of the measurements obtained during the experiments;

3.1.1.11 justifying, if used the significance of prion surrogates;

3.1.1.12 showing, where in absence of direct measurements, models or comparisons with other processes are used, that the factors leading to risk reduction are well known and the model of risk reduction is well established;

3.1.1.13 providing data for the entire process on direct measurements of all factors leading to the risk reduction which demonstrate that these factors are homogeneously applied throughout the treated batch.

3.2 The HACCP plan referred to in paragraph 2, subparagraph 2.2 of this Chapter must be based on the critical parameters which are used to obtain the risk reduction, in particular:

3.2.1 temperature,

3.2.2 pressure,

3.2.3 time, and

3.2.4 microbiological criteria.

4. The critical limits retained in the HACCP plan must be defined, based on the results of the experimental validation and/ or of the model provided.

5. If the successful functioning of the process can only be demonstrated with reference to technical parameters which are specifically related to the equipment used in the process, the HACCP plan must also include the technical limits which must be met, in particular energy uptake, number of pump strokes or dosage of chemicals.

6. Information must be given on the critical and technical parameters that are to be monitored and recorded in a continuous manner or after defined intervals and on the methods used for measuring and monitoring.

7. The variability of parameters under typical production conditions must be taken into account.

8. The HACCP plan must reflect normal and abnormal/ emergency operating conditions including a breakdown of the process and it must specify possible corrective actions which are to be applied in the case of abnormal/emergency operating conditions.

9. The applications shall also contain sufficient information on:

9.1. the risks associated with interdependent processes, and in particular on the outcome of an evaluation of possible indirect impacts, which may:

9.1.1. affect the level of risk reduction of a given process;

9.1.2. arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water.

9.2. the risks associated with the intended end use of the products, in particular:

9.2.1. the intended end use of any products generated during the process must be specified;

9.2.2. the likely risks for human health and animal health and possible impacts on the environment must be assessed on the basis of the risk reduction estimated in accordance with paragraph 2, subparagraph 2.4 of this Chapter.

10. Applications shall be submitted with documentary evidence, in particular:

10.1. a flow diagram showing the functioning of the process;

10.2. the evidence referred to in paragraph 2, subparagraph 2.4 of this Chapter, as well as other evidence aiming to substantiate the information provided in the framework of the application as set out in paragraph 2 of this Chapter.

11. Applications shall include a contact address for the interested party, which shall include the name and full address, telephone and/or fax number and/or the electronic mail address of a particular person that is responsible as or on behalf of the interested party

ANNEX VI COLLECTION, TRANSPORT AND TRACEABILITY

CHAPTER I COLLECTION AND TRANSPORT

Section 1 Vehicles and containers

1. As from the starting point in the manufacturing chain referred to in Article 4, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 animal by-products and derived products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.

2. Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products or derived products, other than derived products which are placed on the market in accordance with specific legislation on placing on the market and use of feed and which are stored and transported in accordance with specific legislation on feed hygiene, must be maintained in a clean condition.

3. In particular, unless they are dedicated to the carriage of particular animal by-products or derived products in a way which avoids cross-contamination, they must be:

3.1. clean and dry before use; and

- 3.2.cleaned, washed and/or disinfected after each use to the extent necessary to avoid cross-contamination.
- 4.Reusable containers must be dedicated to the carriage of a particular animal by-product or derived product to the extent necessary to avoid cross-contamination.
- 5.However, reusable containers may be used, provided the competent authority has authorised such use:
- 5.1.for the carriage of different animal by-products or derived products provided that they are cleaned and disinfected between the different uses in a manner which prevents cross-contamination;
- 5.2.for the carriage of animal by-products or derived products referred to in Article 10, paragraph 1, subparagraph 1.6 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption, following their use for the carriage of products intended for human consumption, under conditions which prevent cross-contamination.
- 6.Packaging material must be disposed of, by incineration or by other means in accordance with legislation in force.

Section 2

Temperature conditions

- 1.The transport of animal by-products destined for the production of feed material or raw petfood must take place at an appropriate temperature, in the case of animal by-products from meat and meat products which have been destined for purposes other than human consumption, at a maximum of 7 °C, in order to avoid any risk to animal or public health.
- 2.Unprocessed Category 3 material destined for the production of feed material or petfood must be stored and transported chilled, frozen or ensiled, unless:
- 2.1.it is processed within 24 hours after collection or after the end of storage in chilled or frozen form, if the subsequent transport takes place in means of transport in which the storage temperature is maintained;
- 2.2.in the case of milk, milk-based products or milk-derived products which have not been subject to any of the treatments referred to in Part I of Section 4 of Chapter II of Annex VIII of this Administrative Instruction, it is transported chilled and in insulated containers, unless risks can be mitigated by other measures, due to the characteristics of the material.
- 3.The design of vehicles used for refrigerated transport must ensure the maintenance of an appropriate temperature throughout transport, and allow that temperature to be monitored.

Section 3

Derogation for collection and transport of Category 3 material comprising of milk, milk-based products and milk-derived products

Section 1 of this Chapter shall not apply to the collection and transportation of Category 3 material comprising of milk, milk-based products and milk derived products by operators of milk-processing establishments which have been approved in accordance with legislation in force laying down specific rules on hygiene of food of animal origin, where they are receiving products which they have previously delivered and which are returned to them, in particular from their customers.

Section 4

Derogation for collection and transport of manure

By way of derogation from Section 1 of this Chapter, the competent authority may accept the collection and transport of manure transported between two points located on the same farm or between farmers and users under other conditions which provide for the prevention of unacceptable risks to public and animal health.

CHAPTER II

IDENTIFICATION

1. All necessary measures must be taken to ensure that:

1.1. consignments of animal by-products and derived products are identifiable and kept separate and identifiable during collection where the animal by-products originate and during transportation;

1.2. a marking substance for the identification of animal by-products or derived products of a specific category is only used for the category for which its use is required under this Administrative Instruction, or is established or laid down pursuant to paragraph 4 of Chapter II of this Annex;

1.3. consignments of animal by-products and derived products are dispatched in packaging, containers or vehicles which are prominently and, at least for the period of transport, indelibly colour-coded for displaying information as provided for in this Administrative Instruction on the surface or part of the surface of a packaging, container or vehicle, or on a label or symbol applied to them as follows:

1.3.1. in the case of Category 1 materials, using the colour black;

1.3.2. in the case of Category 2 materials (other than manure and digestive tract content), using the colour yellow;

1.3.3. in the case of Category 3 materials, using the colour green with a high content of blue to ensure that it is clearly distinguishable from the other colours;

1.3.4. in the case of imported consignments, the colour referred to for the respective material under sub-subparagraph 1.3.1, 1.3.2 and 1.3.3 of this subparagraph, as from the time when the consignment has passed the border inspection post of Republic of Kosovo.

2. During transport and storage, a label attached to the packaging, container or vehicle must:

2.1 clearly indicate the category of the animal by-products or of the derived products; and

2.2 bear the following words visibly and legibly displayed on the packaging, a container or vehicle, as applicable:

2.2.1 in the case of Category 3 material, **‘not for human consumption’**;

2.2.2 in the case of Category 2 material (other than manure and digestive tract content) and derived products from Category 2 material, **‘not for animal consumption’**; however, when Category 2 material is intended for the feeding of animals referred to in Article 18, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 Laying down health rules for animal by-products and products derived thereof not intended for human consumption under the conditions provided for or laid down in accordance with that Article, the label shall instead indicate **‘for feeding to ...’** completed with the name of the specific species of those animals for the feeding of which the material is intended;

2.2.3 in the case of Category 1 material and derived products from Category 1 material where they are destined for

2.2.3.1 disposal, **‘for disposal only’**;

2.2.3.2 the manufacture of petfood, **‘for manufacture of pet food only’**;

2.2.3.3 the manufacture of a derived product referred to in Article 36 of Administrative Instruction (MAFRD) - No. 05/2022, only **‘for manufacture of derived products only. not for human or animal consumption or for application to land’**;

2.2.4 in the case of milk, milk-based products, milk-derived products, colostrum and colostrum products, **‘not for human consumption’**

2.2.5 in the case of gelatine produced from Category 3 material, **‘gelatine suitable for animal consumption’**

2.2.6 in the case of collagen produced from Category 3 material, **‘collagen suitable for animal consumption’**;

2.2.7 in the case of raw petfood, **‘use as petfood only. keep apart from food. wash hands and clean tools, utensils and surfaces after handling this product’**;

2.2.8 in the case of fish and derived products from fish intended for feed for fish, and treated and packaged before distribution, the name and address of the feed manufacturing establishment of origin, marked clearly and legibly, and

2.2.8.1 in the case of fishmeal from wild fish, bearing the words **‘contains fishmeal from wild fish only – may be used for the feeding of farmed fish of all species’**;

2.2.8.2 in the case of fishmeal from farmed fish, bearing the words **‘contains fishmeal from farmed fish of the [...] species only – may only be used for the feeding of farmed fish of other fish species’**;

2.2.8.3 in the case of fishmeal from wild fish and from farmed fish, bearing the words **'contains fishmeal from wild fish and farmed fish of the [...] species – may only be used for the feeding of farmed fish of other fish species'**;

2.2.9 in the case of blood products from equidae for purposes other than in feed, **'blood and blood products from equidae. not for human or animal consumption'**;

2.2.10 in the case of horns, hooves and other materials for the production of organic fertilisers and soil improvers referred to in Chapter II of Section 12 of Annex XIII to this Administrative Instruction, **'not for human or animal consumption'**;

2.2.11 in the case of organic fertilisers and soil improvers, **'organic fertilisers or soil improvers/no grazing of farmed animals or use of crops as herbage during at least 21 days following application'**;

2.2.12 in the case of material used for feeding in accordance with Section 1 of Chapter II of Annex V of this Administrative Instruction, the name and the address of the collection centre, and the indication **'not for human consumption'**;

2.2.13 in the case of manure and digestive tract content, **'manure'**;

2.2.14 in the case of intermediate products, on the outer packaging, bearing the words **'for medicinal products/ veterinary medicinal products/medical devices/active implantable medical devices/in vitro diagnostic medical devices/laboratory reagents only'**;

2.2.15 in the case of research and diagnostic samples, the words **'for research and diagnostic purposes'**, instead of the label text laid down in subparagraph 2.1 of paragraph 2 of Chapter;

2.2.16 in the case of trade samples, the words **'trade sample not for human consumption'**, instead of the label text laid down in subparagraph 2.1 of the paragraph 2 to this Chapter;

2.2.17 in the case of display items, the words **'display item not for human consumption'**, instead of the label text laid down in subparagraph 2.1 of the paragraph 2 to this Chapter;

2.2.18 in the case of fish oil for the production of medicinal products referred to in Chapter XIII of Annex XI of this Administrative Instruction, the words **'FISH OIL FOR THE PRODUCTION OF MEDICINAL PRODUCTS'**, instead of the label text laid down in subparagraph 2.1 of this paragraph;

2.2.19 in the case of manure which has been subject to the lime treatment set out in point I of Section 2 of Chapter IV of Annex II of this Administrative Instruction, the words **'MANURE-LIME-MIXTURE'**;

2.2.20 in the case of processed manure which has been subject to the treatment set out in paragraph 1, subparagraph 1.2 and 1.3 of Section 2 of Chapter I of Annex IX of this Administrative Instruction, the words **'PROCESSED MANURE'**;

2.2.21 in the case of materials for detoxification referred to in Chapter VII of Annex VI of this Administrative Instruction, the words: 'MATERIALS INTENDED FOR DETOXIFICATION. NOT FIT FOR THE PLACING ON THE MARKET';

2.3 However, the label referred to in subparagraph 2.2, sub-subparagraph 2.2.11 of paragraph 2 of this Chapter shall not be required for the following organic fertilisers and soil improvers:

2.3.1 in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or

2.3.2 in big bags of not more than 1 000 kg in weight, provided that:

2.3.2.1 they are authorised by the competent authority to be applied to land in Republic of Kosovo;

2.3.2.2 it is indicated on those bags that they are not destined for application to land to which farmed animals have access.

3. However:

3.1 Paragraph 1 and 2 of this Chapter shall not apply to the identification of Category 3 material comprising of milk, milk-based products and milk-derived products, by operators of milk-processing establishments which have been approved in accordance with legislation in force, where they are receiving products which they have previously delivered and which are returned to them, in particular from their customers;

3.2 the competent authority may accept the identification of manure which is transported between two points located on the same farm or between farms and users by other means, by way of derogation from paragraph 1 and 2 of Chapter II of this Annex ;

3.3 legislation on placing on the market and use of feed which have been manufactured from animal by-products or from derived products and which are packaged and placed on the market as feed in accordance with specific legislation on placing on the market and use of feed do not have to be identified in accordance legislation in force the feed do not have to be labelled in accordance with paragraph 1 of Chapter II to this Annex.

CHAPTER III COMMERCIAL DOCUMENTS AND HEALTH CERTIFICATES

1. During transportation, a commercial document in accordance with the model set out in this Chapter, or, when required by this Administrative Instruction, a health certificate must accompany animal by-products and derived products.

2. Commercial document or health certificate from paragraph 1 of this Chapter shall not be necessary, provided that:

2.1 derived products from Category 3 material and organic fertilisers and soil improvers are supplied within the Republic of Kosovo by retailers to final users other than business operators;

2.2. milk, milk-based products and milk-derived products which are Category 3 materials are collected and returned to operators of milk-processing establishments, which have been approved in accordance with legislation in force, if those operators are receiving products, in particular from their customers, which they have previously delivered;

2.3 compound feeds as defined in specific legislation on placing on the market and use of feed which have been manufactured from animal by-products or from derived products, are placed on the market packaged and labelled in accordance with specific legislation on placing on the market and use of feed.

2.4 The commercial document must be produced at least in triplicate (one original and two copies).

2.5 The original must accompany the consignment to its final destination.

2.6. The receiver must retain the original.

2.7. The producer must retain one of the copies and the carrier the other;

2.8 Competent Authority may require that proof of the arrival of the consignments is provided by the TRACES system or by a fourth copy of the commercial document which is sent back by the receiver to the producer.

2.9 Health certificates must be issued and signed by the Competent Authority.

2.10 A commercial document in accordance with the model set out under paragraph 8 to this Chapter shall accompany animal by-products and derived products during the transportation as from the starting point in the manufacturing chain referred to in Article 4, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022,

2.11 However, In addition to the authorisation to transmit information by way of an alternative system as referred to in the subparagraph 2 of Article 21, paragraph 3 of Administrative Instruction (MAFRD) - No. 05/2022, the competent authority may authorise that animal by-products and derived products which are transported on national territory are accompanied by:

2.11.1 a different commercial document, in paper or in electronic form, provided that such commercial document contains the information referred to in paragraph 6, sub-paragraph 6.6 of the Chapter III to this Annex;

2.11.2 a commercial document in which the quantity of the material is expressed in weight or volume of the material or in the number of packages.

2.11.3 Records and related commercial documents or health certificates shall be kept for a period of at least (2) two years for presentation to the competent authority.

2.12. Model commercial document shall contain:

2.12.1 documents shall contain the information according to the layout of the model appearing in this Chapter, including, the attestations that are required for the transportation of animal by-products and derived products.

2.12.2 it shall be drawn up in official languages of the Republic of Kosovo and, in the official language of the country of destination, as appropriate. However, it may also be accompanied by an official translation if previously agreed by the competent authority of the country of destination.

2.12.3 the original of each commercial document shall consist of a single sheet of paper, both sides, or, where more text is required it shall be in such a form that all sheets of paper needed are demonstrably part of an integrated whole and indivisible.

2.12.4 if for reasons of identification of the items of the consignment, additional sheets of paper are attached to the commercial document, these sheets of paper shall also be considered as forming part of the original document by the application of the signature of the person responsible for the consignment, on each of the pages;

2.12.5 when the commercial document, including additional sheets of paper referred to in subparagraph 8.4 to this paragraph, comprises more than one page, each page shall be numbered – (page number) of (total number of pages) – at the bottom of the page and shall bear the code number of the document that has been designated by the responsible person at the top of the page;

2.12.6 the original of the commercial document must be completed and signed by the responsible person;

2.12.7 the commercial document must specify:

2.12.8 the date on which the material was taken from the premises;

2.12.9 the description of the material, including;

2.12.10 the identification of the material according to one of the categories referred to in Articles 8, 9 and 10 of Administrative Instruction (MAFRD) - No. 05/2022;

2.12.11 the animal species and the specific reference to the applicable point in Article 10 of Administrative Instruction (MAFRD) - No. 05/2022 for Category 3 material and products derived therefrom which are destined for feeding and,

2.12.12 if applicable, the ear-tag number of the animal;

2.12.13 the quantity of the material, in volume, weight or number of packages;

2.12.14 the name and address of the establishment or plant of origin of the material and its approval or registration number assigned in accordance with Administrative Instruction (MAFRD) - No. 05/2022 or, where applicable, and the nature and the method of the treatment, as applicable;

2.12.15 the name, the address and the registration number of the transporter of the material;

2.12.16 in case of transport in containers, the complete container identification number ('BIC code') issued in accordance with the requirements of the Bureau International des Containers et du Transport Intermodal;

2.12.17 in case of export of processed animal protein and products containing processed animal proteins as referred by the legislation in force On the Control, Prevention and Eradication of TSEs, shall contain the point of exit from Republic of Kosovo.

2.12.18 The colour of the signature of the responsible person shall be different to that of the printing.

2.13. The document reference number and the local reference number shall only be issued once for the same consignment.

Commercial document

For the transport of animal by-products and derived products not intended for human consumption in accordance with Administrative Instruction (MAFRD) - No. 05/2022 within the territory of the Republic of Kosovo and other countries.

Commercial document

For the transport within the Republic of Kosovo of animal by-products and derived products not intended for human consumption in accordance with Administrative Instruction (MAFRD) - No. 05/2022 laying down health rules for animal by-products and products derived thereof not intended for human consumption

REPUBLIC OF KOSOVO

Commercial document

Part I: Details of dispatched consignment	I.1. Consignor				II.2. Document reference No		II.2. Local reference No								
	Name														
	Address				I.3. Central Competent Authority										
	Approval or registration number				I.4. Local Competent Authority										
	Postcode														
	I.5. Consignee				I.6. Registered trader										
Name				Name											
Address				Registration number											
Postcode				Address											
Approval or registration number				Postal code											
Tel.				Country											
I.7.															
I.8. Country of origin		ISO code		I.8. Region of origin		Code		I.10. Country of destination		ISO code		I.11. Region of destination		Code	

1.11. Place of origin Establishment <input type="checkbox"/> Name: _____ Approval or registration number _____ Address _____ Postcode _____	1.13. Place of destination Establishment <input type="checkbox"/> Name: _____ Approval or registration number _____ Address _____ Postcode _____
1.13. Place of loading	1.15. Date of departure
1.16. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: _____	1.17. Transporter Name number _____ Approval or registration number _____ Address _____ Postcode _____ Country _____
1.18. Description of commodity	
1.19. Commodity code (CN code)	
1.20. Total Quantity	
1.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/> Controlled temperature <input type="checkbox"/>	
1.22. Number of packages	
1.23. Seal number if a seal imposed by competent authority and the Container BIC ID number	
1.24. Type of packaging	
1.25. Commodities certified for: Animal feedingstuff <input type="checkbox"/> Petfood use <input type="checkbox"/> Organic fertilisers/soil improvers <input type="checkbox"/> Technical use <input type="checkbox"/> Consignment is subject to requirements laid down in Regulation (EC) No 999/2001 <input type="checkbox"/> Category 3 fish oil/fishmeal with excessive level(s) of dioxin and/or PCBs intended for detoxification according to Regulation (EU) 2015/786. <input type="checkbox"/>	
1.26.	1.27. For transit through Republic of Kosovo <input type="checkbox"/>
1.28. Export <input type="checkbox"/> Other country ISO code _____ Exit point Code _____	1.29.
1.30.	
1.31. Identification of the commodities <div style="text-align: right;">Approval number of establishments _____</div> <div style="display: flex; justify-content: space-between;"> Species Nature of commodity Category Treatment type Manufacturing plant Batch number </div>	

REPUBLIC OF KOSOVO
not intended for human consumption

Animal by-products/derived products

II. Health information

II.2. Certificate reference No

II.2.

II.1 Declaration by the consignor

I, the undersigned, declare that

II.1.1. the information in Part I is factually correct:

II.1.2. all precautions have been taken to avoid contamination of the animal by-products or derived products with pathogenic agents and cross-contamination between various categories

Notes

I.6. Registered trader

Name

Registration number

Address

Postal code

Country

I.7.

Name

Address

Postcode

Approval or registration number

Tel.

I.8. Country of origin

ISO code

I.8. Region of origin

Code

I.10. Country of destination

ISO code

I.11. Region of destination

Code

I.11. Place of origin

Establishment ☐

Name

Approval or registration number

Address

Postcode

I.13. Place of destination

Establishment ☐

Name

Approval or registration number

Address

Postcode

I.13. Place of loading

I.15. Date of departure

I.16. Means of transport

Aeroplane ☐Ship ☐

Railway wagon

Road vehicle ☐Other ☐

Identification:

I.17. Transporter

Name
number

Approval or registration

Address

Postcode

Country

I.18. Description of commodity

I.19. Commodity code (CN code)

I.21. Temperature of product

Ambient ☐Chilled ☐Frozen ☐Controlled temperature ☐

I.20. Total Quantity

I.22. Number of packages

I.24. Type of packaging

I.23. Seal number if a seal imposed by competent authority and the Container BIC ID number

I.25. Commodities certified for:

Animal feedingstuff ☐Petfood use ☐Organic fertilisers/soil improvers ☐Technical use ☐Consignment is subject to requirements laid down in Regulation (EC) No 999/2001 ☐Category 3 fish oil/fishmeal with excessive level(s) of dioxin and/or PCBs intended for detoxification according to Regulation (EU) 2015/786. ☐

1.26.	1.27. For transit through Republic of Kosovo <input type="checkbox"/>
1.28. Export <input type="checkbox"/> Other country ISO code Exit point. Code	1.29.
1.31. Identification of the commodities	

II. Health information

II.a. Certificate reference number

II.b.

II.1. Declaration by the consignor

I, undersigned official veterinarian, declare that Declaration by the consignor
|, the undersigned, declare that:

Nature of commodity: Enter a commodity chosen from the following list: "apiculture by-products", "blood products", "blood",
Health information II.a. Certificate reference No II.b.

II.1.1. the information in Part I is factually correct;

II.1.2. all precautions have been taken to avoid contamination of the animal by-products or derived products with pathogenic
agents and cross-contamination between various categories.

Notes

Part I:

- Box reference I.1: The legal or physical person ordering the transport indicated in the document required by the Convention relative au Contract de Transport International de Marchandises par Route (CMR).
- Box reference I.5: The legal or physical person for which the consignment is destined.
- Box reference I.6 [optional, if appropriate]: Registered trader name, address, registration number.
- Box reference I.9 and I.11: if appropriate.
- Box reference I.12, I.13: approval number or registration number.

In case of:

- products subject to Article 48(3) of Regulation (EC) No 1069/2009 only a storage plant, incineration or co-incineration
- fish oil or fishmeal of Category 3 intended for detoxification according to Regulation (EU) 2015/786 indicate the approval number of the plant of destination according to Regulation (EC) No 183/2005 or Regulation (EU) 2015/786.
- Box reference I.14: complete if different from I.1. and I.12.
- Box reference I.17: registration or approval number of the actual transporter. If this is the same information as in Box I.6, use only box I.17.
- Box reference I.23: in case of transport in container, the complete container identification number ("BIC code") is obligatory.
- Box reference I.25: technical use: any use other than for animal consumption or organic fertilisers or soil improvers OF/SI. Technical products cannot be used in feed, petfood or OF/SI.
- Box reference I.31:

Animal species: For Category 3 material and products derived therefrom destined for use as feed material. Select from the following: Aves, Ruminants, Suidae, other Mammalia, Pesca, Mollusca, Crustacea, Insecta (species, if appropriate), other Invertebrates, Mixed non-ruminant species, Mixed species containing ruminants.

Nature of commodity: Enter a commodity chose form the following list: "apiculture by-products", "blood products", "blood", "bloodmeal", "digestion residues", "digestive tract content", "dog- chews", "fishmeal", "flavouring innards", "gelatine", "greaves", "hides and skins", "hydrolysed proteins", "organic fertilisers/soil improvers", "pet food", "processed animal protein", "animal by- products for the production of pet food", "raw pet food", "rendered fats", "compost", "processed manure", "fish oil", "milk products", "colostrum products", "centrifuge or separator sludge from milk processing", "dicalciumphosphate", "tricalciumphosphate", "collagen", "egg products", "serum of equidae", "game trophies", "wool", "hair", "pig bristles", "feathers", "animal by- products for processing", "derived products", "meat-and-bone meal", "cadavers", "manure", "fat derivatives", "glycerine", "former food stuffs", "catering waste", "used cooking oil", "treated hides and skins", "growing media", "dead pet animals", "dead equidae", "former feed stuffs", "[nature of ABP or DP] mixed with non hazardous waste [EURAL code]", "eggs", "hatchery by products", "embryos in eggs or not".

Category:

Specify Categories 1, 2 or 3 materials.

In case of Category 3 material intended for use as feedstuff, indicate the point of Article 10 of Regulation (EC) No 1069/2009 that refers to the animal by-product concerned (e.g. Article 10(a), Article 10(b) etc).

In the case of Category 3 material for use in raw petfood indicate "3a", "3b(i)" or "3b(ii)" depending on whether the animal by-products are referred to in Article 10(a) or in Article 10(6)(i) or (ii) of Regulation (EC) No 1069/2009.

In the case of hides and skins and products derived therefrom, indicate "3b(iii)" or "3(n)" depending on whether the animal by-products or derived products are referred to in Article 10(b)(iii) or in Article

Category:

Specify Categories 1, 2 or 3 materials.

In case of Category 3 material intended for use as feedstuff, indicate the point of Article 10 of Regulation (EC) No 1069/2009 that refers to the animal by-product concerned (e.g. Article 10(a), Article 10(b) etc).

In the case of Category 3 material for use in raw petfood indicate "3a", "3b(i)" or "3b(ii)" depending on whether the animal by-products are referred to in Article 10(a) or in Article 10(6)(i) or (ii) of Regulation (EC) No 1069/2009.

In the case of hides and skins and products derived therefrom, indicate "3b(iii)" or "3(n)" depending on whether the animal by-products or derived products are referred to in Article 10(b)(iii) or in Article 10(n) of Regulation (EC) No 1069/2009.

Treatment type: For treated hides and skins indicate the treatment:

"(a)" for dried;

"(b)" for dry-salted or wet-salted for at least 14 days prior to dispatch;

"(c)" for sodium carbonate.

For Category 1 and 2 materials, describe the method of processing or transformation. Indicate the relevant processing method (choose a method from 1 to 5 referred to in Chapter III or an alternative method referred to Chapter IV of Annex IV to Regulation (EU) No 142/2011) or processing method for processed manure referred to in Annex XI thereof and indicate date of GTH marking as applicable.

For Category 3 materials destined for use in feed refer to the appropriate Section of Annex X to Regulation (EU) No 142/2011.

For derived products from Category 3 material destined for use in feed, indicate the relevant standard processing method (choose a method from 1 to 7 referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011 in case of processed animal protein (PAP)), an alternative method referred to Chapter IV of Annex IV in case of ensilage, or describe the nature and the methods of treatment set out in Chapter II of Annex X to Regulation (EU) No 142/2011. Fish oil or fishmeal for detoxification shall be labelled as "fish oil or fishmeal with excessive level(s) of dioxins and/or PCBs in accordance with Annex I to Directive 2002/32/EC destined for detoxification in an approved establishment"

Batch number: Enter batch number or ear tag number, if applicable.
Manufacturing plant: in the case of PAP and other feed materials indicate the processing plant

Signature: The signature must be in a different colour to that of the printing.

Signature

Date: on (date)

Signature of the responsible person of place of origin
(name, in capital letters)

CHAPTER IV RECORDS

Section 1 General provisions

1. The records as referred to in Article 22, paragraph 1 of the Administrative Instruction (MAFRD)-No. 05/2022 for animal by-products and derived products, other than compound feeds as defined in specific legislation on placing on the market and use of feed, which have been manufactured from animal by-products or from derived products and which are placed on the market in accordance with legislation in force, shall contain:

1.1 a description of:

1.1.1 the animal species for Category 3 material and derived products therefrom, destined for use as feed material and, if applicable, in the case of whole carcasses and heads, the ear-tag number;

1.2 the quantity of the material;

1.2.1. in the case of records kept by any person consigning animal by-products or derived products, the following information:

1.2.1.1. the date on which the material was taken from the premises;

1.2.1.2. the name and the address of the transporter and of the receiver and, if applicable, their approval or registration number;

1.3. in the case of records kept by any person transporting animal by-products or derived products, the following information:

1.3.1. the date on which the material was taken from the premises;

1.3.2. the place of origin of the material, from where the material is dispatched;

1.3.3. the name and the address of the receiver and, if applicable, its approval or registration number;

1.4. in the case of records kept by any person receiving animal by-products or derived products, the following information:

1.4.1 the date of reception of the material;

1.4.2 the place of origin of the material, from where the material is dispatched;

1.4.3 the name and address of the transporter.

2. By way of derogation from paragraph 1 of this Section, operators do not have to keep the information referred to in paragraph 1, subparagraph 1.1 and 1.2, sub-subparagraph 1.2.1, subparagraph 1.3 sub-subparagraph 1.3.1 and 1.3.3 and subparagraph 1.4, sub-subparagraph 1.4.2 and 1.4.3 separately, if they keep a copy of the commercial document laid down in Chapter III of this Annex for each consignment and make such information available in conjunction with the other information required under paragraph 1 of this Section.

3. Operators of incineration plants and co-incineration plants shall keep records of the quantities and category of the animal by-products and derived products incinerated or co-incinerated, as applicable, and the date at which those operations were carried out.

Section 2

Additional requirements in case of use for special feeding purposes

1. In addition to the records required in accordance with Section 1 of this Chapter, operators shall keep the following records in relation to relevant material if animal by-products are used for special feeding purposes in accordance with Chapter II of Annex IV.

1.1.in the case of final users, the quantity used, the animals that it is intended to be fed to and the date of use;

1.2.in the case of collection centres:

1.3.the quantity handled or treated in accordance with paragraph 4 of Section 1 of Chapter I of Annex IV;

1.4.the name and address of each final user using the material;

1.5.the premises to which the material is taken for use;

1.6. the quantity dispatched; and

1.7.the date on which the material was dispatched.

Section 3

Requirements for the application of certain organic fertilisers and soil improvers to land

1.The person responsible for land to which organic fertilisers and soil improvers, other than the materials referred to in the paragraph 2, subparagraph 2.2 of Article 6 of this Administrative Instruction are applied and to which farmed animals have access or from which herbage is cut for feeding to farmed animals, shall keep records of the following for a period of at least (2) two years:

1.1.the quantities of organic fertilisers and soil improvers applied;

1.2.the date on which the organic fertilisers and soil improvers were applied to land and the places of such application;

1.3. the dates, following the application of the organic fertiliser or soil improver, on which livestock has been allowed to graze on the land or on which the land has been cut for herbage to be used for feeding.

Section 4

Requirements for animal by-products derived from aquatic animals and feeding of fish

1.Processing plants producing fishmeal or other feed originating from aquatic animals shall keep records of the following:

1.1. the quantities produced each day;

1.2. the species of origin, including an indication of whether the aquatic animals were caught in the wild or produced in aquaculture;

1.3. in the case of fishmeal from farmed fish which is intended for feeding to farmed fish of another species, the scientific name of the species of origin.

Section 5

Requirements for the burning and burial of animal by-products

1. In the case of burning or burial of animal by-products as provided for in Article 19, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/ the person responsible for such burning or burial shall keep records of the following:

1.1. the quantities, categories and species of animal by-products burned or buried;

1.2. the date and place of burning and burial.

CHAPTER V

MARKING OF CERTAIN DERIVED PRODUCTS

1. In processing plants for the processing of Category 1 or Category 2 material, derived products shall be permanently marked with glyceroltriheptanoate (GTH) in such a way that:

1.1 GTH is added to derived products that have undergone a preceding sanitising thermal treatment at a core temperature of at least 80 °C and remain subsequently protected from re-contamination;

1.2 all derived products contain homogeneously throughout the substance a minimum concentration of at least 250 mg GTH per kg fat.

2. The operators of processing plants referred to in paragraph 1 of this Chapter shall have in place a system of monitoring and recording of parameters suitable to demonstrate to the competent authority that the required homogeneous minimum concentration of GTH is achieved. That monitoring and recording system shall include the determination of the content of intact GTH as triglyceride in a cleaned petroleum-ether 40-70 extract of GTH from samples taken at regular intervals.

3. the marking with GTH shall not be required for:

3.1 liquid derived products destined for biogas or composting plants;

3.2. biodiesel produced in accordance with point D of Section 2 of Chapter IV of Annex II;

3.3. derived products obtained in accordance with Article 12, paragraph 1, subparagraph 1.1, subparagraph 1.1.2 and subparagraph 1.2, sub-sub-paragraph 1.2.2 and Article 13, paragraph 1, subparagraph 1.1, sub-sub-paragraph 1.1.2, and subparagraph 1.2, sub-sub-paragraph 1.2.2 and Article 16, paragraph 1, subparagraph 1.5 of Administrative Instruction (MAFRD) - No. 05/2022 where such products are:

3.3.1. moved by a closed conveyer system, which may not be by-passed, and provided such a system has been authorised by the competent authority, from the processing plant for:

3.3.2. immediate direct incineration or co-incineration,

3.3.3. immediate use in accordance with a method approved for animal by-products of Category 1 and Category 2 in accordance with Chapter I of Annex II of this Administrative Instruction; or

3.3.4. intended for research and other specific purposes as referred to in Article 17 of Administrative Instruction (MAFRD) - No. 05/2022 which have been authorised by the competent authority;

4.renewable fuels produced from rendered fats, which are derived from Category 1 and Category 2 materials, in accordance with points J and L of Section 2 of Chapter IV of Annex II of this Administrative Instruction.

CHAPTER VI TRANSPORT OF DEAD PET ANIMALS

The conditions of the transport of a dead pet animal for incineration in an establishment or plant located in other country shall be authorized in advance by the competent authority of the country of destination or in case of the border region of another country sharing a common border with Republic of Kosovo shall be concluded by a bilateral agreement on the condition of the transport.

ANNEX VII REQUIREMENTS APPLICABLE TO CERTAIN APPROVED AND REGISTERED ESTABLISHMENTS AND PLANTS

CHAPTER I MANUFACTURING OF PETFOOD

1.Establishments or plants manufacturing petfood as referred to in Article 24, paragraph 1, subparagraph 1.5 of Administrative Instruction (MAFRD) - No. 05/2022 shall have adequate facilities for:

1.1.storing and treating incoming material in complete safety; and

1.2. disposing of unused animal by-products remaining after the production of the products in accordance with this Administrative Instruction, or such material must be sent to an incineration plant, a co-incineration plant, a processing plant or, in the case of Category 3 material, to a biogas or composting plant in accordance with Articles 12, 13 and 14 of Administrative Instruction (MAFRD) - No. 05/2022 and this Administrative Instruction.

CHAPTER II HANDLING OF ANIMAL BY-PRODUCTS AFTER THEIR COLLECTION

1.The requirements of this Chapter shall apply to the storage of animal by-products, as referred to in Article 24, paragraph 1, subparagraph 1.9 of Administrative Instruction (MAFRD) - No. 05/2022 and to the following operations involving the handling of animal by-products after their collection, as referred to in Article 24, paragraph 1, subparagraph 1.8 of that Administrative Instruction :05/2022 as:

1.1 sorting;

1.2 cutting;

1.3 chilling;

- 1.4 freezing;
 - 1.5 salting or other preservation processes;
 - 1.6 removal of hides and skins;
 - 1.7 removal of specified risk material;
 - 1.8 operations involving the handling of animal by-products which are carried out in compliance with obligations under veterinary legislation, such as post-mortem examination or the taking of samples;
 - 1.9 hygienisation/pasteurisation of animal by-products destined for transformation into biogas or composting, prior to such transformation or composting in another establishment or plant in accordance with Annex III;
 - 1.10 sieving;
- 2.phase transition processes of Category 3 materials, such as blood thermo coagulation, blood centrifugation, hydrolyzing of hooves, pig bristles, feathers and hair, destined for processing with processing methods set out in this Administrative Instruction.

Section 1

General requirements

1. Premises and facilities where intermediate operations are carried out shall meet at least the following requirements:
 - 1.1.They must be adequately separated from thorough fares through which contamination may be spread and from other premises such as slaughterhouses.
 - 1.2.The layout of plants shall ensure the total separation of Category 1 and Category 2 material from Category 3 material respectively, from reception until dispatch, unless in a completely separate building.
- 2.The plant must have a covered space to receive and dispatch animal by-products, unless the animal by-products are being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid animal by-products.
- 3.The plant must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids.
4. Floors must be laid down in such a way as to facilitate the draining of liquids.
- 5.The plant must have adequate facilities including lavatories, changing rooms, washbasins for staff and, if appropriate, office space which can be made available to the staff performing official controls.
6. The plant must have adequate protection against rodents, insects and birds.

7. Where necessary, the enterprise must have adequate storage areas with controllable temperature and sufficient capacity for the maintenance of animal products at the appropriate temperature designed to allow monitoring and recording of those temperatures.

8. The plant shall be equipped with adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and for the vehicles, other than ships, in which they are transported. Adequate facilities shall be available for the disinfecting of vehicles.

Section 2

Hygiene requirements

1. The sorting of animal by-products shall be carried out in such a way as to avoid any risk of the propagation of animal diseases.

2. At all times during storage, animal by-products shall be handled and stored separately from other goods and in such a way as to prevent any propagation of pathogens.

3. Animal by-products shall be stored properly, including under appropriate temperature conditions, until final destination.

Section 3

Processing standards for hygienisation/pasteurization

Hygienisation/pasteurisation as referred to in subparagraph 1.9 of the paragraph 1 of this Chapter shall be carried out in accordance with the processing standards referred to in paragraph 1 of Section 1 of Chapter I of Annex III of this Administrative Instruction or in accordance with alternative transformation parameters which have been authorised in accordance with paragraph 1 of Section 2 of Chapter III of the same Annex.

CHAPTER III

REQUIREMENTS FOR STORAGE OF DERIVED PRODUCTS

Section 1

General requirements

1. Premises and facilities storing derived products shall meet at least the following requirements:

1.1. Premises and facilities storing derived products from Category 3 material must not be at the same site as premises storing derived products from Category 1 or Category 2 material, unless cross-contamination is prevented due to the layout and management of the premises, such as by means of storage in completely separate buildings.

2. The plant must:

2.1. have a covered space to receive and dispatch the derived products, unless the derived products are:

2.1.1. being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid products; or

2.1.2. received in packaging, such as in big bags, or in covered leak-proof containers or means of transport;

3.be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids;

4.have adequate facilities including lavatories, changing rooms and washbasins for staff;

5.have appropriate arrangements for protection against pests, such as insects, rodents and birds.

6.the plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which the derived products are received and the vehicles, other than ships, in which they are transported.

7.Derived products must be stored properly until redispached.

Section 2

Specific requirements for storage of certain milk, milk-based products and milk-derived products

The storage of the products referred to in Part II of Section 4 of Chapter II of Annex VIII of this Administrative Instruction shall take place at an appropriate temperature to avoid any risk to public or animal health in a dedicated approved or registered storage establishment or plant or in a dedicated, separate storage area within an approved or registered storage establishment or plant. Samples of the final products taken during storage or at the time of withdrawal from storage, shall at least comply with the microbiological standards set out in Chapter I of Annex VIII of this Administrative Instruction.

CHAPTER IV REGISTERED OPERATORS

1.Operators of registered plants or establishments or other registered operators shall handle animal by-products and derived products under the following conditions:

1.1.premises must be constructed in a way permitting their effective cleaning and disinfection, where appropriate;

1.2.premises must have appropriate arrangements for protection against pests, such as insects, rodents and birds;

1.3.installations and equipment must be kept in hygienic condition, where necessary;

1.4.animal by-products and derived products must be stored under conditions preventing contamination.

2.Operators shall keep records in a form which is accessible to the competent authority.

3. Registered operators transporting animal by-products or derived products, other than between premises of the same operator, shall in particular:

3.1.have information at their disposal with regard to the identification of their vehicles, which allows the verification of the use of the vehicles for the transport of animal by-products or derived products;

3.2.clean and disinfect their vehicles, as appropriate;

3.3.take all other necessary measures to prevent contamination and the spreading of diseases communicable to humans or animals.

ANNEX VIII FEED MATERIALS

CHAPTER I GENERAL REQUIREMENTS FOR THE PROCESSING AND PLACING ON THE MARKET

1.Microbiological standards for derived products.

2.The following microbiological standards shall apply to derived products:

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

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

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

3.2.1 n = number of samples to be tested;

3.2.2 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

3.2.3 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.

4.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.

CHAPTER II SPECIFIC REQUIREMENTS FOR PROCESSED ANIMAL PROTEIN AND OTHER DERIVED PRODUCTS

Section 1 Specific requirements for processed animal protein

A.Raw materials

1.Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than the Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.14,

1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022, may be used for the production of processed animal protein.

2.Processed animal protein derived from farmed insects, intended for the production of feed for farmed animals other than fur animals, may only be obtained from the following insect species:

- 2.1.Black Soldier Fly (*Hermetia illucens*) and Common Housefly (*Musca domestica*);
- 2.2. Yellow Mealworm (*Tenebrio molitor*) and Lesser Mealworm (*Alphitobius diaperinus*);
- 2.3. Insects *Acheta domesticus*, *Gryllobates sigillatus* and *Gryllus assimilis*.
- 2.4. Silkworm (*Bombyx mori*).

B.Processing standards

1.Processed animal protein of mammalian origin must have been submitted to processing method 1 (pressure sterilisation) as set out in Chapter III of Annex II of this Administrative Instruction.

2.However, porcine blood or fractions of porcine blood for the production of bloodmeal may have been submitted instead to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex II of this Administrative Instruction, provided that in the case of processing method 7, a heat treatment throughout its substance at a temperature of 80 °C has been applied;

3.processed animal protein of mammalian origin.

4.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 II of this Administrative Instruction, provided that it is subsequently disposed of or used as a fuel for combustion;

5.where it is exclusively destined for use in petfood, it 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 II of this Administrative Instruction, provided that it is:

5.1 transported in dedicated containers that are not used for the transport of animal by-products or feedingstuffs for farmed animals, and

5.2 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.

5.3 Non-mammalian processed animal protein, with the exception of fishmeal, must have been submitted to any of processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex II of this Administrative Instruction.

6.Fishmeal must have been submitted to:

6.1 any of the processing methods set out in Chapter III of Annex II of this Administrative Instruction;
or

6.2 another method which ensures that the product complies with the microbiological standards for derived products set in Chapter I of this Annex.

C. Storage

1.Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins or in storage sheds.

2.Products in conveyors, elevators and bins must be protected from casual contamination.

3.Equipment for handling processed animal protein must be maintained in a clean and dry condition and must have adequate inspection points so that equipment can be examined for cleanliness.All storage facilities must be emptied and cleaned regularly, to the extent necessary to prevent contamination.

4. Processed animal protein must be kept dry.

Leakages and condensation in the storage area must be prevented.

Section 2

Specific requirements for blood products

A. Raw material

Only blood referred to in Article 10, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022 may be used for the production of blood products.

B. Processing standards

1.Blood products must have been submitted to:

1.1. any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex II of this Administrative Instruction; or

1.2.another method which ensures that the blood product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

Section 3

Specific requirements for rendered fats, fish oil and fat derivatives from Category 3 material

A. Raw materials

1.Rendered fats

1.1. Only Category 3 material, other than Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.14, 1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022, may be used for the production of rendered fat.

2. Fish oil

2.1. Only Category 3 material referred to in Article 10, paragraph 1, subparagraph 1.9, 1.10 and 1.12 of Administrative Instruction (MAFRD) - No. 05/2022 and Category 3 material of aquatic animal origin referred to in Article 10, paragraph 1, subparagraph 1.5 and 1.6 of that Administrative Instruction may be used for the production of fish oil.

Processing standards

1. Unless the fish oil or rendered fats have been produced in accordance with legislation in force laying down specific rules on hygiene of food of animal origin, respectively, rendered fats must be produced using any of the processing methods 1 to 5 or processing method 7, and fish oils may be produced:

1.1. using processing methods 1 to 7, as set out in Chapter III of Annex II of this Administrative Instruction; or

1.2. in accordance with another method which ensures that the product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

2. Rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight.

3. Fat derivatives from Category 3 rendered fats or fish oil shall be produced in accordance with one of the processing methods referred to in Chapter III of Annex II of this Administrative Instruction.

C. Hygiene requirements

1. Where rendered fat or fish oil is packaged, it must be packaged in new containers or in containers that have been cleaned and disinfected if necessary for the prevention of contamination and all precautions must be taken to prevent its recontamination.

2. Where bulk transport of those products is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or directly to plants must be clean before use.

Section 4

Specific requirements for milk, colostrum and certain other products derived from milk or colostrum

Part I

General requirements

A. Raw material

1. Only milk referred to in Article 10, paragraph 1, subparagraph 1.5 of Administrative Instruction (MAFRD) - No. 05/2022, other than centrifuge or separator sludge, and milk referred to in Article 10, paragraph 1, subparagraph 1.6 and 1.8 of that Administrative Instruction may be used for the production of milk, milk-based products and milk-derived products.

2. Colostrum may only be used provided that it originates from live animals that did not show any signs of disease communicable through the colostrum to humans or animals.

B. Processing standards

1. Milk must be subjected to one of the following treatments:

1.1 sterilisation at an F_0 value of three or more;

1.2 UHT combined with one of the following:

1.2.1 a subsequent physical treatment, by:

1.2.2 a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

1.2.3 lowering the pH below 6 for at least 1 hour;

1.2.4 the condition that the milk, milk-based product or milk-derived product has been produced at least 21 days before shipping and that during that period no case of Foot-and-Mouth disease has been detected;

1.2.5 HTST applied twice;

1.2.6 HTST3 in combination with one of the following:

1.2.7 a subsequent physical treatment, by:

1.2.8 a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

1.2.9 lowering the pH below 6,0 for at least 1 hour;

1.2.10 Milk-based products and milk-derived products must either be subjected to at least one of the treatments provided for in paragraph 1 to this point B or be produced from milk treated in accordance with paragraph 1 of this point B

2. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with paragraph 1 to this point B must:

2.1 either be collected at least 16 hours following milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings; or

2.2 have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected.

3. In addition to the requirements set out in paragraph 1, 2 and 3 of this point B, milk, milk-based products and milk-derived products must meet the following requirements:

- 3.1. after completion of the processing, every precaution must be taken to prevent contamination of the products;
- 3.2. the final product must be labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and it must be:
 - 3.2.1 packed in new containers; or
 - 3.2.2 transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected.
4. Raw milk must be produced under conditions offering adequate guarantees as regards animal health.
5. Colostrum and colostrum products must:
 - 5.1. be obtained from bovine animals kept on a holding on which all bovine herds are recognised as officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free;
 - 5.2. have been produced at least 21 days before shipping and during that period no case of Foot-and-Mouth disease has been detected;
 - 5.3. have undergone a single HTST treatment 3;
 - 5.4. comply with the requirements set out in paragraph 4 of this Point B.

Part II

Derogation for the placing on the market of milk processed in accordance with national standards

1. The requirements laid down in paragraph 2 and 3 of this Part shall apply to the processing, use and storage of milk, milk-based products and milk-derived products which are Category 3 material, as referred to in Article 10, paragraph 1, subparagraph 1.5 of Administrative Instruction (MAFRD) - No. 05/2022, other than centrifuge or separator sludge, and milk, milk-based products and milk-derived products referred to in Article 10, paragraph 1, subparagraph 1.6 and 1.8 of that Administrative Instruction, that have not been processed in accordance with Part I of this Section.
2. The competent authority shall authorise milk processing establishments approved or registered in accordance with legislation in force laying down specific rules on hygiene of food of animal origin to supply milk, milk-based products and milk-derived products for the purposes referred to in paragraph 3 of this Part provided the establishment concerned ensures the traceability of the products.
3. Milk, milk-based products and milk-derived products may be supplied and used as feed material:
 - 3.1. In the Republic of Kosovo and in cross-border areas where the Republic of Kosovo have a mutual agreement to that effect, in the case of derived products, including white water, which have been in contact with raw milk and/or milk pasteurised in accordance with the requirements for heat treatment

set out by legislation in force laying down specific rules on hygiene of food of animal origin, if those derived products have been subject to one of the following treatments:

3.1.1 UHT;

3.1.2 sterilisation whereby either an Fc value equal or greater than 3 is achieved, or which was carried out at a temperature of at least 115 °C for 15 minutes or an equivalent combination of temperature and time;

3.1.3 pasteurisation or sterilisation, other than that referred to in sub-subparagraph 3.1.2 of this subparagraph, followed by:

3.1.3.1 in the case of dried milk or dried milk-based products or milk-derived products, a drying process;

3.1.3.2 in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6;

3.2 In the Republic of Kosovo

3.2.1 in the case of derived products, including white water, which have been in contact with milk that has only been pasteurised in accordance with the requirements for heat treatment set out by the legislation in force laying down specific rules on hygiene of food of animal origin, and whey produced from non heat-treated milk - based products, which has been collected at least 16 hours after milk clotting and where the pH must be recorded as < 6,0 before supplying the whey for feeding, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Republic of Kosovo in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease;

3.2.2 in the case of raw products, including white water that has been in contact with raw milk and other products for which the treatments referred to in subparagraph 3.1 of this paragraph and subparagraph 3.2, sub-subparagraph 3.2.1 of this paragraph be ensured, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of a risk assessment for the best and worst case scenarios carried out by the Republic of Kosovo in preparation of the contingency plans for epizootic diseases, in particular Foot-and-Mouth disease.

3.2.2.1 either directly to a slaughterhouse located in the Republic of Kosovo, or

3.2.2.2 to another holding in the Republic of Kosovo, for which the competent authority guarantees that animals susceptible to Foot-and-Mouth disease may leave the holding only either directly to a slaughterhouse located in the Republic of Kosovo, or if the animals have been dispatched to a holding not feeding the products referred to in subparagraph 3.2.2, after a 21-day standstill period has elapsed from the introduction of the animals.

4. The competent authority may authorise the supply of colostrum which does not comply with the conditions set out in point B, paragraph 6 of Part I of this Section 4 from one farmer to another farmer within the country for feeding purposes, under conditions which prevent the transmission of health risks.

Part III

Special requirements for centrifuge or separator sludge

1. Category 3 material comprising of centrifuge or separator sludge must have been subjected to a heat treatment of at least 70 °C for 60 minutes or of at least 80 °C for 30 minutes, before it may be placed on the market for feeding to farmed animals.

2. By way of derogation from the paragraph 1 of Part 3 the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within territory of the Republic of Kosovo, provided operators can demonstrate that the heat treatment according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the parameters set out in the point 1 of this Part.

Section 5

Specific requirements for gelatine and hydrolysed protein

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10, paragraph 1, subparagraph 1.13, 1.14, 1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/ may be used for the production of gelatine and hydrolysed protein.

B. Processing standards for gelatine

1. Unless the gelatine has been produced in accordance with legislation in force laying down specific rules on hygiene of food of animal origin, it must be produced by a process that ensures that Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses.

2. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

3. After having been subjected to the processes referred to in paragraph 1 to this point B, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.

4 The use of preservatives, other than sulphur dioxide and hydrogen peroxide, shall be prohibited.

C. Other requirements for gelatine

1. Gelatine must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:

1.1. a room or a dedicated place must be provided for storing materials for wrapping and packaging;

1.2. wrapping and packaging must take place in a room or in a place intended for that purpose.

D.Processing standards for hydrolysed protein

1.Hydrolysed protein must be produced using a production process involving appropriate measures to minimise contamination. Hydrolysed protein derived from ruminants shall have a molecular weight below 10 000 Dalton.

2..In addition to the requirements of the paragraph 1 of this point D, hydrolysed proteins entirely or partly derived from ruminants' hides and skins shall be produced in a processing plant dedicated only to hydrolysed protein production, using a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by exposure of the material to:

2.1.a pH of more than 11 for more than three hours at a temperature of more than 80 °C and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar; or

2.2.a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 °C for 30 minutes at 3 bar.

Section 6

Specific requirements for dicalcium phosphate

A.Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10, paragraph 1, subparagraph 1.13, 1.14, 1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022 may be used for the production of dicalcium phosphate.

B. Processing standards

1. Dicalcium phosphate must be produced by a process that comprises the three following stages:

1.1. firstly, ensures that all bone that is Category 3 material is finely crushed and degreased with hot water and treated with dilute hydro chloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

1.2. secondly, following the part of the process referred to in subparagraph 1.1 of this paragraph, applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7;

1.3. finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C.

3.Where dicalcium phosphate is derived from defatted bones, it shall be derived from bones referred to in Article 10, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022

Section 7

Specific requirements for tricalcium phosphate

A.Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10, paragraph 1, subparagraph 1.13, 1.14, 1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022 may be used for the production of tricalcium phosphate.

B.Processing standards

1. Tricalcium phosphate must be produced by a process that ensures:
 - 1.1.that all bone that is Category 3 material is finely crushed and degreased in counterflow with hot water (bone chips must be less than 14 mm);
 - 1.2.continuous cooking with steam at 145 °C during 30 minutes at 4 bars;
 - 1.3.separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation;
 - 1.4.granulation of the tricalcium phosphate after drying in a fluidised bed with air at 200 °C.

Section 8

Specific requirements for collagen

A.Raw materials

1.Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10, paragraph 1, subparagraph 1.13, 1.14, 1.15 and 1.16 of the Administrative Instruction (MAFRD) - No. 05/2022 may be used for the production of collagen.

B. Processing standards

1.Unless the collagen has been produced in accordance with the requirements for collagen set out by legislation in force laying down specific rules on hygiene of food of animal origin, it must be produced by a process ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion. After that treatment collagen may undergo a drying process.

2. The use of preservatives, other than those permitted under legislation in force shall be prohibited.

C. Other requirements

1.Collagen must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:

- 1.1. a room or a dedicated place must be provided for storing materials for wrapping and packaging;

1.2. wrapping and packaging must take place in a room or in a place intended for that purpose.

Section 9

Specific requirements for egg products

A. Raw materials

1. Only animal by-products referred to in Article 10, paragraph 1, subparagraph 1.5 and 1.6 and subparagraph 1.11.2 of subparagraph 1.11 of Administrative Instruction (MAFRD) - No. 05/2022 may be used for the production of egg products.

B. Processing standards

2. Egg products must have been:

2.1. submitted to any of the processing methods 1 to 5 or processing method 7 set out in Chapter III of Annex II of this Administrative Instruction;

2.2. submitted to another method and parameters which ensure that the products comply with the microbiological standards for derived products set out in Chapter I of this Annex; or

2.3. treated in accordance with the requirements for eggs and egg products set out by the legislation in force laying down specific rules on hygiene of food of animal origin.

Section 10

Specific requirements for feeding to farmed animals, other than fur animals, of certain Category 3 material

1. Category 3 material comprising of foodstuffs containing products of animal origin which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise, referred to in Article 10, paragraph 1.6 of the Administrative Instruction (MAFRD) - No. 05/2022, may be placed on the market for feeding to farmed animals, other than fur animals, without further treatment, provided that the material:

1.1. has undergone processing as defined by the legislation in force on hygiene of foodstuff or in accordance with this Administrative Instruction;

1.2. is composed of or contain one or more of the following Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.6 of Administrative Instruction (MAFRD) - No. 05/2022 as:

1.2.1 milk,

1.2.2 milk-based product,

1.2.3 milk-derived products,

1.2.4 eggs,

1.2.5 egg products,

1.2.6 honey,

1.2.7 rendered fats,

1.2.8 collagen,

1.2.9 gelatine;

1.2.10 has not been in contact with any other Category 3 materials; and

1.2.11 all necessary precautions have been taken to prevent the contamination of the material.

CHAPTER III

REQUIREMENTS FOR CERTAIN FISH FEED AND FISHING BAITS

1. Animal by-products from fish or aquatic invertebrates and derived products therefrom that are intended as feed for farmed fish or for other aquaculture species shall:

1.1. be handled and processed separately from material not authorised for that purpose;

1.2. originate;

1.3. from wild fish or other aquatic animals, except sea mammals, landed for commercial purposes, or from animal by-products from wild fish originating in plants manufacturing fish products for human consumption; or

1.4. from farmed fish, provided it is fed to farmed fish of another species;

1.5. be processed in a processing plant in accordance with a method which ensures a microbiologically safe product, including with regard to fish pathogens.

2. The competent authority may lay down conditions, aimed at preventing unacceptable risks for the transmission of diseases communicable to humans or animals, for the use of aquatic animals and of aquatic and terrestrial invertebrates:

2.1. as feed for farmed fish or for aquatic invertebrates, when the animal by-products have not been processed in accordance with paragraph 1, subparagraph 1.3 of this Chapter;

2.2. as fishing bait, including bait for aquatic invertebrates.

ANNEX IX

ORGANIC FERTILISERS AND SOIL IMPROVERS

CHAPTER I

REQUIREMENTS FOR UNPROCESSED MANURE, PROCESSED MANURE AND DERIVED PRODUCTS FROM PROCESSED MANURE

Section 1

Unprocessed manure

1. Trade in unprocessed manure of species other than poultry or equidae shall be subject to the following conditions:

1.1. Trade in unprocessed manure of species other than poultry or equidae shall be prohibited, except for manure:

1.2. from an area which is not subject to restrictions by virtue of a serious transmissible disease; and

1.3. intended for application, under the supervision of the competent authorities, to land forming part of a single holding.

2. However, the competent authority may, having regard to the origin of the manure, its destination and health considerations, grant specific authorisation for the introduction on to its territory of:

2.1. manure intended for:

2.1.1. processing in a plant for the manufacture of derived products which are destined for uses outside the feed chain, or

2.1.2. transformation into biogas or composting in accordance with the Administrative Instruction (MAFRD) - No. 05/2022 and with Annex III to this Administrative Instruction with a view to the manufacture of the products referred to in Section 2 of this Chapter.

2.2. In those cases, the competent authority shall take account of the origin of the manure when authorising the introduction to such plants; or

2.3. manure intended for applying to land on a holding, provided that the competent authority has communicated its agreement to such trade.

3. In the cases referred to in subparagraph 1.2 of this paragraph, a health attestation in accordance with the model set out in paragraph 3 of this Section shall be added to the commercial document which accompanies the consignment of manure.

4. Trade in unprocessed poultry manure shall be subject to the following conditions:

4.1. the manure must originate in an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza;

4.2. in addition, unprocessed manure from poultry flocks vaccinated against Newcastle disease must not be dispatched to a region which has obtained Newcastle disease non-vaccinating status; and

4.3. a health attestation in accordance with the model set out in paragraph 3 shall be added to the commercial document which accompanies the consignment of manure.

5. Model health attestation to be added to the commercial document:

REPUBLIC OF KOSOVO

Commercial document

Part I: Details of dispatched consignment	1.1. Consignor				11.2. Document reference No		11.2. Local reference No				
	Name				1.3. Central Competent Authority						
	Address				1.4. Local Competent Authority						
	Postcode										
	1.5. Consignee				1.6.						
	Name										
	Address										
	Postcode										
	Tel.				1.7.						
	1.8. Country of origin		ISO code	1.8. Region of origin		Code	1.10. Country of destination		ISO code	1.11. Region of destination	
1.11. Place of origin						1.13. Place of destination					
Establishment <input type="checkbox"/>						Establishment <input type="checkbox"/> Other <input type="checkbox"/>					
Name						Name					
Address						Address					
Postcode						Postcode					
1.13. Place of loading						1.15. Date of departure					
1.16. Means of transport						1.17. Transporter					
Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/>						Name					
Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>						Approval number					
Identification:						Address					
						Postcode					
						Country					
1.18. Description of commodity								1.19. Commodity code (CN code)			
								1.20. Total Quantity			
1.21. Temperature of product								1.22. Number of packages			
Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>											
1.23. Seal/ Container number								1.24. Type of packaging			
1.25. Commodities certified for:											
Technical use <input type="checkbox"/>											
1.26. Transit through other country <input type="checkbox"/>						1.27. For transit through Republic of Kosovo <input type="checkbox"/>					
Other country						ISO code					
Exit point						Code					
Entry point						BIP unit No.					
1.28. Export <input type="checkbox"/>						1.29.					
Other country						ISO code					
Exit point.						Code					

Part II: Certification	II. Health information	II.a. Certificate reference number	II.b.
	<p>II. Health attestation</p> <p>I, the undersigned official veterinarian, declare that I understand that the competent authority of the place of destination has given its consent to the introduction of the unprocessed manure on its territory and that the unprocessed manure referred to in box reference 1.18 complies with the following conditions:</p> <p>(a) in case of unprocessed poultry manure (1):</p> <p>[The manure originates from an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza.]</p> <p>and [In the case of unprocessed manure from poultry flocks vaccinated against Newcastle disease, the manure is not dispatched to a region which has obtained Newcastle disease non-vaccinating status pursuant to Article 15(2) of Directive 2009/158/EC.]</p> <p>(b) in case of unprocessed manure of species other than poultry or equidae (2):</p> <p>[The manure originates from an area which is not subject to restrictions by virtue of a serious transmissible disease.]</p> <p>and</p> <p>either [The manure is intended for processing in a plant for the manufacture of derived products which are destined for uses outside the feed chain or manure intended for transformation into biogas or composting in accordance with Regulation (EC) No 1069/2009 with a view to the manufacture of processed manure or processed manure products.]</p> <p>or [The manure is intended for applying to land on a holding.]</p> <p>Notes</p> <p>Part I:</p> <ul style="list-style-type: none"> - Box reference 1.9 and 1.11: if appropriate. - Box reference 1.12, 1.13 and 1.17: approval number or registration number. - Box reference 1.14: complete if different from '1.1. Consignor'. - Box reference 1.25: technical use: any use other than for animal consumption. - Box reference 1.31: <p>Nature of commodity: 'manure'.</p> <p>Part II:</p> <p>(1) Delete as appropriate.</p>		
	<p>Official veterinarian/Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>		

6. Unprocessed manure of equidae may be traded and provided it does not originate from a holding subject to animal health restrictions pertaining to glanders, vesicular stomatitis, anthrax or rabies.

7. The competent authority of the country of destination may require operators dispatching unprocessed manure to transmit further information in relation to an intended dispatch, such as precise geographical indications regarding the place where the manure is to be unloaded and to store the manure before application to land to the competent authority.

8. The competent authority may authorise the dispatch of manure transported between two points located on the same farm subject to conditions for the control of possible health risks, such as obligations for the operators concerned to keep appropriate records.

Section 2

Guano from bats, processed manure and derived products from processed manure

1. The placing on the market of processed manure, derived products from processed manure and guano from bats shall be subject to the following conditions:

1.1. They must come from a plant for derived products for uses outside the feed chain or from a biogas or a composting plant or from a plant for the manufacturing of organic fertilisers or soil improvers;

1.2. They shall have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they shall have been subjected to reduction in spore-forming bacteria and toxin formation, where they are identified as a relevant hazard.

1.3. However, the competent authority may authorise the use of other standardised process parameters than those referred to in subparagraph 1.2 of this paragraph, provided an applicant demonstrates that such parameters ensure minimising of biological risks. That demonstration shall include a validation, which shall be carried out as follows:

1.3.1. Identification and analysis of possible hazards including the impact of input material, based on a full definition of the processing conditions, and a risk assessment, which evaluates how the specific processing conditions are achieved in practice under normal and atypical situations.

2. Validation of the intended process by measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:

2.1. consistently present in the raw material in high numbers,

2.2. not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor;

2.3. relatively easy to quantify and relatively easy to identify and confirm; or

2.4. by measuring the reduction of viability/infectivity, during exposure, of a well-characterised test organism or virus introduced in a suitable test body into the starting material.

3. The validation referred to in sub-subparagraph 1.3.2 of this subparagraph must demonstrate that the process achieves the following overall risk reduction:

3.1. for thermal and chemical processes by reduction of *Enterococcus faecalis* by at least 5 log₁₀ and by reduction of infectivity titre of thermoresistant viruses such as parvovirus, where they are identified as a relevant hazard, by at least 3 log₁₀,

3.2. for chemical processes also by reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log₁₀) of viable stages.

4. Designing a complete control programme including procedures for monitoring the process.

5. Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

6.Details on the relevant process parameters used in a plant as well as other critical control points shall be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant.

7.Information relating to a process authorised under this point must be made available to the Commission on request;

8 .Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

8.1. *Escherichia coli*: $n = 5$, $c = 5$, $m = 0$, $M = 1\ 000$ in 1 g; Or

8.2. *Enterococcaceae*: $n = 5$, $c = 5$, $m = 0$, $M = 1\ 000$ in 1 g;

And

9.Representative samples of the manure taken during or on withdrawal from storage at the plant of production or the biogas or composting plant must comply with the following standards:

- *Salmonella*: absence in 25 g; $n = 5$; $c = 0$; $m = 0$; $M = 0$

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.

10. Processed manure or processed manure products not complying with the standards in this point shall be regarded as unprocessed;

11. They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

11.1. well-sealed and insulated silos or properly constructed storage sheds; or

11.2. properly sealed packs, such as plastic bags or 'big bags'.

CHAPTER II

REQUIREMENTS FOR CERTAIN ORGANIC FERTILISERS AND SOIL IMPROVERS

Section 1

Conditions for the production

1. Organic fertilisers and soil improvers, other than manure, digestive tract content, compost, milk, milk-based products, milk-derived products, colostrum, colostrum products and digestion residues from the transformation of animal by-products or derived products into biogas, shall be produced by:

1.1. applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;

1.2. using processed animal protein, including processed animal protein produced in accordance with point B, paragraph 1, subparagraph 1.2, sub-subparagraph 1.2.2 of Section 1 of Chapter II of Annex VIII of this Administrative Instruction, which has been produced from Category 3 material in accordance with Section 1 of Chapter II of Annex VIII of this Administrative Instruction, or materials which have been subject to another treatment, where such materials may be used for organic fertilisers and soil improvers in accordance with this Administrative Instruction; or

1.3. by applying any of the processing methods 1 to 7, as set out in Chapter III of Annex II of this Administrative Instruction, when Category 3 material is used as starting material which is not used for the production of processed animal protein.

2. Organic fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein, shall be mixed, in a registered establishment or plant, with a sufficient minimum proportion of a component which is authorised by the competent authority, in order to exclude the subsequent use of the mixture for feeding purposes.

3. The competent authority shall authorise the component referred to in paragraph 2 of this Section according to the following:

3.1. the component shall consist of lime, manure, urine, compost or digestion residues from the transformation of animal by-products into biogas or other substances, such as mineral fertilisers, which are not used in animal feed and which exclude the subsequent use of the mixture for feeding purposes according to good agricultural practice;

3.2. the component shall be determined based on an assessment of the climatic and soil conditions for the use of the mixture as a fertiliser, on indications that the component renders the mixture unpalatable to animals or it is otherwise effective in preventing misuse of the mixture for feeding purposes and in accordance with the requirements laid down in legislation in force for the protection of the environment regarding the protection of soil and groundwater.

4. The competent authority shall make the list of the authorised components available to the Commission and to other Member States upon request.

5. However, the requirements referred to in paragraph 2 of this Section shall not apply:

5.1. to organic fertilisers and soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or

5.2 to organic fertilisers and soil improvers in big bags of not more than 1 000 kg in weight, on the packages of which it is indicated that the organic fertilisers are not destined to land to which farmed animals have access, provided that the competent authority, has authorised the use of such big bags on the basis of an assessment of the likelihood of a potential diversion of the materials to farms keeping animals or to land to which farmed animals have Access.

5. Producers of organic fertilisers and soil improvers must ensure that decontamination of pathogens is carried out prior to their placing on the market, in accordance with:

5.1. Chapter I of Annex VIII of this Administrative Instruction, in the case of processed animal protein or derived products from Category 2 or Category 3 material.

6. Section 3 of Chapter III of Annex III of this Administrative Instruction in the case of compost and digestion residues from the transformation of animal by-products or derived products into biogas.

Section 2

Storage and transport

1. After processing or transformation, organic fertilisers and soil improvers shall be properly stored and transported:

1.1. in bulk, under appropriate conditions that prevent contamination;

1.2. packaged or in big bags, in the case of organic fertilisers or soil improvers destined for sale to final users; or

1.3. in the case of storage on farm, in an adequate storage space to which no farmed animals have access.

Section 3

Requirements for approval of establishments or plants

1. In order to be approved in accordance with Article 24, paragraph 1, subparagraph 1.6 of the Administrative Instruction (MAFRD) - No. 05/2022, operators shall ensure that establishments or plants carrying out the activities referred to in paragraph 1 of Section 1 of this Chapter meet the requirements laid down in Article 9 of this Administrative Instruction and:

1.1. have adequate facilities for storage of incoming ingredients to prevent cross-contamination and avoid contamination during storage;

1.2. dispose of unused animal by-products or derived products in accordance with Articles 13 and 14 of the Administrative Instruction (MAFRD) - No. 05/2022.

ANNEX X

INTERMEDIATE PRODUCTS

1. In accordance with Article 34, paragraph 4 of Administrative Instruction (MAFRD) - No. 05/2022, the following conditions shall apply to the importation and transit through the Republic of Kosovo of intermediate products:

1.1. The import and transit of intermediate products shall be authorised, provided that:

1.1.1 they are derived from the following materials:

1.1.2 Category 3 material, other than materials referred to in Article 10, paragraph 1, subparagraph 1.3, 1.14, 1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022;

1.1.3 products generated by the animals referred to in Article 10, paragraph 1, subparagraph 1.9, 1.12, 1.13 of Administrative Instruction (MAFRD) - No. 05/2022; or

1.1.4 mixtures of the materials referred to in sub-subparagraph 1.1.1 and 1.1.2 of this paragraph;

1.2 in the case of intermediate products destined for the production of medical devices, in vitro diagnostic medical devices and laboratory reagents, they are derived from:

1.2.1 materials which fulfil the criteria referred to in subparagraph 1.1.1 of this paragraph, except that they may have originated from animals which have been submitted to illegal treatment as defined in specific legislation concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists or in specific legislation on measures to monitor certain substances and residues thereof in live animals and animal products;

1.2.2 Category 2 material referred to in Article 9, paragraph 1, subparagraph 1.6 and 1.8 of Administrative Instruction (MAFRD) - No. 05/2022; or

1.2.3 mixtures of the materials referred to in subparagraph 1.2.1 and 1.2.2 of this paragraph;

1.3 in the case of intermediate products destined for the production of active implantable medical devices, medicinal products and veterinary medicinal products, they are derived from the materials referred to in subparagraph 1.2 of this paragraph, where the competent authority considers the use of such materials justified for the protection of public or animal health;

1.4 they come from a country listed as a member of the World Organisation for Animal Health (WOAH);

1.5 they come from an establishment or plant registered or approved by the competent authority of a country referred to in subparagraph 1.4 of this paragraph, in accordance with the conditions set out in paragraph 2 of this Annex;

1.6 each consignment is accompanied by a declaration of the importer in accordance with the model declaration set out in paragraph 1, subparagraph 1.36 of Annex XIII of this Administrative Instruction, which must be at least in the official languages of the Republic of Kosovo in which the inspection at the border inspection post must be carried out and of the country of destination;

1.7 in the case of materials referred to in subparagraph 1.2 of this paragraph, the importer demonstrates to the competent authority that the materials;

1.7.1 do not carry any risk of transmission of a disease communicable to humans or animals; or

1.7.2 are transported under conditions which prevent the transmission of any diseases communicable to humans or animals.

2. An establishment or plant may be registered or approved by the competent authority of other country, as referred to in paragraph 1, subparagraph 1.5 of this Annex, provided that:

2.1. the operator or owner of the plant or his representative:

2.1.1 demonstrates that the plant has adequate facilities for the transformation of the materials referred to in paragraph 1, subparagraph 1.1, 1.2 or 1.3 of this Annex, as applicable, to ensure the completion of the necessary design, transformation and manufacturing stages;

2.1.2 establishes and implements methods of monitoring and checking the critical control points on the basis of the process used;

2.1.3 keeps a record of the information obtained pursuant to subparagraph 2.1.2 of this paragraph for a period of at least two years for submission to the competent authority;

2.1.4 informs the competent authority if any available information reveals the existence of a serious animal health or public health risk;

2.2 the competent authority of the other country carries out, at regular intervals, inspections of the establishment or plant and supervises the plant in accordance with the following conditions:

2.2.1 the frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered, based on a system of checks which has been set up in accordance with the hazard analysis and critical control points (HACCP) principles;

2.2.2 if the inspection carried out by the competent authority reveals that the provisions of this Administrative Instruction are not being complied with, the competent authority shall take appropriate action;

2.2.3 the competent authority shall draw up a list of establishments or plants approved or registered in accordance with this Annex and shall assign an official number to each plant, which identifies the establishment or plant with respect to the nature of its activities; that list shall be published on the web page of the competent authority.

3. The intermediate products imported into the Republic of Kosovo shall be checked at the border inspection post and transported directly from the border inspection post either to:

3.1. a registered establishment or plant for the production of laboratory reagents, medical devices and in vitro diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Administrative Instruction (MAFRD) - No. 05/2022, where the intermediate products must be further

mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the legislation in force applicable to the derived product;

3.2an establishment or plant which has been approved for the storage of animal by-products in accordance with Article 24, paragraph 1, subparagraph 1.9 of Administrative Instruction (MAFRD) - No. 05/2022, from where they must only be dispatched to an establishment or plant referred to in subparagraph 3.1 of this paragraph.

4 Intermediate products in transit through the Republic of Kosovo shall be transported in accordance with specific rules for official controls at border control posts to establish the cases where, and the conditions under which, the transit of consignments may be authorised and certain official controls to be performed at border control posts on such consignments, including the cases and conditions for the storage of goods in specially approved customs warehouses or in free zones;

5 .The official veterinarian at the border inspection post concerned shall inform the authority in charge of the establishment or plant at the place of destination of the consignment.

6 .The operator or owner of the establishment or plant of destination or his representative shall keep records in accordance with Article 22 of Administrative Instruction (MAFRD) - No. 05/2022 and shall provide the competent authority on request with the necessary details of purchases, sales, uses, stocks and disposals of surplus of the intermediate products for the purposes of checking compliance with this Administrative Instruction.

7.The competent authority shall ensure, that the consignments of intermediate products are sent from the Republic of Kosovo where the inspection at the border inspection post must be carried out to the plant of destination, as referred to in paragraph 3 of this Annex, in the case of transit, to the border inspection post of exit.

8.The competent authority shall carry out documentary checks at regular intervals for the purpose of reconciliation of the quantities of intermediate products imported on the one hand, and stocked, used, dispatched or disposed of on the other, in order to check compliance with this Administrative Instruction.

9.For consignments of intermediate products in transit, the competent authorities responsible for the border inspection posts of entry and of exit respectively shall cooperate as necessary to ensure that effective checks are carried out and to ensure the traceability of such consignments.

ANNEX XI

PETFOOD AND CERTAIN OTHER DERIVED PRODUCTS

CHAPTER I

General requirements

1.Petfood plants and establishments or plants producing derived products referred to in this Annex shall have adequate facilities for:

1.1. storing and treating incoming material under conditions which prevent the introduction of risks to public and animal health;

1.2. disposing of unused animal by-products and derived products remaining after production, unless the unused material is sent for processing or disposal to another establishment or plant, in accordance with this Administrative Instruction.

CHAPTER II

Specific requirements for petfood, including dogchews

Raw petfood

1. Operators may only manufacture raw petfood from Category 3 material referred to in Article 10, paragraph 1, subparagraph 1.1 paragraph 2, subparagraph 2.2, sub-subparagraph 2.2.1. and 2.2.2 of Administrative Instruction (MAFRD) - No. 05/2022;

1.1 .Raw petfood must be packed in new packaging preventing any leakage.

1.2 Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale.

2.Raw material for processed petfood and for dogchews

2.1 .Operators may manufacture processed petfood and dogchews only from:

2.1.1 Category 3 material, other than material referred to in Article 10, paragraph 1, subparagraph 1.14, 1.15 and 1.16 of Administrative Instruction (MAFRD) - No. 05/2022; and

2.1.2 in the case of imported petfood or petfood produced from imported materials, from Category 1 material comprising of animal by-products derived from animals which have been submitted to illegal treatment as defined in specific legislation concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists or in specific legislation on measures to monitor certain substances and residues thereof in live animals and animal products.

3.Processed petfood

3.1.Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.

3.2.Processed petfood other than canned petfood must:

3.2.1.be subjected to a heat treatment of at least 90 °C throughout the substance of the final product;

3.2.2.be subjected to a heat treatment to at least 90 °C of the ingredients of animal origin; or

3.2.3 be produced as regards feed material of animal origin exclusively using:

3.2.3.1 animal by-products or derived products from meat or meat products which have been subject to a heat treatment of at least 90 °C throughout their substance;

3.2.3.2 the following derived products which have been produced in accordance with the requirements of this Administrative Instruction: milk and milk-based products, gelatine, hydrolysed protein, egg products, collagen, blood products referred to in Section 2 of Chapter II of Annex VIII of this Administrative Instruction, processed animal protein including fishmeal, rendered fat, fish oils, dicalcium phosphate, tricalcium phosphate or flavouring innards;

3.2.4. if authorised by the competent authority, be subject to a treatment such as drying or fermentation, which ensures that the petfood poses no unacceptable risks to public and animal health;

3.2.5. in the case of animal by-products referred to in Article 10, paragraph 1, subparagraph 1.12 and 1.13 of Administrative Instruction (MAFRD) - No. 05/2022 and in the case of animal by-products generated by aquatic animals, aquatic and terrestrial invertebrates, and if authorised by the competent authority, be subject to a treatment which ensures that the petfood poses no unacceptable risks to public and animal health.

3. After production, every precaution must be taken to ensure that such processed petfood is not exposed to contamination.

4. The processed petfood must be packaged in new packaging.

5. Dogchews must be subjected to a treatment that is sufficient to destroy pathogenic organisms, including salmonella. After that treatment, every precaution must be taken to ensure that such dogchews are not exposed to contamination. The dogchews must be packed in new packaging.

6. Random samples must be taken from dogchews and from processed petfood, other than from canned petfood and other than from such processed petfood which has been treated in accordance in paragraph 3, subparagraph 3.2, sub-subparagraph 3.2.5 of this Chapter, during production and/or during storage (before dispatch) to verify compliance with the following standards:

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

1.2. 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.

7. Random samples must be taken from raw petfood during production and/or during storage (before dispatch) to verify compliance with the following standards:

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

7.2. The process of production of raw petfood shall meet the following process hygiene criterion:

7.2.1. Enterobacteriaceae: $n = 5$, $c = 2$, $m = 500$ in 1 g, $M = 5\,000$ 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.

8. Operators shall take measures, as part of their procedures based on hazard analysis and critical control points (HACCP) principles, to ensure that the supply, handling and processing of raw materials and raw petfood under their control are carried out in such a way that the above mentioned safety standards and the process hygiene criterion are met. In the case the safety standards and the process hygiene criterion are not met the operator shall take proportionate corrective actions in accordance with the written procedure referred to in the introductory sentence of Article 29, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022 and the procedures based on HACCP principles as set out in subparagraph 2.5 and 2.6 of paragraph 2 of Article 29 of that Administrative Instruction.

9. The non-compliance and, where determined, its cause, the applied corrective actions and the results of the control measures shall be notified to the competent authority. Where the competent authority is not satisfied that the necessary corrective actions have been taken it can impose on the operator extra actions, including labelling for handling, and may require the microbiological investigation of further samples to be taken by the operator.

End point for processed petfood and dogchews

1. The following may be placed on the market without restrictions in accordance with this Administrative Instruction:

1.1. processed petfood which has been manufactured and packaged in accordance with paragraph 3 of this Chapter and which has been tested in accordance with paragraph 5 of this Chapter; or

1.2. which has been subject to veterinary checks at a border inspection post.

1.3. Dogchews which have been manufactured and packaged in accordance with paragraph 4 of this Chapter and which has been tested in accordance with paragraph 5 of this Chapter; or

1.4. which have been subject to veterinary checks at a border inspection

CHAPTER III

Specific requirements for flavouring innards for the manufacture of petfood

1. Operators may only use animal by-products which may be used as raw material for processed petfood and dogchews in accordance with paragraph 2 of Chapter II of this Annex for the production of liquid or dehydrated derived products used to enhance the palatability values of petfood.

2. Flavouring innards must have been submitted to a treatment method and parameters, which ensure that the product complies with the microbiological standards set out in paragraph 5 of Chapter II of this Annex. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination.

4 The end product must be:

4.2 packed in new or sterilised packaging; or

3.2. transported in bulk in containers or

3.3. other means of transport that were thoroughly cleaned and disinfected.

CHAPTER IV

Specific requirements for blood and blood products from Equidae

1. The placing on the market of blood and blood products from equidae for purposes other than in feed shall be subject to the following conditions:

1.1. Blood may be placed on the market for such purposes provided that it has been collected:

1.1.1 from equidae which at inspection on the date of blood collection do not show clinical signs of any of the compulsorily notifiable diseases listed in specific legislation on animal health conditions governing the movement and importation of Equidae and of equine influenza, equine piroplasmiasis, equine rhinopneumonitis and equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the OIE, 2010 edition;

1.1.2 have been kept for a period of at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order or restrictions pursuant to specific legislation on animal health conditions governing the movement and importation of Equidae;

1.1.3 for the periods laid down in specific legislation on animal health conditions governing the movement and importation of Equidae had no contact with equidae from holdings which were subject to

a prohibition order for animal health reasons pursuant to that Article and for a period of at least 40 days prior to the date of and during blood collection had no contact with equidae from a country not considered free of African horse sickness in accordance with specific legislation on animal health conditions governing the movement and importation of Equidae;

1.2 under veterinary supervision either:

1.2.1.in slaughterhouses registered or approved in accordance with Regulation No. 12/2011 laying down specific rules on hygiene of food of animal origin; or

1.2.2.in facilities approved, furnished with a veterinary approval number and supervised by the competent authority for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.

2 Blood products may be placed on the market for such purposes provided that:

2.1 all precautions have been taken to avoid contamination of the blood products with pathogenic agents during production, handling and packaging;

2.2 the blood products have been produced from blood which:

2.2.1 either fulfils the conditions set out in subparagraph 1.1 of paragraph 1 of this Chapter; or

2.2.2 has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):

2.2.2.1 heat treatment at a temperature of 65 °C for at least three hours,

2.2.2.2 irradiation at 25 kGy by gamma rays,

2.2.2.3 change in pH to pH 5 for two hours,

2.2.2.4 heat treatment of at least 80 °C throughout their substance.

3. Blood and blood products from equidae must be packed in sealed impermeable containers which, in the case of blood from equidae, bear the approval number of the slaughterhouse or facilities of collection referred to in subparagraph 1.2 of paragraph 1 of this Chapter.

CHAPTER V

Specific requirements for hides and skins of ungulates and products derived therefrom

A.Establishments and plants

1. The competent authority may authorise plants handling hides and skins, including limed hides, to supply trimmings and splittings of these hides and skins for the production of gelatine for animal consumption, organic fertilisers or soil improvers, provided that:

1.1 the plant has storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities;

1.2 the storage rooms are kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;

1.3 if raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch;

1.4 in the case of trimmings and splittings derived from limed hides, the trimmings and splittings are submitted to a treatment which ensures that no risks to public and animal health remain before being used for the production of:

1.4.1.gelatine for animal consumption; or

1.4.2.organic fertilisers or soil improvers.

B.Placing on the market of animal by-products and of derived products

1.Untreated hides and skins may be placed on the market subject to the health conditions applicable to fresh meat pursuant to specific legislation laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

2. Treated hides and skins may be placed on the market, provided that:

2.1 they have not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease;

2.2 the commercial document laid down in Chapter III of Annex VI of this Administrative Instruction contains a statement indicating that all precautions have been taken to avoid contamination with pathogenic agents.

C. End point for hides and skins

1.Hides and skins of ungulates which pursuant to the decision of an operator are destined for purposes other than human consumption, and which comply with the requirements of Regulation No. 12/2011 laying down specific rules on hygiene of food of animal origin for raw materials for gelatine or collagen intended for use in food may be placed on the market without restrictions in accordance with this Administrative Instruction.

2.The following treated hides and skins may be placed on the market without restrictions in accordance with this Administrative Instruction:

2.1. hides and skins having undergone the complete process of tanning;

2.2. 'wet blue';

2.3. 'pickled pelts';

2.4. limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).

3. By way of derogation from paragraph 2 of this point C, the competent authority may require that consignments of treated hides and skins referred to in subparagraph 2.3 and 2.4 of paragraph 2 are accompanied by a commercial document in accordance with the model set out under paragraph 8 of Chapter III of Annex VI of this Administrative Instruction, when they are supplied to establishments or plants producing petfood, organic fertilisers or soil improvers or transforming those materials into biogas.

CHAPTER VI

Specific requirements for game trophies and other preparations from animals

A. The provisions of this Chapter are without prejudice to the measures for the protection of wild fauna, adopted pursuant to specific legislation on the protection of species of wild fauna and flora by regulating trade therein

B. Safe sourcing

1. Game trophies and other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they originate from:

1.1. species other than ungulates, birds and animals of the biological class Insecta or Arachnida; and

1.2. animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible.

C. Safe treatment

1. Game trophies or other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they:

1.1. originate from ungulates or birds which have undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;

1.2. are mounted ungulates or birds or mounted parts of such animals;

1.3. have been subject to an anatomical preparation such as by plastination; or

1.4. are animals of the biological class Insecta or Arachnida which have been subject to a treatment such as drying to prevent any transmission of diseases communicable to humans or animals.

1.5. are objects in natural history collections or for the promotion of science and are

1.5.1. preserved in media, such as alcohol or formaldehyde, which allow display of the items;

1.5.2. embedded completely in micro-slides; or

1.5.3. composed of entire skeletons or parts thereof, bones or teeth, to be exchanged exclusively between museums and educational institutions;

1.5.4. are processed DNA samples intended for repositories for the promotion of biodiversity research, ecology, medical and veterinary science or biology.

2. Game trophies or other preparations, other than those referred to under points B and C, paragraph 1 of this Chapter, which come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible, may be placed on the market, provided that:

2.1 in the case of game trophies or other preparations solely of bone, horns, hooves, claws, antlers or teeth,

2.1.1. they have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2.1.2. they have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;

2.1.3. they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and

2.1.4. they are accompanied by a health certificate certifying that the conditions set out in subparagraphs 2.1.1, 2.1.2 and 2.1.3 have been met;

2.2 in case of game trophies or other preparations consisting solely of hides or skin;

2.2.1 they have been:

2.2.1.1 dried,

2.2.1.2 dry - or wet-salted for a period of at least 14 days before the date of dispatch, or

2.2.1.3 subject to a preservation process other than tanning;

2.3 they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and

2.4 they are accompanied by a commercial document or a health certificate certifying that the conditions set out in subparagraph 2.2.1 and 2.2.2 of this paragraph 2 have been met.

CHAPTER VII

Specific requirements for wool, hair, pig bristles, feathers, parts of feathers and down

A. Raw material

1. Untreated wool, untreated hair, untreated pig bristles and untreated feathers, parts of feathers and down must be Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.2.3, 1.2.4 and 1.2.5 and Article 10, paragraph 1, subparagraph 1.14 of Administrative Instruction (MAFRD) - No. 05/2022 .

2. They must be securely enclosed in packaging and dry.

2. However, in the case of untreated feathers, parts of feathers and down sent directly from the slaughterhouse to the processing plant, the competent authority may allow a derogation from the requirement to dry materials transported on its territory, provided that:

2.1. all necessary measures are taken to avoid any possible spread of disease;

2.2. the transport takes place in waterproof containers and/or vehicles which must be cleaned and disinfected immediately after each use.

3. Movements of pig bristles and wool and hair of animals of the porcine species from regions in which African swine fever is endemic shall be prohibited except for pig bristles and wool and hair of animals of the porcine species that have:

3.1. been boiled, dyed or bleached; or

3.2. undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin.

5. Factory washing may not be regarded as a form of treatment for the purposes of this provision.

6. The provisions of paragraph 1 of this point A shall not apply to decorative feathers or feathers:

6.1. carried by travellers for their private use; or

6.2. in the form of consignments sent to private individuals for non-industrial purposes.

B. End point for wool and hair

1. Factory-washed wool and hair, and wool and hair which has been treated by another method which ensures that no unacceptable risks remain, may be placed on the market without restrictions in accordance with this Administrative Instruction.

2. Competent authority may authorise the placing on the market of untreated wool and hair from farms or from establishments or plants which have been registered in accordance with Article 23 of Administrative Instruction (MAFRD) - No. 05/2022 or approved in accordance with Article 24, paragraph 1, subparagraph 1.9 of the same Administrative Instruction without restrictions in accordance with this Administrative Instruction, if they are satisfied that no unacceptable risks to public and animal health arise from the wool and from the hair.

3. Wool and hair produced from animals other than those of the porcine species may be placed on the market without restrictions in accordance with this Administrative Instruction, provided:

3.1. it has undergone factory-washing which consists of the immersion of the wool and hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or

3.3. it is dispatched directly to a plant producing derived products from wool or hair for the textile industry and such wool or hair has undergone at least one of the following treatments:

3.3.1. chemical depilation by means of slaked lime or sodium sulphide;

3.3.2. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;

3.3.3. industrial scouring which consists of the immersion of wool and hair in a water-soluble detergent held at 60–70 °C;

3.3.4. storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days.

C. End point for feathers and down

Feathers, parts of feathers and down which have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes may be placed on the market without restrictions in accordance with this Administrative Instruction.

CHAPTER VIII

Specific requirements for furs

End point

Furs which have been dried at an ambient temperature of 18 °C for two days at a humidity of 55 % may be placed on the market without restrictions in accordance with this Administrative Instruction.

CHAPTER IX

Specific requirements for apiculture by-products

1. Apiculture by-products intended exclusively for use in apiculture must:

1.1. not come from an area which is subject of a prohibition order associated with an occurrence of:

1.1.1 American foulbrood (*Paenibacillus larvae* larvae), except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use, and taken all other necessary measures to ensure no spread of that disease;

1.1.2 acariosis (*Acarapis woodi* (Rennie)), except where the area of destination has obtained additional guarantees in accordance with specific legislation laying down animal health requirements governing trade in and imports of animals, semen, ova, and embryos not subject to animal health requirements;

1.1.3 small hive beetle (*Aethina tumida*); or

1.1.4 *Tropilaelaps* mite (*Tropilaelaps* spp.); and

1.2 meet the requirements provided for in specific legislation laying down animal health requirements governing trade in and imports of animals, semen, ova, and embryos not subject to animal health requirements.

CHAPTER X

Specific requirements for rendered fats from Category 1 or Category 2 materials for oleochemical purposes

1. Rendered fats derived from Category 1 material or from Category 2 material which are destined for oleochemical purposes must be produced using any of the processing methods 1 to 5 as set out in Chapter III of Annex II.

2. Rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight.

CHAPTER XI

Specific requirements for fat derivatives

1. The following processes may be used to produce fat derivatives from rendered fats derived from Category 1 and Category 2 material:

1.1. transesterification or hydrolysis at a temperature of at least 200 °C, under corresponding appropriate pressure, for at least 20 minutes (glycerol, fatty acids and esters);

1.2. saponification with NaOH 12M (glycerol and soap):

1.2.1 in a batch process at 95 °C for three hours; or

1.2.2 in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or

1.3 hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.

2 Fat derivatives produced in accordance with this Chapter may only be placed on the market:

2.1 for uses other than in feed, cosmetics and medicinal products;

2.2 in addition, in the case of fat derivatives from Category 1 material, for uses other than in organic fertilisers and soil improvers.

3 End point for products derived from rendered fats: Fat derivatives which have been processed as referred to in paragraph 1 of this Chapter may be placed on the market for uses indicated in point 2 without restrictions in accordance with this Administrative Instruction.

CHAPTER XII

Specific requirements for horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers

1. The placing on the market of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers shall be subject to the following conditions:

1.1. they must originate from animals that:

1.1.1. either have been slaughtered in a slaughterhouse, after undergoing an ante-mortem inspection, and were found fit, as a result of such inspection, for slaughter for human consumption in accordance with legislation in force; or

1.1.2. did not show clinical signs of any disease communicable through that product to humans or animals;

1.2 they must have undergone a heat treatment for one hour at a core temperature of at least 80 °C;

1.3 the horns must be removed without opening the cranial cavity;

1.4 at any stage of processing, storage or transport, every precaution shall be taken to avoid cross-contamination;

1.5 they shall be packed either in new packaging or containers; or transported in vehicles or bulk containers which have been disinfected prior to loading using a product approved by the competent authority;

1.6 the packaging or containers must:

1.6.1 indicate the type of product (such as horns, horn products, hooves or hoof products);

1.6.2 be marked with the name and address of the approved or registered establishment or plant of destination.

CHAPTER XIII

Specific requirements for fish oil for the production of medicinal products

End point for fish oil for the production of medicinal products. Fish oil derived from the materials referred to in point A, paragraph 2 of Section 3 of Chapter II of Annex VIII of this Administrative Instruction, which has been de-acidified with a NaOH solution at a temperature of 80 °C or more and which has subsequently been purified by distillation at a temperature of 200 °C or more, may be placed on the market for the production of medicinal products without restrictions in accordance with this Administrative Instruction.

ANNEX XII

IMPORTATION, EXPORT AND TRANSIT

CHAPTER I

SPECIFIC REQUIREMENTS FOR THE IMPORTATION INTO AND TRANSIT THROUGH THE REPUBLIC OF KOSOVO OF CATEGORY 3 MATERIAL AND DERIVED PRODUCTS FOR USES IN THE FEED CHAIN OTHER THAN FOR PETFOOD OR FOR FEED TO FUR ANIMALS

Section 1

1. As referred to in paragraph 1, subparagraph 1.1 and paragraph 3 of Article 41 of Administrative Instruction (MAFRD) - No. 05/2022, the following requirements shall apply to imported consignments of Category 3 material and derived products therefrom for uses in the feed chain other than for petfood or for feed to fur animals and consignments of such materials and products in transit:

1.1. they must consist of or have been produced from, as applicable, Category 3 material referred to in the column 'raw materials' of Table 1;

1.2. they must comply with the import and transit conditions set out in the column 'import and transit conditions' of Table 1;

1.3. they must come from an EU country or from a third country or part of a third country listed in the column 'third countries' list' of Table 1;

1.4. they must come from an establishment or plant which is registered or approved by the competent authority of the EU country of third country, as applicable, and which is on the list of such establishments and plants referred to in Article 31 of this Administrative Instruction; and

1.5. they must be:

1.5.1. accompanied during transportation to the point of entry into the Republic of Kosovo where the veterinary checks take place by the health certificate; or

1.5.2. presented at the point of entry into the Republic of Kosovo where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column 'certificates/model documents' of Table 1. (see at the of the Table with Administrative Instruction).

Table 1.

No	Product	Raw materials (reference to provisions of Administrative Instruction (MAFRD) - No. 05/2020 laying down health rules for animal by-products and products derived thereof not intended for human consumption	Import and transit conditions	Third countries' lists	Certificates/model documents

1	Processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such proteins as defined in specific legislation on placing on the market and use of feed	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.4, 1.5, 1.6, 1.8, 1.9, 1.10, 1.11, 1.12, and 1.13	1. The processed animal protein must have been produced in accordance with Section 1 of Chapter II of Annex VII; and 2. the processed animal protein shall comply with the additional requirements set out in Section 2 of this Chapter	1. In the case of processed animal proteins excluding fishmeal: Third countries listed in Part 1 of Annex XIII or Part 1, Section A, of Annex XV to Commission Implementing Regulation (EU) 2021/404 (*), and the following third countries: (AL) Albania (DZ) Algeria (SV) El Salvador. 2. In the case of fishmeal: Third countries listed in Annex IX to Commission Implementing Regulation (EU) 2021/405 (**).	1. In the case of processed animal protein other than those derived from farmed insects: Annex XIII, paragraph 1, subparagraph 1.1. 2. In the case of processed animal protein derived from farmed insects: Annex XIII, paragraph 1, subparagraph 1.2
2	Blood products for feed material	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1 and 1.2.1	The blood products must have been produced in accordance with Section 2 of Chapter II of Annex VIII and Section 5 of Chapter I of Annex XII.	1. In the case of blood products from ungulates: Third countries or parts of third countries listed in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404 or Annex I to Implementing Regulation (EU) 2021/405, from which imports of all categories of fresh meat of the respective species are authorised. 2. In the case of blood products from other species: Third countries listed in Part 1 of Annex XIII or Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404	Annex XIII, paragraph 1, subparagraph 1.12.
3	Rendered fats and fish	1. In the case of rendered fats excluding fish oil: Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 1.10, and 1.11. 2. In the case of fish oil: Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.5, 1.6, 1. and 1.10.	1. The rendered fat and the fish oil must have been produced in accordance with Section 3 of Chapter II of Annex VIII; and 2. The rendered fat shall comply with the additional requirements set out in Section 3 of this Chapter.	1. In the case of rendered fats excluding fish oil: Third countries listed in Part 1 of Annex XIII or Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404, and the following third countries: (AL) Albania (DZ) Algeria (SV) El Salvador 2. In the case of fish oil: Third countries listed in Annex IX to Implementing Regulation (EU) 2021/405.	1. In the case of rendered fats excluding fish oil: Annex XIII, paragraph 1, subparagraph 1.24. 2. In the case of fish oil: Annex XIII, C paragraph 1, subparagraph 1.23
4	Milk, milk-based products and milk-derived products, colostrum, colostrum products	1. Milk, milk-based products: Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.5, 1.6 and 1.8. 2. Colostrum, colostrum products: Category 3 materials from live animals that did not show any signs of disease transmissible through the colostrums to humans or animals.	The milk, milk-based products, colostrum and colostrum products shall comply with the requirements set out in Section 4 of this Chapter.	1. In the case of milk and milk-based products: Third countries listed in Part 1 of Annex XVII or Part 1 of Annex XVIII to Implementing Regulation (EU) 2021/404 for imports of milk of ungulates or Annex X to Implementing Regulation (EU) 2021/405 for imports of milk of solipeds. 2. In the case of colostrum and colostrum products: Third countries listed as authorised in Part 1 of Annex XVII to Implementing Regulation (EU) 2021/404 for imports of milk of ungulates, or Annex X to Implementing Regulation (EU) 2021/405 for imports of milk of solipeds.	1. In the case of milk, milk-based products and milk-derived products: Annex XIII, paragraph 1, subparagraph 1.3. 2. In the case of colostrum and colostrums products: Annex XIII, paragraph 1, subparagraph 1.4.
5	Gelatine and hydrolysed protein	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.5, 1.6, 1.7, 1.9 and 1.10, and, in the case of hydrolysed protein: Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.4, 1.8 and 1.11.	The gelatine and the hydrolysed protein must have been produced in accordance with Section 5 of Chapter II of Annex VIII.	1. Third countries listed in Annexes XII or XIII to Implementing Regulation (EU) 2021/405, and the following third countries: (EG) Egypt 2. In the case of gelatine and hydrolysed proteins from fish: Third countries listed in Annex IX to Implementing Regulation (EU) 2021/405	1. In the case of gelatine: Annex XIII, Chapter 11. 2. In the case of hydrolysed protein: Annex XIII, paragraph 1, subparagraph 1.26.
6	Dicalcium phosphate	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 1.10 and 1.11.	The dicalcium phosphate must have been produced in accordance with Section 6 of Chapter II of Annex VIII.	Third countries listed in Annexes XII or XIII to Implementing Regulation (EU) 2021/405	Annex XIII, paragraph 1, subparagraph 1.27.
7	Tricalcium phosphate	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9 and 1.11.	The tricalcium phosphate must have been produced in accordance with Section 7 of Chapter II of Annex VIII.	Third countries listed in Annexes XII or XIII to Implementing Regulation (EU) 2021/405	Annex XIII, paragraph 1, subparagraph 1.27.
8	Collagen	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.5, 1.6, 1.7, 1.9 and 1.10.	The collagen must have been produced in accordance with Section 8 of Chapter II of Annex X.	Third countries listed in Annexes XII or XIII to Implementing Regulation (EU) 2021/405	Annex XIII, paragraph 1, subparagraph 1.26.
9	Egg products	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.5, 1.6 and 1.11.2.	The egg products must have been produced in accordance with Section 9 of Chapter II of Annex VIII.	Third countries listed in Part 1 of Annex XIII, third countries listed in Part 1 of Annex XIV or third countries listed in Part 1 of Annex XIX to Implementing Regulation (EU) 2021/404	Annex XIII, paragraph 1, subparagraph 1.31.

Section 2

Imports of processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such protein as defined in specific legislation on placing on the market and use of feed

1. The following requirements shall apply to the importation of processed animal protein:

1.1. Before consignments are released for free circulation within the Republic of Kosovo, the competent authority must sample processed animal protein from imported consignments at the border inspection post to ensure compliance with the general requirements of Chapter I of Annex VIII.

2. The competent authority must:

2.1. sample each consignment of products carried in bulk;

2.2. carry out random sampling of consignments of products packaged in the manufacturing plant of origin.

3. By way of derogation from paragraph 1 of this Section, when six consecutive tests on bulk consignments originating in a given country prove negative, the competent authority of the border inspection post may carry out random sampling of subsequent bulk consignments from that country.

4. If one of those random samples proves positive, the competent authority carrying out the sampling must inform the competent authority of the country of origin so that it can take appropriate measures to remedy the situation.

5. The competent authority of the country of origin must bring these measures to the attention of the competent authority carrying out the sampling.

6. In the event of a further positive result from the same source, the competent authority of the border inspection post must sample each consignment from the same source until six consecutive tests again prove negative results.

7. Competent authorities must keep a record for at least three years of the results of sampling carried out on all consignments that have undergone sampling.

8. Where a consignment imported into the Republic of Kosovo proves to be positive for salmonella or where it does not meet the microbiological standards for enterobacteriaceae set out in Chapter I of Annex VIII, it must either:

8.1. be dealt with in accordance with the procedure laid down by specific rules for official controls at border control posts;

8.2. be reprocessed in a processing plant or decontaminated by a treatment authorised by the competent authority. The consignment must not be released until it has been treated, tested for salmonella or enterobacteriaceae, as necessary, by the competent authority in accordance with Chapter I of Annex VIII, and a negative result obtained.

9.Processed animal protein obtained from farmed insects may be imported into the Republic of Kosovo provided that it has been produced in compliance with the following conditions:

9.1.the insects belong to one of the following species:

9.1.1.Black Soldier Fly (*Hermetia illucens*) and Common Housefly (*Musca domestica*),

9.1.2.Yellow Mealworm (*Tenebrio molitor*) and Lesser Mealworm (*Alphitobius diaperinus*),

9.1.3.House cricket (*Acheta domesticus*), Banded cricket (*Gryllodes sigillatus*) and Field Cricket (*Gryllus assimilis*);

9.2.the substrate for the feeding of insects may only contain products of non-animal origin or the following products of animal origin of Category 3 material:

9.2.1 fishmeal;

9.2.2.blood products from non-ruminants;

9.2.3.di and tricalcium phosphate of animal origin;

9.2.4.hydrolysed proteins from non-ruminants;

9.2.5. hydrolysed proteins from hides and skins of ruminants;

9.2.6.gelatine and collagen from non-ruminants;

9.2.7.eggs and egg products;

9.2.8.milk, milk based-products, milk-derived products and colostrum;

9.2.9.honey;

9.2.10. rendered fats;

9.3.the substrate for the feeding of insects and the insects or their larvae have not been in contact with any other materials of animal origin other than those mentioned in subparagraph 6.2 of this Section and the substrate did not contain manure, catering waste or other waste.

Section 3

Imports of rendered fats

1.The following requirements shall apply to the importation of rendered fats:

1.1. Rendered fat shall:

1.1.1.be entirely or partly derived from porcine raw material and come from a country or a part of the territory of a country free from foot-and-mouth disease for the previous 24 months and free from classical swine fever and African swine fever for the previous 12 months;

1.1.2.be entirely or partly derived from poultry raw material and come from a country or a part of the territory of a country free from Newcastle disease and avian influenza for the previous six months;

1.1.3.be entirely or partly derived from ruminant raw material and come from a country or a part of the territory of a country free from Foot-and-Mouth disease for the previous 24 months and free from rinderpest for the previous 12 months; or

1.1.4.where there has been an outbreak of one of the diseases referred to in subparagraph 1.1, 1.2 and 1.3 during the relevant period referred to in those points, have been subjected to one of the following heat treatments:

1.1.4.1.at least 70 °C for at least 30 minutes; or

1.1.4.2. at least 90 °C for at least 15 minutes.

2. Details of the critical control points shall be recorded by operators and maintained so that the owner, operator or their representative and, as necessary, the competent authority can monitor the operation of the plant; and the recorded information shall include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

Section 4

Imports of milk, milk-based products, milk-derived products, colostrum and colostrum products

A.The following requirements shall apply to the importation of milk, milk-based products, milk-derived products, colostrum and colostrum products:

1.Milk, milk-based products and milk-derived products shall:

1.1.have undergone at least one of the treatments provided for in subparagraph 1.1, 1.2, 1.3 and subparagraph 1.4.1. of subparagraph 1.4 of paragraph 1 of point B of Part I of Section 4 of Chapter II of Annex VIII;

1.2. comply with paragraph 2 and 4 of point B and, in the case of whey, paragraph 3 of point B of Part I of Section 4 of Chapter II of Annex VIII.

2.By way of derogation from subparagraph 1.4 of point B of Part I of Section 4 of Chapter II of Annex VIII, milk, milk-based products and milk-derived products may be imported into Republic of Kosovo from third countries listed and authorised for the introduction into EU of consignments of raw milk and dairy products intended for human, provided that the milk, milk-based products or milk-derived products have undergone a single HTST treatment and:

2.1. have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting country; or

2.2. have been presented at a border inspection post of entry into the Republic of Kosovo at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting country.

B. The following requirements shall apply to the importation of colostrum and colostrum products:

1. The materials shall have undergone a single HTST treatment and:

1.1. have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting country; or

1.2. have been presented at a border inspection post of entry into the Republic of Kosovo at least 21 days after production and during that period no case of Foot-and-Mouth disease has been detected in the exporting country.

2. The materials shall have been obtained from bovine animals subject to regular veterinary inspections to ensure that they come from holdings on which all bovine herds are:

2.1. either recognised as officially tuberculosis-free and officially brucellosis-free as defined in specific legislation on animal health problems affecting trade in bovine animals and swine or not restricted under the national legislation of the country of origin of the colostrum regarding eradication of tuberculosis and brucellosis; and

2.2. either recognised as official enzootic-bovine-leukosis-free as defined in specific legislation for leucosis on animal health problems affecting trade in bovine animals and swine or included in an official system for the control of enzootic bovine leukosis and there has been no evidence as a result of clinical and laboratory testing of this disease in the herd during the past two years.

3. After completion of the processing, every precaution shall have been taken to prevent contamination of the colostrum or colostrum products.

4. The final product must bear a label so as to indicate that it contains Category 3 material and is not intended for human consumption, and it must have been:

4.1. packed in new containers; or

4.2. transported in bulk in containers or other means of transport that before use were thoroughly cleaned and disinfected.

Section 5

Imports of blood products for the feeding of farmed animals

1. The following requirements shall apply to the importation of blood products, including spray dried blood and blood plasma which have been derived from porcine animals intended for the feeding of porcine animals:

1.1. These derived products must be:

1.2. subjected to a heat treatment at a temperature of at least 80 °C throughout the substance and the dry blood and blood plasma is of not more than 8 % moisture with a water activity (Aw) of less than 0,60;

1.3. stored in dry warehouse conditions under room temperature for at least 6 weeks.

CHAPTER II

SPECIFIC REQUIREMENTS FOR THE IMPORTATION INTO AND TRANSIT THROUGH THE REPUBLIC OF KOSOVO ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS FOR USES OUTSIDE THE FEED CHAIN FOR FARMED ANIMALS OTHER THAN FUR ANIMALS

Section 1

Specific requirements

1. As referred to in Article 41, paragraph 1, subparagraph 1.1. and paragraph 2, subparagraph 2.3 and paragraph 3 of Administrative Instruction (MAFRD) - No. 05/2022, the following specific requirements shall apply to imported consignments of animal by-products and derived products for uses outside the feed chain for farmed animals and consignments of such products in transit:

1.1. they must consist of or have been produced from animal by-products referred to in the column 'raw materials' of Table 2;

1.2. they must comply with the import and transit conditions set out in the column 'import and transit conditions' of Table 2;

1.3. they must come from an EU country or third country or part of a third country listed in the column 'third countries' list' of Table 2;

1.4. they must come from an establishment or plant which is registered or approved by the competent authority of the EU country or third country, as applicable, and which is on the list of such establishments and plants referred to in Article 31 of this Administrative Instruction and

1.5. they must be:

1.5.1. accompanied during transportation to the point of entry into the Republic of Kosovo where the veterinary checks take place by the health certificate referred to in the column 'certificates/model documents' of Table 2; or

1.5.2. presented at the point of entry into the Republic of Kosovo where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column 'certificates/model documents' of Table 2. (see in Annex 1. Of this Administrative Instruction).

Table 2

No	Product	Raw materials (reference to provisions of Administrative Instruction (MAFRD) - No. 05/2020 laying down health rules	Import and transit conditions	Third countries' lists	Certificates/model documents
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		for animal by-products and products derived thereof not intended for human consumption			
1	Processed manure, derived products from processed manure and guano from bats	Category 2 material referred to in Article 9, paragraph 1, subparagraph 1.1.	The processed manure, the derived products from processed manure and the guano from bats must have been produced in accordance with Section 2 of Chapter I of Annex IX.	Third countries listed in: 1. Part 1 of Annex XIII or Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404 for the processed manure of ungulates, frass or guano from bats, and the following third countries: (AL) Albania (DZ) Algeria (SV) El Salvador; 2. Part 1 of Annex IV to Implementing Regulation (EU) 2021/404 for the processed manure of solipeds; or 3. Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404 for the processed manure of poultry.	Annex XIII, Chapter 17.
2	Blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals	Category 1 material referred to in Article 8, paragraph 1, subparagraph 1.3 and 1.4 and Category 3 material referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.4 and 1.8.	The blood products must have been produced in accordance with Section 2.	The following third countries: 1. in the case of untreated blood products of ungulates: Third countries or parts of third countries listed in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404 from which imports of fresh meat of any domestic ungulate species is authorised and only for the period indicated in columns 7 and 8 of that Part. 2. in the case of untreated blood products of poultry and other avian species: Third countries or parts of third countries listed in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404. 3. in the case of untreated blood products of other animals: Third countries listed in Part 1 of Annex XIII, Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, or in Annex V or Annex VI to Commission Implementing Regulation (EU) 2021/405. 4. in the case of treated blood products of any species: Third countries listed in Part 1 of Annex XIII or Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404, in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404 or in Annex VI to Implementing Regulation (EU) 2021/405, and the following third countries: (AL) Albania (DZ) Algeria (SV) El Salvador	(a) In the case of untreated blood products: Annex XV, Chapter 4 (C). (b) In the case of treated blood products: Annex XV, Chapter 4 (D).
3	Blood and blood products from equidae	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2, 1.4 and 1.8.	The blood and the blood products shall comply with the requirements set out in Section 3.	The following third countries: 1. in the case of blood that has been collected in accordance with Chapter IV, point 1 of Annex XIII or where blood products have been produced in accordance with point 2(b)(i) of that Chapter: Third countries or parts of third countries listed in Part 1 of Annex IV to Implementing Regulation (EU) 2021/404, from which the importation of registered horses or registered equidae is allowed or Annex I to Implementing Regulation (EU) 2021/405. 2. in the case of blood products which have been treated in accordance with Chapter IV, point 2(b)(ii), of Annex XIII: Third countries listed in Part 1 of Annex IV to Implementing Regulation (EU) 2021/404, Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404, from which the importation of registered horses or registered equidae is allowed or Annex I to Implementing Regulation (EU) 2021/405	Annex XV, Chapter 4(A).
4	Fresh or chilled hides and skins of ungulates	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1 and 1.2.3.	The hides and skins shall comply with the requirements set out in Section 4, points 1 and 4.	The hides and skins come from a third country, or, in the case of regionalisation in accordance with Union legislation, a part of a third country listed in Part 1 of Annex	Annex XV, Chapter 5(A).

				XIII to Implementing Regulation (EU) 2021/404 or Annex I to Implementing Regulation (EU) 2021/405, from which Member States authorise imports of fresh meat from the same species.	
5	Treated hides and skins of ungulates	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2.1 and 1.2.3 and 1.1.14.	The hides and skins shall comply with the requirements set out in Section 4, points 2, 3 and 4.	1. In the case of treated hides and skins of ungulates: Third countries listed in Part 1 of Annex IV, Part 1 of Annex XIII or Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404, and the following third countries: (AL) Albania (DZ) Algeria (SV) El Salvador 2. In the case of treated hides and skins of ruminants that are intended for dispatch to the Union and which have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation into the Union. Any third country.	a) In the case of treated hides and skins of ungulates, other than those which comply with the requirements set out in Section 4, point 2: Annex XIII, paragraph 1, subparagraph 1.16. (b) In the case of treated hides and skins of ruminants and of equidae that are intended for dispatch to the Republic of Kosovo and which have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation: The official declaration set out in Annex XIII, paragraph 1, subparagraph 1.17. (c) In the case of treated hides and skins of ungulates which comply with the requirements set out in Section 4, point 2: No certificate is required.
6	Game trophies and other preparations from animals	Category 2 materials referred to in Article 9, paragraph 1, subparagraph 1.6 derived from wild animals not suspected of being infected with a disease communicable to humans or animals and Category 3 material referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2.1, 1.2.3 and 1.14.	The game trophies and other preparations shall comply with the requirements set out in Section 5.	1. In the case of game trophies and other preparations referred to in Section 5, point 2: Any third country. 2. In the case of game trophies and other preparations referred to in Section 5, point 3: (i) Game trophies from birds: Third countries listed in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, from which the Member States authorise imports of fresh poultry meat, and the following countries and territories: (GL) Greenland (TN) Tunisia. (ii) Game trophies from ungulates: Third countries listed in the appropriate columns for fresh meat of ungulates in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404, including any restrictions laid down in the column for specific conditions for fresh meat, or in Annex I to Implementing Regulation (EU) 2021/405 in case of solipeds.	(a) In the case of game trophies referred to in Section 5, point 2: Annex XIII, paragraph 1, subparagraph 1.18. (b) In the case of game trophies referred to in Section 5, point 3: Annex XIII, paragraph 1, subparagraph 1.19. (c) In the case of game trophies referred to in Section 5, point 1: No certificate is required.
7	Pig bristles	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.2.4.	The pig bristles must have been obtained from animals originating, and slaughtered in a slaughterhouse, in the third country of origin.	1. In the case of untreated pig bristles: Third countries, or, in the case of regionalisation, regions thereof, listed in Part 1 of Annex XIII or Section A of Part 1 of Annex XV to Implementing Regulation (EU) 2021/404 and the following third countries which have been free of African swine fever during the period of 12 months prior to the date of importation into the Union: (AL) Albania (DZ) Algeria (SV) El Salvador 2. In the case of treated pig bristles: Third countries listed in Part 1 of Annex XIII or Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404 and the following third countries which may not have been free of African swine fever during the period of 12 months prior to the date of importation into the Union: (AL) Albania (DZ) Algeria (SV) El Salvador	(a) If no case of African swine fever has occurred during the 12 previous months: Annex XIII, paragraph 1, subparagraph 1.20. (b) In case one or more cases of African swine fever have occurred during the previous 12 months: Annex XIII, paragraph 1, subparagraph 1.21.
8	Untreated wool and hair produced from animals other than those of the porcine species	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.8 and 1.14.	(1) The dry untreated wool and hair must be: (a) securely enclosed in packaging; and (b) sent directly to a plant producing derived products for uses outside the feed chain or a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents. (2) The wool and hair are wool and hair as referred to in Article 27, paragraph 2, subparagraph 2.5.	(1) Any third country. (2) Third country or region thereof (a) listed in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404 and authorised for imports into the Union of fresh meat of ruminants not subject to additional specific conditions; and (b) free of foot and mouth disease and, in the case of wool and hair of sheep and goats, of sheep pox and goat pox in accordance with Part A of Annex IV to Commission Delegated Regulation (EU) 2020/ 692 (*).	(1) For imports of untreated wool and hair, no health certificate is required. (2) A declaration importer in of the accordance with Annex XIII, paragraph 1, subparagraph 1.37 is required.

9	Treated feathers, parts of feathers and down	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.2.5 and 1.8 and 1.14	The treated feathers or parts of feathers shall comply with the requirements set out in Section 6.	Any third country.	For imports of treated feathers, parts of feathers and down, no health certificate is required.
10	Apiculture by-products	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.5.	a) In the case of apiculture by-products intended for use in apiculture, other than beeswax in the form of honeycomb: (i) The apiculture by-products have been subjected to a temperature of -12°C or lower temperature for at least 24 hours, or (ii) In the case of beeswax, the material has been processed in accordance with any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex II, and refined before importation. (b) In the case of beeswax, other than beeswax in the form of honeycomb, for purposes other than feeding to farmed animals, the beeswax has been refined or processed in accordance with any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex II before importation.	1 In the case of apiculture by-products intended for use in apiculture: Third countries listed in Part 1 of Annex XIII or Section A of Part 1 of Annex XV to Implementing Regulation (EU) 2021/404, and the following third countries: (AL) Albania (CM) Cameroon (DZ) Algeria (SV) El Salvador. 2 In the case of beeswax for purposes other than feeding to farmed animals: Any third country	(a) In the case of apiculture by-products intended for use in apiculture: Annex XIII, paragraph 1, subparagraph 1.28. (b) In the case of beeswax for purposes other than feeding to farmed animals: A commercial document attesting the refinement or processing.
11	Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) for uses other than as feed material, organic fertiliser or soil improver	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2.1., 1.2.3 and 1.8.	The products shall comply with the requirements set out in Section 7.	Any third country.	The products shall be accompanied by: (a) a commercial document as set out in Section 7, point 2; and (b) a declaration of the importer in accordance with Annex XIII, paragraph 1, subparagraph 1.32. in official languages of Republic of Kosovo.
12	Petfood, including dogchews	(a) In the case of processed petfood and of dogchews: materials referred to in Article 35, paragraph 1, subparagraph 1.1 and 1.2. (b) In the case of raw petfood: materials referred to in 35, paragraph 1, subparagraph 1.3.	The petfood and the dogchews must have been produced in accordance with Chapter II of Annex XI.	1 In the case of raw petfood: Third countries listed in Part 1 of Annex XIII, Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404 or Annex I to Implementing Regulation (EU) 2021/405, from which Member States authorise imports of fresh meat from the same species and where bone-in meat is authorised. In the case of fish materials, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405. 2. In the case of dogchews and petfood other than raw petfood: Third countries listed in Part 1 of Annex XIII, Part 1 of Annex XIV or Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404, and the following third countries: (AL) Albania (EC) Ecuador (DZ) Algeria (GE) Georgia (only processed petfood other than canned petfood) (LK) Sri Lanka (SA) Saudi Arabia (only processed petfood of poultry origin) (SV) El Salvador (TW) Taiwan In the case of processed petfood derived from fish materials, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405. In the case of raw petfood: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat	(a) In the case of canned petfood: Annex XIII, paragraph 1, subparagraph 1.5. (b) In the case of processed petfood other than canned petfood: Annex XIII, paragraph 1, subparagraph 1.6. (c) In the case of dogchews: Annex XIII, paragraph 1, subparagraph 1.7. (d) In the case of raw petfood: Annex XIII, paragraph 1, subparagraph 1.8.

				<p>from the same species and where only bone-in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC. Third countries listed in Part I of Annex II to Regulation (EU) No 206/2010, and the following countries:</p> <p>(JP) Japan (EC) Ecuador (LK) Sri Lanka (TW) Taiwan (SA) Saudi Arabia (only processed petfood of poultry origin)</p> <p>In the case of processed petfood derived from fish materials, third countries listed in Annex II to Decision 2006/766/EC</p>	
13	Flavouring innards for the manufacture of petfood	Materials referred to in Article 35, paragraph 1, subparagraph 1.1.	The flavouring innards must have been produced in accordance with Chapter III of Annex XI.	<p>Third countries listed in Part I of Annex XIII to Implementing Regulation (EU) 2021/404 or Annex I to Implementing Regulation (EU) 2021/405, from which Member States authorise imports of fresh meat from the same species and where bone-in meat is authorised. In the case of flavouring innards from fish materials, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405. In the case of flavouring innards of poultry origin, third countries listed in Part I of Annex XIV to Implementing Regulation (EU) 2021/404, from which Member States authorise imports of fresh poultry meat. In the case of flavouring innards from certain wild land mammals and leporidae, third countries listed in Annex V or Annex VI to Implementing Regulation (EU) 2021/405 from which Member States authorise imports of fresh meat from the same species</p>	Annex XIII, paragraph 1, subparagraph 1.9.
14	Animal by-products for the manufacture of petfood other than raw petfood and of derived products for uses outside the feed chain	<p>(a) Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1 to 1.13.</p> <p>(b) In the case of materials for the manufacture of petfood, Category 1 materials referred to in Article 8, paragraph 1, subparagraph 1.3.</p> <p>(c) In the case of fur for the manufacture of derived products, Category 3 materials referred to in Article 10(n).</p>	The products shall comply with the requirements set out in Section 8.	<p>1. In the case of animal by-products for the manufacture of petfood: (i) In the case of animal by-products from bovine, ovine, caprine, porcine and equine animals, including farmed and wild animals: Third countries or parts of third countries listed in Part I of Annex XIII to Implementing Regulation (EU) 2021/404 or Annex I to Implementing Regulation (EU) 2021/405, from which imports of fresh meat for human consumption is authorised. (ii) In the case of raw material from poultry including raites: Third countries or parts of third countries from which Member States authorise imports of fresh poultry meat, which are listed in Part I of Annex XIV to Implementing Regulation (EU) 2021/404. (iii) In the case of raw material from fish: Third countries listed in Annex IX to Implementing Regulation (EU) 2021/405. (iv) In the case of raw material from other wild land mammals and leporidae: Third countries listed in Annexes V or VI to Implementing Regulation (EU) 2021/405.</p> <p>2. In the case of animal by-products for the manufacture of pharmaceuticals: Third countries listed in Part I of Annex XIII, Part I of Annex XIV or Part I, Section A, of Annex XV to Implementing Regulation (EU) 2021/404 or in Annex I, Annex V or Annex VI to Implementing Regulation (EU) 2021/405, and the following third countries: (AL) Albania (DZ) Algeria (PH) Philippines (SV) El Salvador (TW) Taiwan.</p> <p>3. In the case of animal by-products for the manufacture of products for uses outside the feed chain for farmed animals, other</p>	<p>(a) In the case of animal by-products for the manufacture of processed petfood: Annex XV, Chapter 3(F).</p> <p>(b) In the case of animal by-products for the manufacture of products for uses outside the feed chain for farmed animals: Annex XIII, paragraph 1, subparagraph 1.22.</p>

				than pharmaceuticals. Third countries listed in Part 1 of XIII or Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, in Annex I, Annex V or Annex VI to Implementing Regulation (EU) 2021/405. In the case of material from fish, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405. (4) In the case of fur for the manufacture of derived products: Third countries listed in Part 1 of Annex XIII to Commission Implementing Regulation (EU) 2021/404 from which the entry into the Union of fresh meat of ungulates is authorised.	
15	Animal by-products for use as raw petfood	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1 and Article 10, paragraph 1, subparagraph 1.2.1 and 1.2.2.	The products shall comply with the requirements set out in Section 8.	Third countries listed in Part 1 of Annex XIII or Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, or in Annex I to Implementing Regulation (EU) 2021/405, from which Member States authorise imports of fresh meat from the same species and where bone in meat is authorised. In the case of fish materials, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405.	Annex XIII, paragraph 1, subparagraph 1.8.
16	Animal by-products for use in feed for fur animals	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1. to 1.13.	The products shall comply with the requirements set out in Section 8.	Third countries listed in Part 1 of Annex XIII or Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, or Annex I to Implementing Regulation (EU) 2021/405 from which Member States authorise imports of fresh meat from the same species and where bone in meat is authorised. In the case of fish materials, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405.	Annex XIII, paragraph 1, subparagraph 1.8.
17	Rendered fats for certain purposes outside the feed chain for farmed animals	a) In the case of materials destined for the production of biodiesel, oleochemical products or renewable fuels referred to in point L of Section 2 of Chapter IV of Annex II: Categories 1, 2 and 3 materials referred to in Articles 8, 9 and 10. (b) In the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex II: Category 2 and 3 materials referred to in Articles 9 and 10. (c) In the case of materials destined to organic fertilisers and soil improvers: Category 2 materials referred to in Article 9, paragraph 1, subparagraph 1.3, 1.4 and 1.6.1 and Category 3 materials referred to in Article 10, other than in paragraph 1, subparagraph 1.3 and 1.16. (d) In the case of materials destined to other purposes: Category 1 materials referred to in Article 8, paragraph 1, subparagraph 1.2, 1.3 and 1.4, Category 2 materials referred to in Article 9, paragraph 1, subparagraph 1.3, 1.4 and 1.6.1 and Category 3 materials referred to in Article 10, other than in paragraph 1, subparagraph 1.3 and 1.16.	The rendered fats shall comply with the requirements set out in Section 9.	Third countries listed in Part 1 of Annex XIII or Section A of Part 1 of Annex XV to Implementing Regulation (EU) 2021/404 and the following third countries: (AL) Albania (DZ) Algeria (SV) El Salvador. In the case of fish materials, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405.	Annex XIII, paragraph 1, subparagraph 1.24.
18	Fat derivatives	(a) In the case of fat derivatives for uses outside the feed chain for farmed animals: Category 1 materials referred to in Article 8, paragraph 1, subparagraph 1.2, 1.3 and 1.4 Category 2 materials referred to in Article 9, paragraph 1, subparagraph 1.3 and 1.4 and Article 9, paragraph 1, subparagraph 1.6.1 and Category 3 materials referred to in Article 10. (b) In the case of fat derivatives for use as feed: Category 3 materials other than materials referred to in Article 10, paragraph 1, subparagraph 1.14, 1.15 and 1.16.	The fat derivatives shall comply with the requirements set out in Section 10.	Any third country.	(a) In the case of fat derivatives for uses outside the feed chain for farmed animals: Annex XIII, paragraph 1, subparagraph 1.29. (b) In the case of fat derivatives for use as feed: Annex XIII, paragraph 1, subparagraph 1.30.

19	Photogelatine	Category 1 materials referred to in Article 8, paragraph 1, subparagraph 1.2 and Category 3 materials referred to in Article 10.	The imported photogelatine shall comply with the requirements set out in Section 11.	Photogelatine may only be imported from establishments of origin in the United States and in Japan that are authorised in accordance with Section 11	Annex XIII, paragraph 1, subparagraph 1.34.
20	Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the production of organic fertilisers or soil improvers	Category 3 materials referred to in Article 10, paragraph 1, subparagraph 1.1, 1.2 and 1.14.	The products shall comply with the requirements set out in Section 12.	Any third country.	Annex XIII, paragraph 1, subparagraph 1.34.

Section 2

Imports of blood and blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals

1. The following requirements shall apply to the import of blood and blood products, excluding those from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals:

1.1. The blood products must originate from a plant for the production of derived products for uses outside the feed chain for farmed animals which meets the specific conditions laid down in this Administrative Instruction or from the establishment of collection.

2. The blood from which blood products for the manufacture of derived products for uses outside the feed chain for farmed animals are produced must have been collected under veterinary supervision:

2.1. in slaughterhouses:

2.1.1. approved in accordance with legislation laying down specific rules on hygiene of food of animal origin; or

2.1.2. approved and supervised by the competent authority of the country of collection; or

2.1.3. from live animals in facilities approved and supervised by the competent authority of the country of collection.

3. In the case of blood products for the manufacture of derived products for uses outside the feed chain for farmed animals which have been derived from animals belonging to the taxa Artiodactyla, Perissodactyla and Proboscidea, including their crossbreeds, they must comply with the conditions of either subparagraph 3.1 or 3.2:

3.1. the products must have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in subparagraph 3.2. of this paragraph:

3.2. heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check;

3.4 irradiation at 25 kg y by gamma rays, followed by an effectiveness check;

3.5 heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check;

3.6 in the case of animals other than Suidae and Tayassuidae only: change in pH to pH 5 for two hours, followed by an effectiveness check;

3.7 in the case of blood products not treated in accordance with subparagraph 3.1 of this paragraph the products must originate from a country or region:

3.8 where no case of rinderpest, peste des petits ruminants (PPR), and Rift Valley fever has been recorded for a period of at least 12 months and in which vaccination has not been carried out against those diseases for a period of at least 12 months;

3.9 where no case of Foot-and-Mouth disease has been recorded for a period of at least 12 months, and,

3.10 in which vaccination has not been carried out against this disease for a period of at least 12 months, or

3.10.in which vaccination programmes against Foot-and-Mouth disease are being officially carried out and controlled in domestic ruminant animals for a period of at least 12 months; in this case, following the veterinary checks at the border inspection post, the products must be transported directly to the registered establishment or plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

4.In addition to sub-subparagraph 3.2.1 and 3.2.2. of subparagraph 3.2, in the case of animals other than Suidae and Tayassuidae, one of the following conditions must be complied with:

4.1 in the country or region of origin no case of vesicular stomatitis and bluetongue (including the presence of seropositive animals) has been recorded for a period of at least 12 months and vaccination has not been carried out against those diseases for a period of at least 12 months in the susceptible species;

4.2 following the veterinary checks provided at the border inspection post, the products must be transported directly to the plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

5.In addition to sub-subparagraph 3.1.2.1 and 3.1.2.2. of subparagraph 3.1, in the case of Suidae and Tayassuidae, in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for a period of at least 12 months, vaccination has not been carried out against those diseases for a period of at least 12 months and one of the following conditions are complied with:

5.1.in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for a period of 12 months and vaccination has not been carried out against this disease for a period of at least 12 months in the susceptible species;

5.2.following the veterinary checks provided at the border inspection post, the products must be transported directly to the registered establishment or plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

6. In the case of blood products for the manufacture of derived products for uses outside the feed chain for farmed animals which have been derived from poultry and other avian species, they must comply with the following conditions of either subparagraph 4.1 or 4.2;

6.1 the products must have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in subparagraph 4.2:

6.2 heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check

6.3 irradiation at 25 kGy by gamma rays, followed by an effectiveness check;

6.4 heat treatment of at least 70 °C throughout their substance, followed by an effectiveness check;

6.5 in case of blood products not treated in accordance with subparagraph 4.1 the products must originate from a country or region:

6.5.1 which has been free from Newcastle disease and highly pathogenic avian influenza as listed in the Animal Health Code of WOA;H;

6.5.2 which during the last 12 months has not carried out vaccination against avian influenza;

6.5.3 where the poultry or other avian species from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

Section 3

Imports of blood and blood products from equidae

1. The following requirements shall apply to the import of blood and blood products from equidae:

1.1. The blood must comply with the conditions set out in paragraph 1, subparagraph 1.1 of Chapter IV of Annex XI and must be collected under veterinary supervision:

1.1.1. in slaughterhouses:

1.1.2. approved in accordance with legislation in force laying down specific rules on hygiene of food of animal origin; or

1.1.3. approved and supervised by the competent authority of the country of collection; or

1.1.4. from live equidae in facilities approved and furnished with a veterinary approval number and supervised by the competent authority of the country of collection for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.

2. The blood products must comply with the conditions set out in paragraph 2 of Chapter IV of Annex XI.

3. In addition, the blood products referred to in subparagraph 2.2.1 of Chapter IV of Annex XI must be produced from blood collected from equidae which have been kept for a period of at least three months, or since birth if less than three months old, prior to the date of collection on holdings under veterinary supervision in the third country of collection which during that period and the period of blood collection has been free of:

3.1. African horse sickness in accordance with specific legislation;

3.2. Venezuelan equine encephalomyelitis for a period of at least two years;

3.3. glanders:

3.4. for a period of three years; or

3.5. for a period of six months where the animals have shown no clinical signs of glanders (*Burkholderia mallei*) during the post-mortem inspection in the slaughterhouse referred to in subparagraph 1.1 of paragraph 1 of this Section, including a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum;

3.6. in the case of blood products other than serum and plasma, vesicular stomatitis for a period of at least six months.

4. Blood products must come from an establishment or plant which has been approved or registered by the competent authority of the country of origin.

5. Blood and blood products shall be packed and labelled in accordance with paragraph 3 of Chapter IV of Annex XI.

Section 4 **Imports of hides and skins of ungulates**

1. The following requirements shall apply to the import of hides and skins of ungulates:

2. Fresh or chilled hides and skins may be imported if:

2.1 they come from an EU country or third country referred to in the applicable column of row 4 of Table 2 set out in Section 1 of this Annex, which, as appropriate to the species concerned:

2.2 for a period of at least 12 months before dispatch, has been free from all of the following diseases:

2.2.1 classical swine fever;

2.2.2 African swine fever, and

2.2.3 Rinderpest; and

2.2.4 has been free from foot-and-mouth disease for a period of at least 12 months before the date of dispatch and where, for a period of at least 12 months before the date of dispatch, no vaccination has been carried out against that disease;

2.2.5 they have been obtained from:

2.2.5.1 animals that have remained in the territory of the country of origin for a period of at least three months before being slaughtered or since birth in the case of animals less than three months old;

2.2.5.2 in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of Foot-and Mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of Foot-and-Mouth disease for 30 days;

2.2.5.3 in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days; or

2.2.5.4 animals that have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have shown no evidence of Foot-and-Mouth disease, Rinderpest, Classical Swine Fever, African swine fever or swine vesicular disease; and

2.2.5.5 they have undergone all precautions to avoid recontamination with pathogenic agents.

3. Treated hides and skins referred to in point C, paragraph 2 of Chapter V of Annex XI may be imported without any restrictions.

4. Other treated hides and skins may be imported if:

4.1. they come either from:

4.1.1. EU country or a third country or, in the case of regionalisation in accordance with legislation in force, from a part of a third country, appearing on the list set out in point (a) of the column 'third countries' list' of row 5 of Table 2 set out in Section 1 from which imports of fresh meat of the corresponding species are authorised and they have been treated as referred to in subparagraph 1.28.1, 1.28.2 and 1.28.3 of paragraph 1 of Article 3 of this Administrative Instruction;

4.1.2. EU country or a third country appearing on the list set out in point (a) of the applicable column of row 5 of Table 2 set out in Section 1 and they have been treated as referred to in subparagraph 1.28.3 of paragraph 1 of Article 3 of this Administrative Instruction; or

4.1.3. equidae or ruminant animals from an EU country or third country appearing on the list set out in point (b) of the column 'third countries' list' of row 5 of Table 2 of Section 1, and have been treated as referred to in subparagraph 1.28.1, 1.28.2 and 1.28.3 of paragraph 1 of Article 3 of this Administrative Instruction and after treatment have been kept separate for a period of at least 21 days; and

4.1.4 in the case of salted hides and skins transported by ship, they have been treated as referred to in subparagraph 1.28.2 and 1.28.3 of paragraph 1 of Article 3 of this Administrative Instruction and have

been kept separated after treatment during transportation for a period of at least 14 days in the case of the treatment referred to in subparagraph 1.28.2 or seven days in the case of the treatment referred to in point subparagraph 1.28.3 before importation and the health certificate accompanying the consignment attests such treatment and the duration of the transportation.

5. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed under the responsibility of the competent authority of the country of dispatch.

Section 5

Imports of game trophies and other preparations from animals

1. The following requirements shall apply to the import of game trophies and other preparations from animals:

1.1. Game trophies or other preparations from animals which fulfil the conditions referred to in points B and C, paragraph 1 of Chapter VI of Annex XI may be imported without restrictions.

1.2. Treated game trophies or other preparations from birds and ungulates, being solely comprised of bones, horns, hooves, claws, antlers, teeth, hides or skins, from EU countries or third countries may be imported if they comply with the requirements of point C, paragraph 1, subparagraph 1.1 and point C, paragraph 2, subparagraph 2.1.1 to 2.1.3 and 2.2.1 and 2.2.2 of Chapter VI of Annex XI.

1.3. However, in the case of dry-salted or wet-salted skins transported by ship, the skins need not be salted 14 days before dispatch, provided that they are salted for 14 days before importation.

2. Game trophies or other preparations from birds and ungulates consisting of entire anatomical parts, not having been treated in any way may be imported if:

2.1. they come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible;

2.2. they were packaged without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination.

Section 6

Imports of treated feathers, parts of feathers and down

1. Treated feathers and parts of feathers and down may be imported:

1.1. if they are treated decorative feathers, treated feathers carried by travelers for their private use or consignments of treated feathers or down sent to private individuals for non-industrial purposes; or

1.2. if they are accompanied by a commercial document stating that the feathers and parts of feathers or down have been treated with a steam current or by another method that ensures that no unacceptable risks remain and are securely enclosed in packaging and dry; and

1.3. unless the commercial document states that they have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes, they are sent to a registered establishment or plant for such treatment.

Section 7

Imports of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for use other than as feed material, organic fertilisers or soil improvers

1. Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) may be imported to produce derived products for uses outside the feed chain if:

1.1. the products are dried before export to the Republic of Kosovo and not chilled or frozen;

1.2. the products are conveyed from the country of origin directly to a border inspection post of entry into the Republic of Kosovo;

1.3. following the document checks provided at the border inspection post, the products are conveyed directly to the registered establishment or plant of destination.

2. Each consignment must be accompanied by a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:

2.1. the country of origin;

2.2. the name of the establishment or plant of production;

2.3. the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and

2.4. confirmation that the product is not intended at any stage to be diverted for any use in the manufacturing of food, feed material, organic fertilisers or soil improvers, and

2.5. was derived from healthy animals slaughtered in a slaughterhouse; and

2.6. either was dried for a period of 42 days at an average temperature of at least 20 °C; and/or

2.7. was heated for one hour to a temperature of at least 80 °C to the core; and/or

2.8. was incinerated to ash for one hour at a temperature of at least 800 °C to the core; and/or

2.9. underwent an acidification process such that the pH was maintained for at least one hour at less than 6 to the core.

3. On dispatch to the Republic of Kosovo, the material must be enclosed in sealed containers or vehicles.

4.If transported in containers, the containers, and in all cases all the accompanying documents, must bear the name and the address of the registered establishment or plant of destination.

5.Following the veterinary checks provided at the border inspection post, the material must be transported directly to the registered establishment or plant of destination.

Section 8

Imports of animal by-products for the manufacture of feed for fur animals, petfood, other than raw petfood, and derived products for uses outside the feed chain for farmed animals

1. Animal by-products intended for the manufacture of feed for fur animals, petfood, other than raw petfood, and for derived products for uses outside the feed chain for farmed animals may be imported provided that:

1.1. the animal by-products have been deep-frozen at the plant of origin or have been preserved in accordance with legislation in force in such a way to prevent spoiling between dispatch and delivery to the establishment or plant of destination;

1.2. the animal by-products have undergone all precautions to avoid contamination with pathogenic agents;

1.3. the animal by-products were packed in new packaging preventing any leakage or in packaging which has been cleaned and disinfected before use;

1.4. following the veterinary checks provided for in at the veterinary border post, the animal by-products are transported directly either to:

1.4.1.a petfood plant or to a registered establishment or plant of destination, which has provided a guarantee that the animal by-products shall be used only for the purpose of producing the products for which it has been registered or approved, as applicable, as specified by the competent authority if necessary, and shall not leave the establishment or plant untreated other than for direct disposal;

1.4.2. an establishment or plant which has been approved in accordance with Article 24, paragraph 1, subparagraph 1.8 of Administrative Instruction (MAFRD) - No. 05/2022;

1.4.3. a registered user or collection centre, which has provided a guarantee that the animal by-products shall be used only for permitted purposes, as specified by the competent authority if necessary; or

1.4.4. an establishment or plant which has been approved in accordance with Article 24, paragraph 1, subparagraph 1.1 of Administrative Instruction (MAFRD) - No. 05/2022; and

1.5 in the case of raw material for petfood production referred to in Article 35, paragraph 1, subparagraph 1.1.2 of Administrative Instruction (MAFRD) - No. 05/2022, the raw material shall:

1.5.1 be marked in the country before entry into the Republic of Kosovo by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, or, when the raw material is transported in pallets which are not divided into separate consignments during transport to the petfood plant of

destination, on each outer side of each pallet, in such a way that the marking covers at least 70 % of the diagonal length of the side of the frozen block and is at least 10 cm in width;

1.5.2 in the case of material which is not frozen, be marked in the country of origin before entry into the Republic of Kosovo by spraying it with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material;

1.5.3 be transported directly to:

1.5.3.1 the petfood plant of destination in accordance with subparagraph 1. 4.1 of paragraph 1.4 of this Section; or

1.5.3.2 an establishment or plant of destination which has been approved in accordance with Article 24, paragraph 1, subparagraph 1.8 of Administrative Instruction (MAFRD) - No. 05/, in accordance with subparagraph 4.2 of paragraph 4 of this Section and from there directly to the petfood plant referred to under subparagraph 5.1.3.1. of this paragraph, provided that the plant of destination:

1.5.3.2.1 only handles material covered by paragraph 5, or

1.5.3.2.2 only handles material destined for a petfood plant as referred to under 5.3.1 of this paragraph; and

1.5.4 be manipulated to remove the marking provided for in subparagraph 5.1 and 5.2 of this paragraph only in the petfood plant of destination and only immediately prior to use of the material for the manufacture of petfood, in accordance with the conditions applicable to petfood produced from Category 3 material set out in Chapter II of Annex XI;

1.6 in the case of consignments made up of raw material, which has been treated as referred to in paragraph 5 above and other non-treated raw material, all the raw materials in the consignment have been marked as laid down in subparagraph 5.1 and 5.2 of paragraph 5 above;

1.7 the marking referred to in subparagraph 5.1 and 5.2 and paragraph 6 remains visible from the dispatch and until the delivery to the petfood plant of destination;

1.8 In the petfood plant of destination, raw material for petfood production referred to in Article 35, paragraph 1, subparagraph 1.1.2 of Administrative Instruction (MAFRD) - No. 05/2022 shall be stored before production, used and disposed of under conditions authorised by the competent authority, which allow official controls on the amounts of material received, used for production and disposed of, if applicable.

2. The competent authority may authorise the operator of the petfood plant to store such materials together with Category 3 material.

Section 9

Imports of rendered fats for certain purposes outside the feed chain for farmed animals

1. Rendered fats which are not destined to the production of feed for farmed animals, the manufacture of cosmetics, medicinal products or medical devices, may be imported, provided:

1.1. they are derived from:

1.2. in the case of materials destined for the production of biodiesel, oleo chemical products or for the production of renewable fuels which have undergone the treatment referred to in point L of Section 2 of Chapter IV of Annex II of this Administrative Instruction, animal by-products referred to in Articles 8, 9 and 10 of Administrative Instruction (MAFRD) - No. 05/2022;

1.3. in the case of materials destined to the production of organic fertilisers and soil improvers, Category 2 materials referred to in subparagraphs 1.3, 1.4 and 1.6.1 of Article 9 of Administrative Instruction (MAFRD) - No. 05/2022, or Category 3 materials, other than materials referred to in subparagraph 1.3 and 1.16 of Article 10 of Administrative Instruction (MAFRD) - No. 05/2022;

1.4. in the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex II of this Administrative Instruction, Category 2 materials referred to in Article 9 of Administrative Instruction (MAFRD) - No. 05/2022 and Category 3 materials referred to in Article 10 of that Administrative Instruction;

1.5. in the case of other materials Category 1 materials referred to in subparagraph 1.2, 1.3 and 1.4 of Article 8 of Administrative Instruction (MAFRD) - No. 05/2022, Category 2 materials referred to in subparagraph 1.3 and 1.4 of Article and subparagraph 1.6.1 of Article 9 of Administrative Instruction (MAFRD) - No. 05/2022 or Category 3 materials, other than the materials referred to in subparagraph 1.3 and 1.16 of Article 10 of that Administrative Instruction;

1.5.1. they have been processed by processing method 1 (pressure sterilisation) or in accordance with one of the other processing methods referred to in Chapter III of Annex II of this Administrative Instruction;

1.5.2. in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight have been removed;

1.5.3. they have been marked before shipment to the Republic of Kosovo so that the minimum concentration of GTH referred to in subparagraph 1.2 of Chapter V of Annex VI of this Administrative Instruction is achieved;

1.5.4. following the veterinary checks provided for in at the border inspection post, the rendered fats are transported directly to the registered establishment or plant of destination, under conditions which prevent contamination; and

1.5.5. they bear labels, on the packaging or container indicating '**NOT FOR HUMAN OR ANIMAL CONSUMPTION**'.

Section 10

Imports of fat derivatives

1. Fat derivatives may be imported if the health certificate accompanying the consignment certifies:

1.1 whether the fat derivatives derive from Category 1, 2 or 3 materials;

1.2 in the case of fat derivatives produced from Category 2 material, that the products:

1.2.1 have been produced using a method that at least meets the standards of one of the processes referred to in paragraph 1 of Chapter XI of Annex XI; and

1.2.2 shall only be used in organic fertiliser or soil improvers or other uses outside the feed chain for farmed animals, other than in cosmetics, pharmaceuticals and medical devices;

1.2.3 in the case of fat derivatives produced from Category 1 material, that the products must not be used in organic fertilisers and soil improvers, cosmetics, pharmaceuticals and medical devices; however, they may be used for other purposes outside the feed chain for farmed animals.

2. The health certificate referred to in paragraph 1 of this Section must be presented to the competent authority at the border inspection post at the entry of the goods into the Republic of Kosovo, and thereafter a copy must accompany the consignment until its arrival at the plant of destination.

3. Following the veterinary checks provided for in at the border inspection post, the fat derivatives shall be transported directly to the registered establishment or plant of destination.

Section 11

Imports of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers

1. Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers, may be imported, provided that:

1.1. they have been produced in accordance with Chapter XII of Annex XI; and

1.2. they are conveyed following the veterinary checks provided for in at the border inspection post, directly to an approved or registered establishment or plant.

CHAPTER III

SPECIAL RULES FOR CERTAIN SAMPLES

Section 1

Research and diagnostic samples

1. Unless they are kept for reference purposes or redispached to the country of origin, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:

1.1. as waste by incineration;

1.2. by pressure sterilisation and subsequent disposal or use in accordance with Articles 12 to 14 of Administrative Instruction (MAFRD) - No. 05/2022; or

1.3. in accordance with subparagraph 4.2 of paragraph 4 of Section 1 of Chapter I of Annex IV in case:

1.3.1. of quantities not exceeding 2 000 ml; and

1.3.2. provided the samples or derived products have been produced in and dispatched from EU countries or from countries or parts of countries, from which imports to EU of fresh meat of domestic bovine animals is authorized.

Section 2 **Trade samples**

1..The competent authority may authorise the import and transit of trade samples, provided that:

1.1. they originate from:

1.1.1. EU countries or third countries referred to in the column ‘third countries’ list’ of row 14 of Table 2 of Section 1 of Chapter II of this Annex;

1.2.in the case of trade samples which consist of milk, milk-based products or milk-derived products, EU countries or from third countries listed and authorised for the introduction into EU of consignments of raw milk and dairy products intended for human;

1.3.they are accompanied by a health certificate as referred to in Annex XIII, paragraph 1, subparagraph 1.23. and

1.4.following the veterinary checks provided for in at the border inspection post, they are transported directly to the approved or registered establishment or plant indicated in the authorisation of competent authority.

2. Unless the trade samples are kept for reference purposes, they shall be:

2.1.disposed of or used in accordance with Articles 12, 13 and 14 of Administrative Instruction (MAFRD) - No. 05/2022; or

2.2. redispached to the country of origin.

3.If trade samples are used for testing of machinery, the testing shall be carried out:

3.1 with dedicated equipment; or

3.2 with equipment which is cleaned and disinfected before it is used for purposes other than the testing.

4.During transport to the approved or registered establishment or plant, the trade samples must be packaged in leak- proof containers.

Section 3 **Display items**

1. Import and transit of display items shall take place in accordance with the following conditions:

- 1.1. they originate from EU countries or third countries referred to in the column 'third countries' list' of row 14 of Table 2 of Section 1 of Chapter II;
 - 1.2. their introduction has been authorised in advance by the competent authority where the display item is intended to be used;
 - 1.3. following the veterinary checks provided for in at the border inspection post, display items must be sent directly to the authorised user.
2. Each consignment must be packed in packaging preventing any leakage and must be accompanied by a commercial document which specifies:
- 2.1 the description of the material and the animal species of origin;
 - 2.2 the category of the material;
 - 2.3 the quantity of the material;
 - 2.4 the place of dispatch of the material;
 - 2.5 the name and the address of the consignor;
 - 2.6 the name and the address of the consignee; and
 - 2.7 details allowing the identification of the authorisation of the competent authority of destination.
3. After the exhibition or after the artistic activity has been concluded, display items shall be:
- 3.1. redispached to the country of origin;
 - 3.2. dispatched to another country, if such dispatch has been authorised by the competent authority of the country of destination in advance; or
 - 3.3. disposed of in accordance with Articles 12, 13 and 14 of the Administrative Instruction (MAFRD) - No. 05/2022

CHAPTER IV SPECIFIC REQUIREMENTS FOR CERTAIN MOVEMENTS OF ANIMAL BY-PRODUCTS

Section 1 Imports of certain Category 1 material

1. Materials referred to in Article 28 of this Administrative Instruction shall be imported under the following conditions:

- 1.1. The materials shall be imported with a label attached to the packaging, container or vehicle which indicates '**Prohibited in food, feed, fertilisers, cosmetics, medicinal products and medical devices**'.

2.The materials shall be directly delivered to an approved or registered establishment or plant for the manufacture of derived products, other than the products referred to in paragraph 1 of this Section.

3.Unused or surplus materials shall be used or disposed of in accordance with Article 12 Administrative Instruction (MAFRD) - No. 05/2022.

Section 2

Imports of certain materials for purposes other than feeding to farmed land animals

1.The competent authority may authorise the import of the following materials for purposes other than feeding to farmed land animals, except for feeding to fur animals, provided there is no unacceptable risk for the transmission of diseases communicable to humans or animals:

1.1.animal by-products from aquatic animals and derived products from aquatic animals;

1.2. aquatic invertebrates and derived products from aquatic invertebrates;

1.3. terrestrial invertebrates, including any of their transformation forms, such as larvae, and derived products therefrom;

1.4. products generated by the animals referred to in subparagraph 1.1, 1.2 and 1.3 of this Section, such as fish eggs;

1.5. Category 3 material comprising of animals and parts thereof of the zoological orders of Rodentia and Lagomorpha

2.Imports of consignments of the materials referred to in paragraph 1 to this Section shall take place in accordance with sanitary certification requirements in accordance with national rules.

CHAPTER V

RULES FOR THE EXPORT OF CERTAIN DERIVED PRODUCTS

1. Rules applicable to the export of the derived products listed below as referred to in Article 27, paragraph 4 of this Administrative Instruction:

	Derived products	Rules for export
1	<ul style="list-style-type: none">• Processed manure• Organic fertilizers, compostor digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure	<p>The following derived products must comply at least with the conditions set out in subparagraph 1.1, 1.2, 1.4 and 1.5 of paragraph 1 of Section 2 of Chapter I of Annex IX:</p> <ul style="list-style-type: none">• Processed manure

	<ul style="list-style-type: none"> • Processed animal protein containing processed manure as a mixing component 	<ul style="list-style-type: none"> • Organic fertilizers, compost or digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure • Processed manure as a mixing component in processed animal protein
2	Blood products and intermediate products	Blood, blood products and intermediate products produced in the Republic of Kosovo or imported into the Republic of Kosovo in accordance with health requirements laid down in Annex X or Sections 2 and 3 of Chapter II of this Annex for use outside the feed chain of farm animals, provided they comply with the import requirements of the country of destination.

CHAPTER VI

REQUIREMENTS FOR THE ENTRY OF CONSIGNMENTS OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS ORIGINATING FROM, AND RETURNING TO THE REPUBLIC OF KOSOVO FOLLOWING REFUSAL OF ENTRY BY OTHER COUNTRY

Section 1

Unpackaged or in bulk animal by-products and derived products, originating from, and returning to, the Republic of Kosovo following refusal of entry by other country not listed as a whole or part of its territory in Annex XII

1. The competent authority at the border control post shall only authorise the entry into the Republic of Kosovo of consignments of unpackaged or in bulk animal by-products or derived products originating from, and returning to, the Republic of Kosovo following a refusal of entry by other country not listed as a whole or part in Republic of Kosovo of its territory in Annex XII for the entry into the Republic of Kosovo of the type of product, where the following conditions are met:

1.1.the consignment is accompanied by the official certificate or document, either in its original or as authenticated copy, or by the electronic equivalent of such certificate, issued by the competent authority of the country of export;

1.2. the consignment is accompanied by a declaration from the competent authority in the country of destination in which that authority agrees to receive the consignment and indicates the place of destination;

1.3.the consignment complies with both of the following conditions:

1.3.1.it has remained sealed with an intact original seal, if the application of a seal prior to leaving the country was mentioned in the original certificate referred to in subparagraph 1.1 of paragraph 1 or another official document issued by the authority in the country;

1.3.2. it is accompanied by an official declaration of the competent authority or other public authority of the country which refused the entry of the consignment indicating the reason for the refusal.

2.By way of derogation from subparagraph 1.1 of paragraph 1 of this Section, in the case where the consignment was exported without accompanying official certificate or document, the origin of the consignment shall be authenticated in another way based on documented evidence presented by the operator responsible for the consignment.

3.The transport of consignments of products referred to in paragraph 1 of this Section from the border control post to the place of destination shall be monitored in accordance with specific legislation as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination.

Section 2

Unpackaged or in bulk animal by-products and derived products originating from, and returning to, the Republic of Kosovo following refusal of entry by a another country

1.The competent authority at the border control post shall only authorise the entry into the Republic of Kosovo of consignments of unpackaged or in bulk animal by-products or derived products originating from, and returning to, the Republic of Kosovo following a refusal of entry by another country listed as a whole or part of its territory in Annex XII for the entry into the Republic of Kosovo of the type of product, where the requirements set out in paragraphs 1.1, 1.2 and 1.3.2., 2 and 3 of Section 1 are met.

2.Where the products referred to in paragraph 1 of this Section have been unloaded, stored, re-loaded or the original seal has been replaced in or upon entry into another country or part of its territory listed in Annex XII, the consignment shall be accompanied by an official declaration of the competent authority or other public authority of that country or territory:

2.1 indicating the place and date of unloading, storage and re-loading and the seal number put on the container after reloading;

2.2 confirming that:

2.2.1 the seal on the vehicle or container of the consignment was only broken for the purpose of official controls;

2.2.2 the products were handled only to the extent necessary, and in particular;

2.2.3 at the appropriate temperature required for the relevant types of animal by-products or derived products; and

2.2.4 in a way that prevents cross contamination of the products during the controls;

2.2.5 the vehicle or container was immediately re-sealed after the official controls;

2.2.6 indicating the reasons for unloading and storage.

Section 3

Packaged animal by-products and derived products originating from, and returning to, the Republic of Kosovo following a refusal of entry by another country

1. The competent authority at the border control post shall only authorise the entry into the Republic of Kosovo of consignments of packaged animal by-products or derived products originating from, and returning to, the Republic of Kosovo following a refusal of entry by another country where the requirements set out in Section 1 are met and the individual packaging of the products has remained intact as compared to its state before exportation.

2. Where the products referred to in paragraph 1 of this Section have been unloaded in another country, the consignment is accompanied by an official declaration of the competent authority or other public authority of another country attesting that the products:

2.1. have not been subjected to any handling other than unloading, storage and re-loading;

2.2. were handled at the required temperature for the relevant types of animal by-products or derived products.

ANNEX XIII

LIST OF HEALTH CERTIFICATES

1. List of health certificates and declarations that shall accompany consignments of animal by-products and derived products as referred in Article 32, paragraph 2:

2. Health certificate for processed animal protein, other than those derived from farmed insects, not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through the Republic of Kosovo;

3. Health certificate for processed animal protein derived from farmed insects not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through the Republic of Kosovo;

4. Health certificate for milk, milk-based products and milk-derived products not intended for human consumption for dispatch to or transit through the Republic of Kosovo;

5. Health certificate for colostrum and colostrum products from bovine animals not intended for human consumption for dispatch to or transit through the Republic of Kosovo;

6. Health certificate for canned petfood intended for dispatch to or for transit through the Republic of Kosovo;

7. Health certificate for processed petfood other than canned petfood, intended for dispatch to or for transit through the Republic of Kosovo;

8. Health certificate for dogchews intended for dispatch to or for transit through the Republic of Kosovo;

9. Health certificate for raw petfood for direct sale or animal by-products to be fed to fur animals, intended for dispatch to or for transit through the Republic of Kosovo;

10. Health certificate for flavouring innards for use in the manufacture of petfood, intended for dispatch to or for transit through the Republic of Kosovo;
11. Health certificate for animal by-products for the manufacture of petfood, intended for dispatch to or for transit through the Republic of Kosovo;
12. Health certificate for the import of blood and blood products from equidae to be used outside the feed chain, for dispatch to or for transit through the Republic of Kosovo;
13. Health certificate for blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through the Republic of Kosovo;
14. Health certificate for untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals, intended for dispatch to or for transit through the Republic of Kosovo;
15. Health certificate for treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals, intended for dispatch to or for transit through the Republic of Kosovo;
16. Health certificate for fresh or chilled hides and skins of ungulates, intended for dispatch to or for transit through the Republic of Kosovo;
17. Health certificate for treated hides and skins of ungulates, intended for dispatch to or for transit through the Republic of Kosovo;
18. Official declaration for treated hides and skins of ruminants and of equidae that are intended for dispatch to or for transit through the Republic of Kosovo and have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation;
19. Health certificate for treated game trophies and other preparations of birds and ungulates, consisting only of bones, horns, hooves, claws, antlers, teeth, hides or skins, for dispatch to or for transit through the Republic of Kosovo;
20. Health certificate for game trophies or other preparations of birds and ungulates consisting of entire parts not having been treated, intended for dispatch to or for transit through the Republic of Kosovo;
21. Health certificate for pig bristles from third countries or regions thereof that are free from African Swine Fever, intended for dispatch to or for transit through the Republic of Kosovo;
22. Health certificate for pig bristles from third countries or regions thereof that are not free from African Swine Fever, intended for dispatch to or for transit through the Republic of Kosovo;
23. Health certificate for animal by-products to be used for purposes outside the feed chain or for trade samples, intended for dispatch to or for transit the Republic of Kosovo;

24. Health certificate for fish oil not intended for human consumption to be used as feed material or for purposes outside the feed chain, intended for dispatch to or for transit through the Republic of Kosovo;
25. Health certificate for rendered fats not intended for human consumption to be used as feed material, intended for dispatch to or for transit the Republic of Kosovo;
26. Health certificate for rendered fats not intended for human consumption to be used for certain purposes outside the feed chain, intended for dispatch to or for transit through the Republic of Kosovo;
27. Health certificate for gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain, intended for dispatch to or for transit through the Republic of Kosovo;
28. Health certificate for hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as feed material or for uses outside the feed chain.
29. Intended for dispatch to or for transit through the Republic of Kosovo;
30. Health certificate for apiculture by-products intended exclusively for use in apiculture, intended for dispatch to or for transit through the Republic of Kosovo;
31. Health certificate for fat derivatives not intended for human consumption to be used outside the feed chain, intended for dispatch to or for transit through the Republic of Kosovo;
32. Health certificate for fat derivatives not intended for human consumption to be used as feed or outside the feed chain, intended for dispatch to or for transit through the Republic of Kosovo;
33. Health certificate for egg products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through the Republic of Kosovo;
34. Declaration by the importer of bones and bone products, horns and horn products and hooves and hoof products intended for use other than as feed material, organic fertiliser or soil improvers for dispatch to the Republic of Kosovo;
35. Health certificate for processed manure, derived products from processed manure and guano from bats intended for dispatch to or for transit through the Republic of Kosovo;
36. Health certificate for horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers intended for dispatch to or for transit through the Republic of Kosovo;
37. Health certificate for gelatine not intended for human consumption to be used by the photographic industry, intended for dispatch to the Republic of Kosovo;
38. Declaration for the import from other countries and for the transit through the Republic of Kosovo of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products,

medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products;

39. Declaration by the importer of untreated wool and hair referred to in Article 27, paragraph 2, subparagraph 2.5 for import to the Republic of Kosovo.

40. Notes relevant to health certificates and declarations form paragraph 1 of this Annex are as follows:

40.1. Veterinary certificates shall be produced by the exporting country, based on the models listed out in this Annex, according to the layout of the model that corresponds to the animal by-products or derived products concerned. They shall contain, in the numbered order that appears in the model, the attestations that are required for any country and, as the case may be, those supplementary guarantees that are required for the exporting country or part thereof;

40.2. Where the model certificate states that certain statements shall be kept as appropriate, statements which are not relevant may be crossed out and initialled and stamped by the certifying officer, or completely deleted from the certificate;

41. The original of each certificate shall consist of a single sheet of paper, both sides, or, where more text is required; it shall be in such a form that all sheets of paper needed are part of an integrated whole and indivisible;

42. It shall be drawn up in the official languages of the Republic of Kosovo EU in which the inspection at the border post shall be carried out and of the country of destination. However, these countries may allow other languages, accompanied, if necessary, by an official translation.;

43. If for reasons of identification of the items of the consignment, additional sheets of paper are attached to the certificate, these sheets of paper shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, in each of the sheets of paper;

44. When the certificate, including additional schedules referred to in e), comprises more than one page, each page shall be numbered – (page number) of (total number of pages) – at the bottom of the page and shall bear the code number of the certificate that has been designated by the competent authority at the top of the page;

45. The original of the certificate must be completed and signed by an official veterinarian. In doing so, the competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in specific legislation for certification of animals and animal products are followed;

46. The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

47. The original of the certificate must accompany the consignment at the border inspection post;

48. If health certificates are used for consignments in transit, box No I.5 ('Consignee') of the relevant health certificate shall be completed with the name and address of the border inspection post through which the consignment is intended to leave the Republic of Kosovo.

ANNEX XIV

OFFICIAL CONTROLS

CHAPTER I

OFFICIAL CONTROLS IN PROCESSING PLANTS

Section 1

Supervision of the production

1.The competent authority shall supervise processing plants to ensure compliance with the requirements of Administrative Instruction (MAFRD) - No. 05/2022 and with this Administrative Instruction. It shall, in particular:

1.1. check:

1.1.1. the general conditions of hygiene of the premises, equipment and staff;

1.1.2. the efficacy of the own checks carried out by the operator of the processing plant, in accordance with Article 28 of Administrative Instruction (MAFRD) - No. 05/2022; such checks must include an examination of the results of those checks and if necessary, the taking of samples;

1.1.3. the effective implementation of the permanent written procedure based on the HACCP principles in accordance with Article 29, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022; such checks must include an examination of the results of this implementation and if necessary, the taking of samples;

1.1.4. the standards of the products after processing; the analyses and tests must be carried out in accordance with scientifically recognised methods, in particular, those laid down in the legislation in force or, where no such methods are laid down in legislation, in accordance with recognised international standards or, in their absence, national standards; and

1.1.5. the storage conditions;

1.1.6. take any samples required for laboratory tests; and

1.1.7. make any other checks it considers necessary to ensure compliance with the Administrative Instruction (MAFRD) - No. 05/2022 and with this Administrative Instruction.

2.To allow it to carry out its responsibilities under paragraph 1 of this Section, the competent authority must have free access at all times to all parts of the processing plant and to records, commercial documents and health certificates.

Section 2

Validation procedures

1. Prior to issuing an approval for a processing plant, as provided for in Article 44, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022, the competent authority must check that a validation

of the processing plant has been carried out by the operator in accordance with the following procedures and indicators:

- 1.1 a description of the process by a process flow diagram;
- 1.2 an identification of critical control points (CCPs) including the material process rate for continuous systems;
- 1.3 the compliance with the specific process requirements laid down by this Administrative Instruction; and
- 1.4 the achievement of the following requirements:
 - 1.4.1 particle size for batch-pressure and continuous processes, defined by the mincer hole or the anvil gap size;
 - 1.4.2 temperature, pressure, processing time and, in the case of continuous processing systems, the material processing rate, as specified in paragraph 2 and 3 of this Section.
- 1.5 In the case of a batch pressure system:
 - 1.5.1. the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;
 - 1.5.2. the pressure stage must be monitored with a permanent pressure gauge; pressure must be plotted against real time;
 - 1.5.3. the processing time must be shown by time/temperature and time/pressure diagrams. At least once a year the thermocouple and the pressure gauge must be calibrated.
- 1.6. In the case of a continuous pressure system:
 - 1.6.1. the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges must be used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it; the temperature and pressure must be plotted against real time;
 - 1.6.2. measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers, such as manganese dioxide, or a method which offers equivalent guarantees. Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:
 - 1.6.3. feed screw revolutions per minute (rev./min.);

1.6.4. the electric power (amps at given voltage);

1.6.5. the evaporation/condensation rate; or

1.6.6. the number of pump strokes per unit time.

2. All measuring and monitoring equipment must be calibrated at least once a year.

3. The competent authority must repeat the checks on the validation procedures when it considers it necessary, and in any case each time any significant alterations are made to the process, such as modifications of the machinery or changes of raw materials.

CHAPTER II

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS

Section 1

Official controls regarding marking of derived products

The competent authority shall carry out a performance check of the monitoring and recording system referred to in paragraph 2 of Chapter V of Annex VIII to this Administrative Instruction to ascertain compliance with this Administrative Instruction and may, where necessary, request the testing of additional samples in accordance with the method referred to in the second subparagraph of that paragraph.

Section 2

Official controls in low-capacity incineration plants

The competent authority shall inspect a low-capacity incineration plant for incineration of specified risk materials before approval, and at least once a year to monitor compliance with Administrative Instruction (MAFRD) - No. 05/2022 and with this Administrative Instruction.

Section 3

Official controls in remote areas

In the case of disposal of animal by-products in remote areas in accordance with Article 19, paragraph 1, subparagraph 1.2 of the Administrative Instruction (MAFRD) - No. 05/, the competent authority shall monitor regularly the areas categorised as remote areas to ensure that those areas and the disposal operations are properly controlled.

Section 4

Official controls in registered farms for the feeding of fur animals

1. The competent authority shall take the necessary measures to control:

1.1 the appropriate composition, processing and use of the feed containing meat-and-bone meal or other products which have been processed in accordance with the processing methods set out in Chapter III of Annex II of this Administrative Instruction and which are derived from the bodies or parts of bodies of animals of the same species;

1.2 that the animals are fed with the feed referred to in subparagraph 1.1 of this paragraph, including:

1.2.1. strict supervision of the health status of those animals; and

1.2.2. appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

2. The samples referred to in sub-subparagraph 1.2.2 of the paragraph 1 of this Section shall include samples taken from animals showing neurological symptoms and from older breeding animals.

Section 5

Official controls regarding collection centres

1. The competent authority shall:

1.1. include collection centres into the list drawn up in accordance with Article 47, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022;

1.2. assign an official number to each collection centre; and

1.3. update the list of collection centres and make it available together with the list drawn up in accordance with Article 47, paragraph 1 of Administrative Instruction (MAFRD) - No. 05/2022.

1.4. The competent authority shall carry out official controls at collection centres in order to verify compliance with this Administrative Instruction

Section 6

Official controls regarding the feeding of wild animals and certain zoo animals with Category 1 material

1. The competent authority shall monitor the health status of the farmed animals in the region where feeding is carried out as referred to in Sections 2, 3 and 4 of Chapter II of Annex IV of this Administrative Instruction and shall carry out appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

2. Those samples shall include samples taken from suspected animals and from older breeding animals.

Section 7

Official controls regarding the application of certain organic fertilisers and soil improvers

1. The competent authority shall carry out controls along the entire chain of production and use of organic fertilisers and soil improvers subject to the restrictions referred to in paragraph 2 and 3 of Article 6 of this Administrative Instruction.

2. Controls from paragraph 1 of this Section shall include checks on the mixing with a component referred to in paragraph 2 of Section 1 of Chapter II of Annex IX of this Administrative Instruction, and checks on the stocks of such products kept on farm and the records kept in accordance with Administrative Instruction (MAFRD) - No. 05/2022.

Section 8
Official controls regarding approved photographic factories

The competent authority shall carry out documentary checks in approved photographic factories referred to in Table 3 of paragraph 1 of Section 11 of Chapter II of Annex XII on the channelling chain from the border inspection posts of entry to the approved photographic factories for the purpose of reconciliation of the quantities of products imported, used and disposed.

Section 9
Official controls regarding certain imported rendered fats

The competent authority shall carry out documentary checks in registered establishments or plants receiving rendered fats which have been imported in accordance with Section 9 of Chapter II of Annex XII of this Administrative Instruction on the channelling chain from the border inspection posts of entry to the registered establishment or plant for the purpose of reconciliation of the quantities of products imported, used and disposed of.

Section 10
Official controls regarding plants approved for the combustion of animal by-products

The competent authority shall carry out documentary checks in accordance with the procedures referred to in Article 6, paragraph 7 and 8 in approved plants referred to in Chapter V of Annex I of this Administrative Instruction.