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ANNEX

ANNEXES

to the

Commission Delegated Regulation

amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for live bivalve molluscs

DISCLAIMER: *This document is a draft still at the consultation stage and therefore does not represent the Commission's position.*

ANNEX

Annexes II and III to Regulation (EC) No 853/2004 are amended as follows:

(1) in Annex II, Section I, point A.3 is replaced by the following:

‘3. An identification mark is not required:

- on packs of eggs when a packing centre code is applied in accordance with Part A of Annex XIV to Council Regulation (EC) No 1308/2013;
- in the case of live bivalve molluscs sent unpurified from an approved intermediary operator to another operator.’

(2) in Annex III, Section VII is amended as follows:

(a) A new point 1b is inserted after point 1a:

‘1b. For the purpose of this section, ‘re-immersion’ means the activity carried out by approved intermediary operators with facilities to store live bivalve molluscs in clean seawater in tanks, floats or natural sites after harvesting from the original production area to ensure the live bivalve molluscs are in a good state of vitality.’;

(b) Chapter I is replaced by the following:

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

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than through 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, including an intermediary operator, moves a batch of live bivalve molluscs from production areas, relaying areas, or from any establishments, before they are packaged and labelled for retail sale, the registration document laid down in Chapter X must accompany the consignment.
4. The registration document must be issued 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) classification of the production area;
 - (v) the bivalve molluscs 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 point (a) and the following information:

(i) the identification of the relaying area;

and

(ii) the date of starting and the date of ending 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 point (a) and the following information:

(i) the address and approval number of the purification centre;

(ii) the date and time of starting and ending of purification;

and

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

(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) or (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 a class A production area and was 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 at least 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 classification 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;

(vii) When a food business operator carries out the activity of a registered or approved intermediary operator with facilities, these must be separate from those used for other approved activities.

If the molluscs have not been purified, this must be specified in the registration document.

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.

7. However, where:

(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, a registration document is not necessary if that competent authority so permits.

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), point (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, splitting, conditioning, or re immersing; 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 or to a processing establishment;

(b)

from class B production areas only to purification centres, processing establishments or to another intermediary operator; the intermediary operator may send live bivalve

molluscs from a class B production area to a relaying area if the competent authority so authorises

(c)

from class C production areas to processing establishments or to an approved intermediary operator; the intermediary operator may send live bivalve molluscs from a C area to a relaying area if the competent authority so authorises.

10. Approved intermediary operators are not allowed to send live bivalve molluscs to registered intermediary operators.

11. From XX/XX/202X (*OP: please insert date=twenty-four months after entry into force of this regulation*), the following requirements relating to the use of the Trade Control and Expert System (TRACES) shall apply:

(a) food business operators shall issue in TRACES the registration document referred to in point 3 and laid down in Chapter X;

(b) food business operators at the place of destination responsible for receiving a consignment of live bivalve molluscs shall confirm the arrival of the consignment by completing in TRACES Part III of the registration document laid down in Chapter X;

(c) the competent authorities of each Member State shall list in TRACES the food business operators indicated in boxes I.5, I.6, I.7, I.9 and I.10 of Part I of the registration document laid down in Chapter X.

(c) Chapter X is replaced by the following:

‘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 – DESCRIPTION OF CONSIGNMENT		
QR CODE	I.1 IMSOC Reference	I.2 Local reference
I.3 Consignor		I.4 Consignee
Name		Name
Address		Address

Country	ISO Country code	Country	ISO Country code
I.5 Place of dispatch Name Registration/Approval No Address Activity Country ISO Country code		I.6 Place of destination Name Registration/Approval No Address Activity Country ISO Country code	
I.7 Production area			
Name Code of area Country ISO Country code		Classified production area <input type="checkbox"/> Yes <input type="checkbox"/> No Classification of production area <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
		Type of production <input type="checkbox"/> Aquaculture Registration No <input type="checkbox"/> Natural Banks	
		Harvest in accordance with Article 62(2) of Implementing Regulation (EU) No 2019/627 <input type="checkbox"/> Yes <input type="checkbox"/> No	
I.8 Date and time of departure			
I.9 History of the consignment			
Conditioning <input type="checkbox"/> Yes <input type="checkbox"/> No Establishment/Area: Classification of area: Start date End Date	Re-immersion <input type="checkbox"/> Yes <input type="checkbox"/> No Establishment/Area: Classification of area: Start date End Date	Relaying <input type="checkbox"/> Yes <input type="checkbox"/> No Establishment/Area: Classification of area: Start date End Date	

III.2 Declaration of consignee

I, the undersigned food business operator responsible for receiving the consignment declare that the consignment has arrived in my premises on (dd/mm/yyyy).

Name of signatory

Signature

Date

Explanatory notes

Part I – DESCRIPTION OF CONSINGMENT

This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs, live echinoderms, live tunicates or live marine gastropods

Box	Description
I.1	IMSOC reference number This is the unique alpha-numeric code assigned by the IMSOC
I.2	Local reference This box may be used by the dispatching food business operator to indicate an internal reference number.
I.3	Consignor Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the food business operator responsible for dispatching the consignment.
I.4	Consignee

	Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the food business operator receiving the consignment.
I.5	<p>Place of dispatch</p> <p>Indicate the registration or approval number of the establishment. Indicate the activity (production area, purification centre, dispatch centre, auction hall, place of relaying or intermediary operator).</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 echinoderms 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>
I.6	<p>Place of destination</p> <p>Indicate the registration or approval number of the establishment. Indicate the activity (production area, purification centre, dispatch centre, auction hall, place of relaying processing plant or intermediary operator).</p> <p>In the case of production or relaying areas please indicate the area as authorised by the competent authority.</p>
I.7	<p>Production area</p> <p>Indicate the area as authorised by the competent authorities. In the case of live pectinidae, marine gastropods or echinoderms, indicate the location of the production area.</p>
I.8	<p>Date and time of departure</p> <p>Indicate the date and the time, when the consignment is scheduled to leave the place of dispatch.</p>
I.9	History of the consignment

	<p>Indicate if the consignment was submitted to conditioning, re-immersion, relaying, purification or grouping.</p> <p>Indicate the period (start and end date, in case of purification centre, please indicate also the hour of starting and finish of the purification) and the place where conditioning, re-immersion, relaying, purification or grouping took place.</p> <p>In case of conditioning, re-immersion or relaying, indicate the classification of the area and its location or the approval number of the establishment.</p> <p>In the case of grouping, indicate also the health status of the production area from where the molluscs were harvested and the batch number of the grouping. The batch number must refer to bivalves of the same species, harvested on the same day and coming from the same production area.</p>
I.10	<p>Description of the consignment</p> <p>Indicate as required, the Combined Nomenclature code, species, quantity, type of packaging (bags, bulk, etc), number of packages, batch number, date of harvesting and name, address and registration number of the gatherer.</p>
Part II – DECLARATION	
Box	Description
II.1	<p>Declaration of the consignor</p> <p>Indicate the name of the signatory and the date of the signature.</p>
Part III – Follow-up	
<p>This part of the document shall be filled by the consignee receiving a batch of live bivalve molluscs, live echinoderms, live tunicates or live marine gastropods.</p>	
Box	Description
III.1	<p>Local reference</p> <p>This box may be used by the food business operator receiving the batch to indicate an internal reference number.</p>
II.2	Declaration of the consignee

	<p>Indicate the date of arrival of the batch of live bivalve molluscs, live echinoderms, live tunicates or live marine gastropods at the premises of the consignee. In the case of an intermediary operator without premises, indicate the date of purchase of the batch. Include the name of the signatory and date of signature.</p>
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