

ANNEX VI

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:
 - (a) the description of the material and the animal species of origin;
 - (b) the category of the material;
 - (c) the quantity of the material;
 - (d) the place of origin and the place of dispatch of the material;
 - (e) the name and the address of the consignor;
 - (f) 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 point 38 of Annex I 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:
 - (a) as waste by incineration or co-incineration;
 - (b) in case of the animal by-products or derived products referred to in Article 8 (a)(iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No 1069/2009 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⁽¹⁾ and subsequent disposal as waste or wastewater in accordance with relevant Union legislation;
 - (c) by pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
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 point 1 and the date and method of disposal of the samples and of any derived products.

6. By way of derogation from points 1, 4 and 5, 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 points 1 to 4 and 6 of Section 1.
2. Unless trade samples are kept for reference purposes, they shall be, after the particular studies or analyses have been concluded:
 - (a) redispached to the Member State of origin;
 - (b) dispatched to another Member State or third country, if such dispatch has been authorised by the competent authority of the Member State or third country of destination in advance; or
 - (c) disposed of or used in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
3. After the exhibition or after the artistic activity has been concluded, display items shall be redispached to the Member State of origin, dispatched or disposed of, in accordance with point 2.

CHAPTER II

SPECIAL FEEDING RULES

Section 1

General requirements

Category 2 and 3 materials as referred to in Article 18(1) of Regulation (EC) No 1069/2009 may be fed to the animals referred to in paragraph (1)(a), (d), (f), (g) and (h) 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(1) of that Regulation:

1. 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 VIII.
2. Collection centres shall be registered by the competent authority, provided that:
 - (a) they comply with the requirements for plants carrying out the intermediate operations set out in Chapter II of Annex IX; and
 - (b) 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 Regulation.

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3. Member States may authorise the use of a processing plant for Category 2 material as a collection centre.
4. 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:
 - (a) 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;
 - (b) sterilisation by boiling or steaming under pressure until every piece of material is cooked throughout; or
 - (c) 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(2)(b) of Regulation (EC) No 1069/2009 for the feeding of the following endangered and protected species in feeding stations under the following conditions:
 - (a) The material must be fed to:
 - (i) one of the following species of necrophagous birds in the following Member States:

Member State	Animal species
Bulgaria	bearded vulture (<i>Gypaetus barbatus</i>) black vulture (<i>Aegypius monachus</i>) Egyptian vulture (<i>Neophron percnopterus</i>) griffon vulture (<i>Gyps fulvus</i>) golden eagle (<i>Aquila chrysaetos</i>) imperial eagle (<i>Aquila heliaca</i>) white-tailed eagle (<i>Haliaeetus albicilla</i>) black kite (<i>Milvus migrans</i>) red kite (<i>Milvus milvus</i>)
Greece	bearded vulture (<i>Gypaetus barbatus</i>) black vulture (<i>Aegypius monachus</i>) Egyptian vulture (<i>Neophron percnopterus</i>) griffon vulture (<i>Gyps fulvus</i>) golden eagle (<i>Aquila chrysaetos</i>)

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	imperial eagle (<i>Aquila heliaca</i>) white-tailed eagle (<i>Haliaeetus albicilla</i>) black kite (<i>Milvus migrans</i>)
Spain	bearded vulture (<i>Gypaetus barbatus</i>) black vulture (<i>Aegypius monachus</i>) Egyptian vulture (<i>Neophron percnopterus</i>) griffon vulture (<i>Gyps fulvus</i>) golden eagle (<i>Aquila chrysaetos</i>) Spanish imperial eagle (<i>Aquila adalberti</i>) black kite (<i>Milvus migrans</i>) red kite (<i>Milvus milvus</i>)
France	bearded vulture (<i>Gypaetus barbatus</i>) black vulture (<i>Aegypius monachus</i>) Egyptian vulture (<i>Neophron percnopterus</i>) griffon vulture (<i>Gyps fulvus</i>) golden eagle (<i>Aquila chrysaetos</i>) white-tailed eagle (<i>Haliaeetus albicilla</i>) black kite (<i>Milvus migrans</i>) red kite (<i>Milvus milvus</i>)
Italy	bearded vulture (<i>Gypaetus barbatus</i>) black vulture (<i>Aegypius monachus</i>) Egyptian vulture (<i>Neophron percnopterus</i>) griffon vulture (<i>Gyps fulvus</i>) golden eagle (<i>Aquila chrysaetos</i>) black kite (<i>Milvus migrans</i>) red kite (<i>Milvus milvus</i>)
Cyprus	black vulture (<i>Aegypius monachus</i>) griffon vulture (<i>Gyps fulvus</i>)
Portugal	black vulture (<i>Aegypius monachus</i>) Egyptian vulture (<i>Neophron percnopterus</i>) griffon vulture (<i>Gyps fulvus</i>) golden eagle (<i>Aquila chrysaetos</i>)
Slovakia	golden eagle (<i>Aquila chrysaetos</i>) imperial eagle (<i>Aquila heliaca</i>) white-tailed eagle (<i>Haliaeetus albicilla</i>) black kite (<i>Milvus migrans</i>) red kite (<i>Milvus milvus</i>)

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- (ii) one of the species of the order Carnivora which are listed in Annex II to Directive 92/43/EEC, in special areas of conservation which have been set up under that Directive; or
 - (iii) one of the species of the orders Falconiformes or Strigiformes, which are listed in Annex I to Directive 2009/147/EC, in special protection areas which have been set up under that Directive;
- (b) The competent authority has granted an authorisation to the operator responsible for the feeding station.

The competent authority shall grant such authorisations provided that:

 - (i) 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;
 - (ii) an appropriate surveillance system for TSEs as laid down in Regulation (EC) No 999/2001 is in place involving regular laboratory testing of samples for TSE;
- (c) The competent authority must ensure coordination with any other competent authorities responsible for the supervision of the requirements laid down in the authorisation;
- (d) 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;
- (e) The authorisation granted by the competent authority must:
 - (i) refer to and name the species actually concerned;
 - (ii) describe in detail the location of the feeding station in the geographical area where feeding shall take place; and
 - (iii) be immediately suspended in the case of:
 - a suspected or confirmed link to the spread of TSE until the risk can be excluded, or
 - non-compliance with any of the rules provided for in this Regulation.
- (f) The operator responsible for the feeding shall:
 - (i) 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;
 - (ii) 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 Annex III to Regulation (EC) No 999/2001 and, if applicable, in accordance with a Decision adopted in accordance with the second subparagraph of Article 6(1b) of that Regulation; and

- (iii) 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.
2. When a Member State applies to the Commission to be included into the list set out under point 1(a), it shall submit:
- (a) a detailed justification for the extension of the list to include certain species of necrophagous birds in that Member State, including an explanation of the reasons why it is necessary to feed such birds with Category 1 material instead of with Category 2 or Category 3 material;
 - (b) an explanation of the measures which will be taken in order to ensure compliance with point 1.

Section 3

Feeding of wild animals outside feeding stations

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 point 1(a) of Section 2 under the following conditions:

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;
2. The competent authority must identify in the authorisation, holdings or herds within a geographically defined feeding zone under the following conditions:
 - (a) The feeding zone must not extend to areas where intensive farming of animals takes place;
 - (b) 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;
 - (c) Feeding must be immediately suspended in the case of:
 - (i) a suspected or confirmed link to the spread of TSE in a holding or herd, until the risk can be excluded;
 - (ii) 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
 - (iii) non-compliance with any of the rules provided for in this Regulation;
 - (d) The competent authority must specify in the authorisation:
 - (i) 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

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- 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;
- (ii) 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 point (i);
 - (iii) the conditions for the imposition of penalties as referred to in Article 53 of Regulation (EC) No 1069/2009 which are applicable to infringements of measures referred to under point (i) by the persons or entities referred to under point (ii) of this point (d);
- (e) 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

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:

- (a) The competent authority must have granted an authorisation to the operator responsible for the feeding. The competent authority shall grant such authorisations provided that:
 - (i) 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;
 - (ii) 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 in Regulation (EC) No 999/2001 is in place involving regular laboratory testing of samples for TSEs;
- (b) The authorisation granted by the competent authority must be immediately suspended in the case of:
 - (i) a suspected or confirmed link to the spread of TSEs until the risk can be excluded; or
 - (ii) non-compliance with any of the rules provided for in this Regulation;
- (c) The operator responsible for the feeding shall:
 - (i) 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;

- (ii) ensure that ruminant animals intended to be used for feeding are included in the TSE monitoring programme carried out in accordance with Annex III to Regulation (EC) No 999/2001 and, if applicable, in accordance with a Decision adopted in accordance with the second subparagraph of Article 6(1b) of that Regulation;
- (iii) 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(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009, such disposal may take place:
 - (a) by burning or burial on the premises on which the animal by-products originate;
 - (b) in an authorised landfill; or
 - (c) 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(1)(b), (c) and (e) of Regulation (EC) No 1069/2009 must be carried out in such a way to ensure that they are burnt:
 - (a) on a properly constructed pyre and the animal by-products reduced to ash;
 - (b) without endangering human health;
 - (c) 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;
 - (d) 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(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009 must be carried out to ensure that they are buried:
 - (a) in such a way that carnivorous or omnivorous animals cannot gain access to them;

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- (b) 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(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009, 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:
- (a) the animal by-products are transported in secure, leak-proof containers or vehicles;
 - (b) the loading and unloading of the animal by-products is supervised by the competent authority, if appropriate;
 - (c) the vehicle wheels are disinfected upon leaving the site of origin;
 - (d) containers and vehicles used for transporting animal by-products are thoroughly cleansed and disinfected after unloading of the animal by-products; and
 - (e) 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

The maximum percentage as referred to in Article 19(2) of Regulation (EC) No 1069/2009 shall not exceed the following:

- (a) 10 % of the bovine population of the Member State concerned;
- (b) 25 % of the ovine and caprine population of the Member State concerned;
- (c) 10 % of the porcine population of the Member State concerned; and
- (d) 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(1)(f) of Regulation (EC) No 1069/2009, 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

By way of derogation from Article 14 of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of the Category 3 materials referred to in Article 10(f) of that Regulation by means other than burning or burial on site provided that:

- (a) 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;
- (b) the materials are collected, transported and disposed of by means which prevent the transmission of unacceptable risks to public and animal health;
- (c) 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 Section.

Member States may decide to increase the volume referred to in point (a) to a maximum of 50 kg per week, provided that they present a detailed justification to the Commission and to the other Member States in the framework of the Standing Committee on the Food Chain and Animal Health referred to in Article 52(1) of Regulation (EC) No 1069/2009, which specifies the nature of the activities for which the volume is to be increased, the species of origin of the animal by-products concerned, and an explanation of the reasons why it is necessary to increase the volume, in view of the adequate system for the handling and disposal of animal by-products and derived products on their territory, as referred to in Article 4(4) of that Regulation.

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- (1) CEN TC/102 – Sterilisers for medical purposes – EN 285:2006 + A2:2009 – Sterilization - Steam Sterilisers - Large Sterilisers, reference published in [OJ C 293, 2.12.2009, p. 39](#).