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[...](2020) **XXX** draft

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of **XXX****

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

(Text with EEA relevance)

**NON-PAPER of **March 2020****

**This draft has not been adopted or endorsed by the European Commission.  
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is addressed for discussions and may contain confidential and/or privileged material.**

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>1</sup> lays down specific hygiene rules for different food of animal origin. In order to maintain a high level of food safety to the consumers, these rules need to be kept up to date taking into account the experience gained from the implementation, technological developments and their practical consequences and changes in patterns of consumption.

The following amendments are therefore proposed by this Delegated Regulation:

- introduction of more flexibility for slaughter of bovine and equine animals at the holding of provenance for animal welfare reasons and to avoid risks for the handler (e.g. in case of free range animals), under strict conditions of hygiene and official controls. This action is part of Commissions Green Deal, since it contributes to animal welfare (avoiding transport of live difficult to handle animals) as part of the Farm to Fork strategy.
- sorting out practical difficulties/inconsistencies in the handling of stomachs for rennet production, the handling of heads and feet, including temperature conditions for storage.
- aligning the role of the official veterinarian in case of emergency slaughter with the new requirements in Delegated Regulation (EU) 2019/624.
- introduction of specific hygiene conditions in collection centres for wild game.
- extension of hygiene requirements for farmed game, snails and frogs' legs to new species/families placed on the market for human consumption (e.g. lama)
- adaptation of storage conditions for grease and animal fat to new technologies such as vacuum packaging
- deletion of pectenotoxins from the list of marine biotoxins to be analysed in live bivalve molluscs **as it interferes with the detection of other analogues.**
- establishing a specific model of the registration document that must accompany movements of live bivalve molluscs after harvesting and until their placing on the market
- aligning the rules for echinoderms fixed in ... to the limitations in derogation established by the Parliament and the Council in Regulation 2017/625
- fixing specific temperature requirements for fishery products handled on board of fishing vessels, specific hygiene requirements for reefer vessels as regards transport temperature and cold store maintenance, obligation on board vessels that containers used for fishery products are not used for other purposes.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

Several of the proposed amendments were requested by competent authorities of a Member State and certain private stakeholders' organisations. They have been discussed during several meetings of the relevant expert group, representing competent authorities of all Member States, and are largely supported by these experts.

<sup>1</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

In addition, private stakeholders' organisations were consulted within the framework of the Advisory Group on the Food Chain and Animal and Plant Health.

Before adopting this Delegated Regulation the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement on Better Law-Making.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

Amendments to the Annex III of Regulation (EC) No 853/2004 should be made by introducing a Delegated Regulation in accordance with Article 10.1 of Regulation (EC) No 853/2004.

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of XXX**

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation, (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>2</sup>, and in particular Article 10.1(b), (c) and (f) thereof,

Whereas:

- (1) Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council lays down specific hygiene rules for different food of animal origin. The Commission is allowed to amend these rules in Annex III by the adoption of a Delegated Regulation when it deemed necessary in order to maintain a high level of food safety to the consumers, taking into account the experience gained from the implementation, technological developments and their practical consequences and changes in patterns of consumption.
- (2) Rennet is a complex of enzymes used for the production of certain cheeses. Rennet is collected from the stomachs of young ruminants. In order to optimise the collection of rennet from young sheep and goats, it is appropriate to allow that such stomachs can leave the slaughterhouse without being emptied or cleaned.
- (3) There is an increased demand for heads and feet to be skinned or scalded and depilated outside the slaughterhouse in specialised approved establishments for further processed for food. Heads and feet should therefore be allowed for transport to these establishments under certain conditions that ensure that the safety of the food.
- (4) In accordance with Article 18(7)(c) of Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>3</sup> and Article 4 of Commission Delegated Regulation (EU) 2019/624<sup>4</sup>, ante-mortem inspection must be carried out by an official veterinarian in case of emergency slaughter. Requirements on emergency slaughter in Regulation (EC) No 853/2004 should be made consistent with the requirements in Regulation (EU) 2017/625.
- (5) Improving animal welfare is one of the actions proposed in the draft Farm to Fork Strategy on Sustainable Food System, being part of the Commissions' Green Deal. There is in particular an increasing demand of farmers and consumers to avoid possible animal

<sup>2</sup> OJ L 139, 30.4.2004, p. 55

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welfare constrains during catching and transport of large domesticated animals intended for slaughter.

- (6) Regulation (EC) 853/2004 already allows killing and slaughter on the farm of otherwise healthy animals such as by approved mobile slaughterhouses, slaughtering several animals at the same time. Additional possibilities should be introduced to allow killing and bleeding on the farm of an individual large domestic animal when live transport of such animal would create a risk for the handler or welfare of the animal. Such practice should be subject to strict conditions to maintain a high level of food safety of the meat derived from such animal.
- (7) Specific hygiene requirements for the production and placing on the market of meat from even-toed farmed game mammals are only laid down in Section III of Annex III to Regulation (EC) No 853/2004 when derived from Cervidae or Suidae. Similar requirements should also be applied to meat derived from other even-toed farmed game mammals such as lama's to avoid a possible food safety risk from the increasing consumption of such meat.
- (8) The bodies and viscera of hunted wild game might be brought together and stored in a collection centre before transport to a game-handling establishment. Specific hygiene rules on the handling and storage of these bodies and viscera in such collection centres to ensure the safety of their meat.
- (9) Live bivalve molluscs when moving from a production or relaying area or between establishments must be accompanied by a registration document. Batches of bivalve molluscs can be sent also to an intermediate operator. The registration document should also include this possibility. Moreover, in order to harmonise the information contained in the registration document, a common model should be established.
- (10) Bivalve molluscs placed on the market must not contain marine biotoxins. Pectenotoxins (PTX) in shellfish are always accompanied by toxins from the Okadaic acid (OA) group. EFSA in its opinion<sup>5</sup> concluded that because PTX-group toxins do not share the same mechanism of action as OA- group toxins they should not be included in the regulatory limit for OA-group toxins. EFSA moreover concluded that there are no reports on adverse effects in humans associated with PTX-group toxins. It is opportune to remove PTX from the list of marine biotoxins that should be tested in bivalve molluscs.
- (11) The presence of Norovirus in oysters represents, especially during the winter months, a serious risk for public health. In order to minimise the risk for the consumers related to the consumption of raw oysters, specific control measures, including microbiological criteria, should be established in raw oysters.
- (12) Article 11 of Commission Delegated Regulation 2019/624 establishes that the classification of production and relaying areas is not required in relation to the harvesting of Holothuroidea. Chapter IX of Section VII should be amended accordingly.
- (13) Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Also holds , tanks, or containers used for storing, cooling or freezing fishery products shall not be used for other purposes than the production and or storage of fishery products

<sup>5</sup> <https://doi.org/10.2903/j.efsa.2009.1109>

~~(8)~~(14) Freezer vessels and reefer vessels should be equipped with freezing equipment fit for the purpose and storage holds should not be used for freezing products if freezer equipment is not in compliance with those rules. The same requirements shall be applied to cold stores on land.

~~(9)~~(15) Specific hygiene rules in Section XI of Annex III to Regulation (EC) No 853/2004 are limited to frogs' legs of the species RNA (family Ranidae). Specific hygiene rules for snails in that Section are limited to terrestrial gastropods of the species *Helix pomatia* Linné, *Helix aspersa* Muller, *Helix lucorum* and species of the family Achatinidae. Due to changes eating habits, frogs' legs and snails of other species are also produced and placed on the market for human consumption. The specific hygiene rules should be extended to these species to ensure the safety of food derived from these species.

~~(10)~~(16) Specific temperature requirements for the storage of greaves intended for human consumption are laid down in Section XII of Annex III to Regulation (EC) No 853/2004. These requirements prevent innovation and are not relevant in case of certain packaging techniques e.g. vacuum-packaging. These temperature conditions should therefore be deleted while the food business operator must ensure the safety of food derived from the greaves by good hygiene practices and procedures based on the Hazard Analysis and Critical Control Point (HACCP) principles in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>6</sup>.

~~(11)~~(17) Since the requirements in Regulation (EC) No 853/2004 allowing the slaughter of bovine and equine animals on the holding of provenance will only apply from 21 April 2021 on, the amendment of the criteria and conditions for ante-mortem inspection on the holding of provenance should only apply from that date on.

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Annex III is amended as follows:

1) In Chapter IV of Section I, point 18 is replaced by the following:

“18. When destined for further handling:

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

- (i) only need to be emptied in case of young bovine animals
- (ii) do not need to undergo any handling in 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.

<sup>6</sup>

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\* 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)

2) In ~~Chapter VI~~ of Section I, Chapter VI is amended as follows:

(a) the word "veterinarian" is replaced by "official veterinarian" in points 2, ~~and~~ 3;

(b) ~~and 6, first quotation~~ point 6 is replaced by the following:

'The official certificate laid down in Annex V of Commission Regulation (EU) 2019/628\*\* shall accompany the slaughtered animal to the slaughterhouse.

\*\* Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

3) The following Chapter VIa is inserted after Chapter VI in Section I:

"CHAPTER VIa: SLAUGHTER ON THE FARM OTHER THAN EMERGENCY SLAUGHTER

Food business operators may slaughter one domestic bovine animals ~~(and or one~~ domestic solipeds~~?)~~ on the farm only with the authorisation of the competent authority for each individual animal and in compliance with the following requirements.

- a) ~~A single~~The animal ~~(or 2/few?)~~ cannot be transported, to avoid any risk for the handler or to protect the welfare of the animal.
- b) The farm shall undergo regularly veterinary inspection.
- c) The owner of the animal shall submit a request and inform the competent authority in advance of the date and time of slaughter if the animal.
- d) An official veterinarian carrying out an ante-mortem inspection of the animal intended for slaughter shall be present at the time of killing.
- e) The farm or vehicle for transport to the slaughterhouse has facilities suitable for the hygienic handle, slaughter, bleeding of the animal, and the proper disposal of blood.
- f) The slaughtered and bled animal shall 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 veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.
- g) If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal shall be refrigerated. Where climatic conditions so permit, active chilling is not necessary.
- h) The slaughterhouse shall be informed in advance on the arrival of the slaughtered animal and further handle it without undue delay after arrival.

- i) During the transport to the slaughterhouse, the certificate laid down in [Part III of Annex IV to Commission Implementing Regulation (EU) 2019/628]\* shall accompany the slaughtered animal.

\* .....

4) In Section III, point 1 is replaced by the following:

‘The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals (~~Cervidae and Suidae~~), unless the competent authority considers them inappropriate.’

45) The following point 9-10 is at the end of Chapter II to Section IV:

‘9-10. The bodies and viscera of large wild game may be transport and stored in a collection centre before transport to a game handling establishment if:

- (a) the collection centre is
  - (i) registered as an food business carrying out primary production when located in the area where the large wild game was hunted, or
  - (ii) approved as a food business operator when collecting bodies and viscera of large wild game from different hunting areas;
- (b) the temperature conditions in point 5 are complied with;
- (c) storage time is kept to the minimum possible;
- (d) no other handling takes place on the bodies and viscera of the large wild game; however the initial examination by a trained person and the removal of viscera may take place under the conditions laid down in points 2 to 4.’

56) The following point 8 is inserted at the end of Chapter III to Section IV:

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

- (a) the collection centre is:
  - (i) registered as a food business carrying out primary production when located in the area where the small wild game was hunted, or
  - (ii) approved as a food business operator when collecting bodies, including viscera of small wild game from different hunting areas;
- (b) the temperature conditions in point 5-4 are complied with;
- (c) storage time is kept to the minimum possible;
- (d) no other handling takes place on the bodies, including viscera, of the large wild game; however the initial examination by a trained person may take place.’

(4)

7) Section VII Chapter I is amended as follows:

#### CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

**Kommenterede [DSK(1):** R 2019/628 will be repealed by 21 April 2021, so this reference will be updated. Consequently the provision on slaughter at the farm can only be applied from then on.

**Kommenterede [DSK(2):** To include other species such as lama (see DE AOB of the 11/12 meeting)

**Kommenterede [DSK(3):** Several MS don't like approval here. However "registration" would contradict Article 4, only allowing derogation from approval in the cases referred to in Article 4.2.

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1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.

2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in points 3 to 7 have been complied with.

3. Whenever a food business operator moves a batch of live bivalve molluscs **from a production or relaying area** or between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.

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4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.

(a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:

(i) the gatherer's identity and address;

(ii) the date of harvesting;

(iii) the location of the production area described in as precise detail as is practicable or by a code number;

(iv) the health status of the production area;

(v) the shellfish species and quantity;

and

(vi) the destination of the batch.

(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:

(i) the location of the relaying area;

and

(ii) the duration of relaying.

(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:

(i) the address of the purification centre;

(ii) the duration of purification;

and

(iii) the dates on which the batch entered and left the purification centre.

(d) In the case of a batch is sent to an intermediate operator for splitting or for conditioning as defined in Annex I point 2.3 of this Regulation, a registration document must accompany the batch after splitting or conditioning. The registration document must contain at least the information referred to in (a) and the following information:

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(i) the intermediary identity and address

(ii) in case of conditioning the duration of conditioning, the status of the area where the conditioning took place, the date when the conditioning started and the date of the end of the conditioning

5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.

6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).

7. However, if:

(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs;

and

(b) a single competent authority supervises all the establishments concerned,

registration documents are not necessary if that competent authority so permits.

8) Section VII Chapter V is amended as follows:

#### CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 853/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.

2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

(a) for paralytic shellfish poison (PSP), 800 micrograms per kilogram;

(b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;

(c) for okadaic acid, and dinophysistoxins ~~pectenotoxins~~ together, 160 micrograms of okadaic acid equivalents per kilogram;

(d) for yessotoxins, 3,75 milligrams of yessotoxin equivalent per kilogram;

and

(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

**3. Food business operators operating in dispatch centres and in purification centres shall identify NoV as a hazard within the HACCP plan.**

**4. 10% of the batches of live bivalve molluscs destined to, or intended to be, eaten raw shall be tested, if placed on the market in the period from November to April, for the presence of enteric viruses as Norovirus, before leaving the dispatch centre [in production and relaying areas where live are cultivated];**

**those molluscs must not exceed the viral limit of 500 copies per gram (cpg) measured in the whole body.**

9) Section VII Chapter VII is amended as follows:

#### CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.

2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:

(a) the species of bivalve mollusc (common name and scientific name);

and

(b) the date of packaging, comprising at least the day and the month.

By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry 'these animals must be alive when sold'.

**(c) For bivalve molluscs not destined to or not intended to be eaten raw the sentence "to be cooked before consumption".**

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents

10) Section VII Chapter IX is amended as follows:

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

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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 Chapter II, Part B, and meet the standards laid down in Chapter V, as demonstrated by a system of own-checks;

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 Chapter II, Part A, 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, live marine gastropods and live **Holothuroidea** which are not filter feeders, must comply with the following requirements:

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

(b) with the requirements of Chapter VI, point 2 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.

## 11° CHAPTER X

### MODEL OF REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS			
Part I – Supplier	<b>I.1 IMSOC Reference number</b>		<b>I.2 Internal reference number (dispatching)</b>
	<b>I.3 Supplier</b>		<b>I.4 Receiving operator</b>
	Name Address Registration or Approval No Country ISO Country code		Name Address Registration or Approval No Country ISO Country code

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**I.5 Description of goods**

- CN code | species | quantity | package | date of harvesting | production area | health status
- CN code | species | quantity | package | date of harvesting | production area | health status
- CN code | species | quantity | package | date of harvesting | production area | health status

**I.6 From relaying area** Yes ☐No ☐Relaying areaDuration of relaying**I.7 From purification centre** Yes ☐No ☐Purification centreDate of entry Date of exitDuration of purification**I.8 Intermediary operator**NameAddressRegistration or Approval NoCountry ISO Country code**I.9 Receiving operator**NameAddressRegistration or Approval NoCountry ISO Country code**I.10 Origin of goods****Supplier**NameAddressRegistration or Approval NoCountry ISO Country code

- CN code | species | quantity | package | date of harvesting | production area | health status
- CN code | species | quantity | package | date of harvesting | production area | health status
- CN code | species | quantity | package | date of harvesting | production area | health status

**I.11 Description of goods**

- CN code | species | quantity | package | date of starting of conditioning | date of end of conditioning | production area | health status

**I.12 Declaration of the dispatching operator**

I, the undersigned operator responsible for dispatching the consignment declare that, to the best of my knowledge and belief, the information provided in Part I of this document is true and complete.

Date Name of signatory Signature

**II.1 Internal reference number (receiving)**

**II.2 Declaration of the receiving operator**

I, the undersigned operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises.

Name of signatory \_\_\_\_\_ Signature \_\_\_\_\_

### Explanatory notes

<b>Box</b>	<b>Description</b>
<b><u>Part I – Dispatching operator</u></b>  <u>This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs.</u>	
<b><u>I.1</u></b>	<b><u>IMSOC reference number</u></b>  <u>This is the unique alpha-numeric code assigned by the IMSOC</u>
<b><u>I.2</u></b>	<b><u>Local reference number (dispatching)</u></b>  <u>This box may be used by the dispatching operator to indicate an internal reference number.</u>
<b><u>I.3</u></b>	<b><u>Supplier</u></b>  <u>Indicate the name and address street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In case of production or relaying areas please indicate the area as authorised by the CAs.</u> <u>Where applicable, indicate the registration or approval number. Indicate the activity (gatherer, purification centre, dispatch centre or intermediary activities)</u>
<b><u>I.4</u></b>	<b><u>Receiving operator</u></b>  <u>Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. In case of production or relaying areas please indicate the area as authorised by the CAs.</u> <u>Where applicable, indicate the registration or approval number. Indicate the activity (gatherer, purification centre, dispatch centre or intermediary activities)</u>
<b><u>I.5</u></b>	<b><u>Description of goods</u></b>  <u>Indicate as required, the Common Nomenclature code, species, quantity, type of packaging( bags, bulk, etc)date of harvesting, production area and its health status (classification of the production area).</u>
<b><u>I.6</u></b>	<b><u>From relaying area</u></b>  <u>In case the batch of live bivalve molluscs is dispatched from a relaying area, indicate the location of the relaying area, , as authorised by the CAs, and the duration of the relaying.</u>
<b><u>I.7</u></b>	<b><u>From purification centre</u></b>  <u>In case the batch of live bivalve molluscs is dispatched from a purification centre, indicate the address of the purification centre, the duration of the purification and the dates on which the batch entered and left the purification centre.</u>
<b><u>I.8</u></b>	<b><u>Intermediary operator</u></b>  <u>Indicate the name and address street, city and region/province/state, as appropriate), country and ISO country code of the operator.</u> <u>Where applicable, indicate the registration or approval number.</u>

<b><u>1.9</u></b>	<b><u>Receiving operator</u></b>  Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. <u>Where applicable, indicate the registration or approval number. Indicate the activity (gatherer, purification centre, dispatch centre or intermediary activities). This Section must be filled in only in the case that the receiving operator receives the batch from an intermediary</u>
<b><u>1.10</u></b>	<b><u>Origin of goods</u></b>  Indicate the name and address street, city and region/province/state, as appropriate), country and ISO country code of the production area of origin. Please indicate the area as authorised by the CAs.
<b><u>1.11</u></b>	<b><u>Description of goods</u></b>  <b><u>In case of splitting indicate only CN code   species   quantity   package</u></b>
<b><u>1.12</u></b>	<b><u>Declaration of the dispatching operator</u></b>  Include the date, name of the signatory and the signature.
<b><u>Part II – Receiving operator</u></b>  This part of the document shall be filled by the food business operator receiving a batch of live bivalve molluscs.	
<b><u>II.1</u></b>	<b><u>Local reference number (receiving)</u></b>  This box may be used by the food business operator receiving the batch to indicate an internal reference number.
<b><u>II.2</u></b>	<b><u>Declaration of the receiving operator</u></b>  Indicate the date of arrival of the batch of live bivalve molluscs at the premises of the receiving operator.  Include the name of the signatory and the signature.



~~6127)~~ Section VIII, Chapter I is amended as follows:

**1. STRUCTURAL REQUIREMENTS**

**A. requirements for all vessels**

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. **Holds, tanks, or containers used for storing, cooling or freezing fishery products shall not be used for other purposes than the production and or storage of fishery products.**

**C. Requirements for freezer vessels**

Freezer vessels must:

1. have freezing equipment with sufficient capacity to **freeze quickly, 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 **shall not be used for freezing unless they respect the conditions of 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.

**E. Requirements for reefer vessels**

**Reefer vessels transporting and/or storing fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in part C, point 2.**

**II. HYGIENE REQUIREMENTS**

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 products must be washed immediately and thoroughly. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice as close as possible to 0°C, or be frozen.

13) Section VIII, Chapter III is amended as follows:

**A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS**

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

**B. REQUIREMENTS FOR FROZEN PRODUCTS**

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

~~148)~~ The following points 7 and 8 are inserted at the end of Section XI:

'7. The requirements 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.

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8. ~~The requirements in points 1 to 5 also apply to frogs' legs of any other species of the Family of Ranidae or Dicroglossidae, when intended for human consumption.'~~

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

~~7159~~) Point 5 in Chapter II to Section XII is deleted.

*Article [...]*

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply immediately, however Article 1(3) shall only apply from 21 April 2021 on.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission  
The President  
[...]*

**Kommenterede [DSK(4):** Based on FR proposal, expressing concerns on invasive exotic species when too broad.

