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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Delegations will find attached document C(2021) 199 final ANNEX.

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Brussels, 12.4.2021
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ANNEX

ANNEX

to the

Commission Delegated Regulation

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin

ANNEX

Annex III to Regulation (EC) No 853/2004 is amended as follows:

(1) Section I is amended as follows:

(a) Chapter IV is amended as follows:

(i) point 2(b)(ii) is replaced by the following:

‘(ii) animals slaughtered at the holding of provenance in accordance with Chapter VIa of this Section or in accordance with point 3 of Section III;’

(ii) point 18 is replaced by the following:

‘18. Unless intended for use as animal by-product in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council*:

(a) stomachs must be scalded or cleaned; however, when intended for rennet production, the stomachs:

(i) are only required to be emptied in the case of young bovine animals

(ii) are not required to be emptied, scalded or cleaned in the case of young ovine and caprine animals;

(b) intestines must be emptied and cleaned;

(c) heads and feet must be skinned or scalded and depilated; however, when authorised by the competent authority, visibly clean heads, not containing specified risk materials in accordance with Article 8 of Regulation (EC) No 999/2001 of the European Parliament and of the Council**, and visibly clean feet, intended for processing into food, may be transported to and skinned or scalded and depilated in an approved establishment.

* Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

(OJ L 300, 14.11.2009, p. 1).

** Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).’

(b) Chapter VI is amended as follows:

(i) points 2 and 3 are replaced by the following:

‘2. The official veterinarian must carry out an ante-mortem inspection of the animal.

3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the

official veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.’

(ii) point 6 is replaced by the following:

‘The official certificate set out in Chapter 5 of Annex IV to Commission Implementing Regulation (EU) 2020/2235* shall accompany the slaughtered animal to the slaughterhouse or be sent in advance in any format.

* Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020 p. 1).’

(c) The following Chapter VIa is inserted after Chapter VI:

‘CHAPTER VIa: SLAUGHTER AT THE HOLDING OF PROVENANCE OF DOMESTIC BOVINE, OTHERS THAN BISONS, AND PORCINE ANIMALS AND DOMESTIC SOLIPEDS OTHER THAN EMERGENCY SLAUGHTER

Up to three domestic bovine, others than bisons, or up to six domestic porcine animals or up to three domestic solipeds may be slaughtered at the same occasion at the holding of provenance, when authorised by the competent authority in accordance with the following requirements:

- (a) the animals cannot be transported to the slaughterhouse, to avoid any risk for the handler and to prevent any injuries to the animals during transport;
- (b) there is an agreement between the slaughterhouse and the owner of the animal intended for slaughter; the owner must inform the competent authority in writing of such an agreement;
- (c) the slaughterhouse or the owner of the animals intended for slaughter must inform the official veterinarian at least three days in advance of the date and time of intended slaughter of the animals;
- (d) the official veterinarian who carries out the ante-mortem inspection of the animal intended for slaughter must be present at the time of slaughter;
- (e) the mobile unit to be used for the bleeding and transport of the slaughtered animals to the slaughterhouse must allow their hygienic handling and bleeding, and the proper disposal of their blood and must be part of a slaughterhouse approved by the competent authority in accordance with Article 4(2); however the competent authority may allow bleeding outside the mobile unit if the blood is not intended for human consumption and the slaughter does not take place in restricted zones as defined in Article 4(41) of Regulation (EU) 2016/429 or establishments in which animal health restrictions are applied in accordance with Regulation (EU) 2016/429 and any acts adopted on its basis;

- (f) the slaughtered and bled animals must be transported directly to the slaughterhouse hygienically and without undue delay; removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian; any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to each individual animal;
 - (g) if more than two hours elapse between the time of slaughter of the first animal and the time of arrival at the slaughterhouse of the slaughtered animals, the slaughtered animals must be refrigerated; where climatic conditions so permit, active chilling is not necessary;
 - (h) the owner of the animal must inform the slaughterhouse in advance of the intended time of arrival of the slaughtered animals, which must be handled without undue delay after arrival at the slaughterhouse;
 - (i) in addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animals to the slaughterhouse or be sent in advance in any format.'
- (d) In Chapter VII, point 4 is replaced by the following:

‘4 Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:

- (i) in the case of meat for which a ‘use by’ date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council*, before the expiry of that date;
- (ii) without undue delay to a temperature of -18°C or lower;
- (iii) ensuring that the date of freezing is documented and provided either on the label or by other means;
- (iv) excluding meat that has been frozen before (defrosted meat); and,
- (v) in accordance with any condition laid down by the competent authorities for freezing and further use as food.

* Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).'

(2) Section II is amended as follows:

(a) In Chapter V, point 5 is replaced by the following:

‘5 Meat intended for freezing must be frozen without undue delay.

However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:

- (i) in the case of meat for which a ‘use by’ date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011, before the expiry of that date;
 - (ii) without undue delay to a temperature of -18°C or lower;
 - (iii) ensuring that the date of freezing is documented and provided either on the label or by other means;
 - (iv) excluding meat that has been frozen before (defrosted meat); and,
 - (v) in accordance with any condition laid down by the competent authorities for freezing and further use as food.’
- (b) Chapter VI is amended as follows:
- (i) point 6 is deleted;
 - (ii) point 7 is replaced by the following:
‘7 In addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animal to the slaughterhouse or cutting plant, or be sent in advance in any format.’
- (3) Section III is amended as follows:
- (a) point 1 is replaced by the following:
‘1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals, unless the competent authority considers them inappropriate.’
 - (b) point 3(j) is replaced by the following:
‘(j) the official certificate set out in Chapter 3 of Annex IV to Commission Implementing Regulation (EU) 2020/2235, issued and signed by the official veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animal to the slaughterhouse or was sent in advance in any format.’
- (4) Section IV is amended as follows:
- (a) the following introductory sentence is added:
‘For the purpose of this Section, ‘collection centre’ means an establishment used to store the bodies and viscera of wild game before their transport to a game handling establishment.’
 - (b) Chapter II is amended as follows:
 - (i) point 4(c) is replaced by the following:
‘(c) If no trained person is available to carry out the examination referred to in point 2 in a particular case, the head, except for tusks, antlers and horns, and all the viscera, except for the stomach and the intestines, must

accompany the body which must be transported to a game handling-establishment as soon as possible after killing.’

- (ii) in point 8(b), the first subparagraph is replaced by the following:

‘(b) may be sent to a game handling establishment in another Member State only if, during transport to that game-handling establishment, it is accompanied by an official certificate set out in Chapter 2 of Annex II to Implementing Regulation (EU) 2020/2235 issued and signed by an official veterinarian, attesting that the requirements set out in point 4 of this Chapter as regards the availability of a declaration, when relevant, and the accompaniment of relevant parts of the body, have been complied with.’

- (iii) the following point 10 is added:

‘10. The bodies and viscera of large wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:

- (a) the collection centre is either:

- (1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or
- (2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;

- (b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;

- (c) killed animals are transported to the collection centre hygienically and without delay;

- (d) the temperature conditions laid down in point 5 are complied with;

- (e) storage time is kept to the minimum possible;

- (f) no other handling takes place on the bodies and viscera of the large wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 2, 3 and 4.’

- (c) Chapter III is amended as follows:

- (i) point 3 is replaced by the following:

‘3 Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1 or, if no trained person is available to carry out that examination in a particular case, as soon as possible after killing’.

- (ii) the following point 8 is added:

‘8. The bodies, including viscera, of small wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:

- (a) the collection centre is either:
 - (1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or
 - (2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;
- (b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;
- (c) killed animals are transported to the collection centre hygienically and without delay;
- (d) the temperature conditions laid down in point 4 are complied with;
- (e) storage time is kept to the minimum possible;
- (f) no other handling takes place on the bodies, including viscera, of the small wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 1 and 2.’

(5) Section VII is amended as follows:

(a) In the introductory part, the following point 1a is inserted:

‘1a. For the purpose of this Section, ‘intermediary operator’ means a food business operator, including traders, other than the first supplier, with or without premises, who carries out its activities between production areas, relaying areas or any establishments.’

(b) Chapter I is amended as follows:

(i) point 3 is replaced by the following:

‘3. Whenever a food business operator moves a batch of live bivalve molluscs between production areas, relaying areas or any establishments, a registration document must accompany the batch.’

(ii) in point 4, the following point (d) is added:

‘(d) Where a batch of live bivalve molluscs is sent by an intermediary operator, a new registration document, filled-in by the intermediary operator, must accompany the batch. The registration document must contain at least the information referred to in points (a), (b) and (c) and the following information:

- (i) the name and address of the intermediary operator;
- (ii) in the case of conditioning or in the case of re-immersion for storing purpose, the date of starting, the date of end and the place of the conditioning or the re-immersion;

- (iii) if a conditioning in a natural site was carried out, the intermediary operator must confirm that the natural site where the conditioning took place was classified at the time of conditioning as an class A production area open for harvest;
 - (iv) if a re-immersion in natural site was carried out, the intermediary operator must confirm that the natural site where the re-immersion took place was classified at the time of re-immersion with the same classification of the production area where the live bivalve molluscs were harvested.
 - (v) if a re-immersion was carried out in an establishment, the intermediary operator must confirm that the establishment was approved at the time of the re-immersion. The re-immersion shall not cause additional contamination to the live bivalve molluscs.
 - (vi) in the case of grouping, the species, the date when the grouping started, the date of the end of the grouping, the status of the area where the live bivalve molluscs were harvested, and the batch of the grouping, that always consists of the same species, captured on the same date, and in the same production area.’
- (iii) the following points 8 and 9 are added:
- ‘8. Intermediary operators must be:
- (a) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) if they do not have premises or if they have premises where they only handle, wash and store at ambient temperature live bivalve molluscs, without grouping nor conditioning, or
 - (b) approved by the competent authority as a food business operator in accordance with Article 4(2) if, in addition to carrying out the activities referred to in point (a), they have a cold store or they group or split batches of live bivalve molluscs or they carry out conditioning or re-immersion.
9. Intermediary operators may receive live bivalve molluscs from production areas classified as A, B or C, from relaying areas or from other intermediary operators. Intermediary operators can send live bivalve molluscs:
- (a) from class A production areas to dispatch centres or another intermediary operator;
 - (b) from class B production areas only to purification centres, processing establishments or to another intermediary operator;
 - (c) from class C production areas to processing establishments or to another intermediary operator with premises.’
- (c) In Chapter IV point 1 of Part A is replaced by the following:
- ‘1. Before purification commences, live bivalve molluscs must be free of mud and accumulated debris and washed if necessary, using clean water.’
- (d) In Chapter V, point 2:

a) point (a) is replaced by: ‘(a) for paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalents diHCl per kilogram;’

(b) point (c) is replaced by: ‘(c) for okadaic acid and dinophysistoxins together 160 micrograms of okadaic acid equivalents per kilogram;’

(e) Chapter IX is replaced by the following:

‘CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE, MARINE GASTROPODS AND HOLOTHUROIDEA WHICH ARE NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae, marine gastropods and holothuroidea which are not filter feeders, outside classified production areas or handling such pectinidae, and/or such marine gastropods and/or holothuroidea must comply with the following requirements:

1. Pectinidae, marine gastropods and holothuroidea which are not filter feeders, must not be placed on the market unless they are harvested and handled in accordance with Part B of Chapter II and meet the standards laid down in Chapter V, as demonstrated by a system of own-checks by the food business operators operating a fish auction, a dispatch centre or a processing establishment;

2. In addition to point 1, where data from official monitoring programmes enable the competent authority to classify fishing grounds — where appropriate, in cooperation with food business operators — the provisions of Part A of Chapter II apply by analogy to pectinidae;

3. Pectinidae, marine gastropods and holothuroidea which are not filter feeders, must not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae and/or such marine gastropods, and/or holothuroidea food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV;

4. Food business operators handling pectinidae, marine gastropods and holothuroidea which are not filter feeders, must comply with the following requirements:

(a) with the documentary requirements of points 3 to 7 of Chapter I, where applicable. In this case, the registration document must clearly indicate the location of the area, indicating the system used to describe the coordinates, where the live pectinidae and/or live marine gastropods and/or live holothuroidea were harvested; or

(b) with the requirements of point 2 of Chapter VI concerning the closing of all packages of live pectinidae, live marine gastropods and live holothuroidea dispatched for retail sale and Chapter VII concerning identification marking and labelling.’

(f) The following Chapter X is added:

‘CHAPTER X

Explanatory notes

Box	Description
Part I – Supplier	
This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs.	
I.1	<p>IMSOC reference number</p> <p>This is the unique alpha-numeric code assigned by the IMSOC</p>
I.2	<p>Internal reference number</p> <p>This box may be used by the dispatching food business operator to indicate an internal reference number.</p>
I.3	<p>Supplier</p> <p>Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In the case of production areas, please indicate the area as authorised by the competent authorities (CAs). In the case of live pectinidae, marine gastropods or holothuroidea, indicate the location of the harvesting area.</p> <p>Where applicable, indicate the registration or approval number of the establishment. Indicate the activity (gatherer, purification centre, dispatch centre, auction hall or intermediary activities).</p> <p>Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and Holothuroidea which are not filter feeders harvested outside classified production areas, from a fish auction, indicate the approval number and the address of the purification centre /dispatch centre or fish auction.</p>
I.4	<p>Receiving food business operator</p> <p>Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. In the case of production or relaying areas please indicate the area as authorised by the CAs.</p> <p>Where applicable, indicate the registration or approval number of the establishment. Indicate the activity (gatherer, purification centre, dispatch centre, processing establishment or intermediary activities).</p>
I.5	<p>Description of goods</p> <p>Indicate as required, the Combined Nomenclature code or FAO 3-Alpha code, species, quantity, type of packaging (bags, bulk, etc), batch, date of harvesting, date of starting and end of conditioning (when applicable), place of conditioning (indicate the classification of the production area and its location or the approval number of the establishment, when applicable), date of starting and end of re-immersion (when applicable), place of re-immersion (indicate the classification of the production area and its location or the approval number of the establishment when applicable), date of starting and end of grouping (when applicable), production area and its health status (classification of the production area when applicable). When LBMs have been harvested in accordance with Article 62 (2) of the Implementing Regulation 2019/627 then this should be explicitly stated.</p> <p>When grouping of live bivalve molluscs is performed, the batch must refer to bivalves of</p>

	<p>the same species, harvested on the same day and coming from the same production area.</p> <p>Delete as appropriate</p>
I.6	<p>From relaying area</p> <p>Where the batch of live bivalve molluscs is sent from a relaying area, indicate the relaying area, as authorised by the CAs, and the duration of the relaying (date of starting and end).</p>
I.7	<p>From purification centre/dispatch centre or fish auction</p> <p>Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and holothuroidea which are not filter feeders harvested outside classified production areas, from an auction hall, indicate the approval number and the address of the purification centre /dispatch centre or auction hall.</p> <p>If sent from a purification centre the duration of the purification and the dates on which the batch entered and left the purification centre. Delete as appropriate</p>
I.8	<p>From intermediary operator</p> <p>Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the intermediary operator.</p> <p>Where applicable, indicate the registration or approval number and the activity.</p>
1.9	<p>Declaration of the supplier</p> <p>Include the date, name of the signatory and the signature.</p>
<p>Part II – Receiving food business operator</p> <p>This part of the document shall be filled by the food business operator receiving a batch of live bivalve molluscs.</p>	
II.1	<p>Internal reference number (receiving)</p> <p>This box may be used by the food business operator receiving the batch to indicate an internal reference number.</p>
II.2	<p>Declaration of the receiving food business operator</p> <p>Indicate the date of arrival of the batch of live bivalve molluscs at the premises of the receiving food business operator. In the case of an intermediary operator without premises indicate the date of purchase of the batch.</p> <p>Include the name of the signatory and the signature.</p>

- (6) Section VIII is amended as follows:
- (a) Chapter I is amended as follows:
- (i) Point 1 is replaced by the following:

‘1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, and reefer vessels comply with the structural and equipment requirements laid down in Part I; and’

(ii) In Part I.A, the following point 5 is added:

‘5. Vessels must be designed and constructed so as not to cause contamination of the fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Holds, tanks, or containers used for storing, cooling or freezing unprotected fishery products including those destined for the production of feed, shall not be used for other purposes than the storing, cooling or freezing those products, as well as ice or brine used for such purposes. In the case of reefer vessels, the provisions applicable to unprotected fishery products apply to all the products transported.’

(iii) In Part I.C, points 1 and 2 are replaced by the following:

‘1. have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than -18 °C;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 °C. Storage holds must not be used for freezing unless they fulfil the conditions laid down in point 1, and must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;’

(iv) In Part I, the following point E is added:

‘E. Requirements for reefer vessels

Reefer vessels transporting and/or storing frozen fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in point 2 of part C concerning their capacity to maintain the temperature.’

(v) In Part II, point 6 is replaced by the following

‘6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the fishery products must be washed immediately. The viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from fishery products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or preserved under ice, at a temperature approaching that of melting ice; or be frozen.’

(vi) in Part II, point 7 is replaced by the following:

‘7. Where freezing in brine of the whole fish intended for canning is practiced, a temperature of not more than -9 °C must be achieved for the fishery product. Even if it is subsequently frozen at a temperature of -

18°C, the whole fish initially frozen in brine at a temperature of not more than -9 °C must be destined for canning. The brine must not be a source of contamination for the fish.'

(b) Chapter III is amended as follows:

(i) In Part A, point 4. is replaced by the following:

'4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water is drained away and does not remain in contact with any fishery products.'

(ii) Part B is replaced by the following:

'B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out, that satisfies the requirements for freezer vessels laid down in Section VIII, Chapter I part I.C, points 1 and 2 and.'

(7) In Section XI, the following points 7 and 8 are added:

'7. The requirements laid down in points 1, 3, 4 and 6, also apply to any other snails of the Family of *Helicidae*, *Hygromiidae* or *Sphincterochilidae*, when intended for human consumption.

8. The requirements laid down in points 1 to 5 also apply to frogs' legs of the genus *Pelophylax* from the Family of *Ranidae*, and the genus *Fejervarya*, *Limnonectes* and *Hoplobatrachus* from the Family of *Dicroglossidae*, when intended for human consumption.'

(8) In Section XII, in Chapter II, point 5 is deleted.