



Brussels, **XXX**  
SANTE/10106/2017 CIS  
(POOL/G4/2017/10106/10106-EN  
CIS.doc)  
[...](2017) **XXX** draft

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

**of **XXX****

**amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of  
the Council laying down specific hygiene rules for food of animal origin as regard  
echinoderms harvested outside classified production areas**

# COMMISSION REGULATION (EU) .../...

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**amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin as regard echinoderms harvested outside classified production areas**

(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>1</sup>, and in particular Article 10(1) thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific hygiene rules for food of animal origin for food business operators. It provides, inter alia, that food business operators may place products of animal origin on the market only if they have been prepared and handled exclusively in establishments that meet certain requirements, including the relevant requirements of Annex III thereto.
- (2) Section VII of Annex III to Regulation (EC) No 853/2004 specifies that that Section applies to live bivalve molluscs, and with the exception of the provisions on purification, it also applies to live echinoderms, live tunicates and live marine gastropods. It also specifies that specific requirements are applicable to pectinidae and marine gastropods which are not filter feeders harvested outside production areas.
- (3) Regulation (EC) No 854/2004 of the European Parliament and of the Council<sup>2</sup> lays down specific rules for the organisation of official controls on products of animal origin. It provides that the Member States are to ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as provided for in Annex II thereto. Chapter II of Annex II to Regulation (EC) No 854/2004 provides that production areas are to be classified according to the level of faecal contamination. Filter feeder animals, such as bivalve molluscs, can accumulate micro-organisms representing a risk for public health.
- (4) Echinoderms are generally not filter feeder animals. Consequently, the risk of such animals accumulating micro-organisms related to faecal contamination is remote. In addition, no epidemiological information has been reported to link the provisions for classification of production areas laid down in Annex II to Regulation (EC) No

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<sup>1</sup> OJ L 139, 30.4.2004, p. 55.

<sup>2</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

854/2004 with risks for public health associated with echinoderms which are not filter feeders. For this reason, such echinoderms should also be excluded from provisions on the classification of production areas as laid down in Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004.

- (5) In addition, Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 establishes specific requirements for pectinidae and live marine gastropods which are not filter feeders harvested outside classified production areas. Such requirements should also apply to echinoderms which are not filter feeder.
- (6) Section VII of Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Annex III to Regulation (EC) No 853/2004 is amended in accordance with the Annex to this Regulation.

#### *Article 2*

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

It shall apply from 1 January 2019.

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

Done at Brussels,

*For the Commission*  
*The President*

Jean-Claude JUNCKER

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**Annex**

Section VII of Annex III to Regulation (EC) 853/20004 is amended as follows:

- (1) In the introductory part , point 1 is replaced by the following:
  - ‘1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, live tunicates and live marine gastropods. The provisions on the classification of production areas set out in Chapter II, Part A, of that Section do not apply to marine gastropods and to echinoderms which are not filter feeders. ’
- (2) Chapter IX is replaced by the following:

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

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

1. Pectinidae, marine gastropods and echinoderms 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 echinoderms 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 echinoderms 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 echinoderms 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 echinoderms 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 echinoderms dispatched for retail sale and Chapter VII concerning identification marking and labelling.’