# ANNEX V

# RECOGNISED METHODS FOR THE DETECTION OF MARINE BIOTOXINS IN ACCORDANCE WITH ARTICLE 60

## CHAPTER I

## PARALYTIC SHELLFISH POISON DETECTION METHOD

A. The paralytic shellfish poisoning (PSP) toxins content of the whole body or any part edible separately of bivalve molluscs shall be determined using AOAC official method OMA 2005.06, as published in *AOAC International Journal* 88(6), 1714-1732 (Lawrence method), the mouse bioassay or any other internationally recognised validated method.

B. If the results are challenged, the reference method shall be AOAC official method OMA 2005.06 as referred in Part A.

## CHAPTER II

## AMNESIC SHELLFISH POISON DETECTION METHOD

A. The amnesic shellfish poisoning (ASP) toxins content of the entire body or any part edible separately of bivalve molluscs shall be determined using the high-performance liquid chromatography with ultraviolet detection (HPLC/UV) method or any other internationally recognised validated method.

B. However, for screening purposes, AOAC official method 2006.02, as published in *AOAC International Journal* 90, 1011-1027 (ASP enzyme-linked immunosorbent assay (ELISA) method), or any other internationally recognised validated method may also be used.

C. If the results are challenged, the reference method shall be the HPLC/UV method.

## CHAPTER III

## LIPOPHILIC TOXIN DETECTION METHODS

A. The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry/mass spectrometry (EURL LC-MS/MS) method. This method shall determine at least the following compounds:

(a) okadaic acid group toxins: OA, DTX1 and DTX2, including their esters (DTX3);

(b) pectenotoxins group toxins: PTX1 and PTX2;

(c) yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX;

(d) azaspiracids group toxins: AZA 1, AZA 2 and AZA 3.

If new analogues of the above toxins appear, for which a toxicity equivalent factor (TEF) has been established, they shall be included in the analysis.

Total toxicity equivalence shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2008) 589, 1-62 or any updated EFSA advice.

B. Methods other than those referred to in Part A, such as the LC-MS method, HPLC with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, may be used as alternatives to, or as well as, the EURL LC-MS/MS method, provided that:

(a) either alone or combined they can detect at least the analogues identified in Part A; more appropriate criteria shall be defined where necessary;

(b) they meet the method performance criteria stipulated by the EURL LC-MS/MS method. Such methods must be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The European Reference Laboratory for marine biotoxins shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation;

(c) their implementation provides an equivalent level of public health protection.

## CHAPTER IV

## DETECTION OF NEW OR EMERGING MARINE TOXINS

Chemical methods, alternative methods with appropriate detection, or the mouse bioassay can be used during the periodic monitoring of production areas and relaying areas for detecting new or emerging marine toxins on the basis of the national control programmes elaborated by the Member States.

**Status:**
Point in time view as at 31/12/2020.

**Changes to legislation:**
There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/627. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.