



Australian Government

Australian Quarantine and Inspection Service

MARKET ACCESS ADVICE No:11/03

Date of Issue: 3 February 2011
Date of Effect: IMMEDIATE

Country: EUROPEAN UNION

Change in testing methodology required for bivalve molluscs exported to the European Union

The European Commission (EC) has published Commission Regulation (EU) No 15/2011 which amends Regulation (EC) No 2074/2005, with regard to recognised testing methods for detecting marine biotoxins in bivalve molluscs.

Specifically, the EC has substituted the required biological testing method for lipophilic biotoxins (mouse bioassay and rat bioassay) with the alternative technique of liquid chromatography (LC) mass spectrometry (MS).

In line with Commission Regulation (EU) No 15/2011, all trading partners are required to adapt their testing methods to the chemical method (LCMS) testing **no later than 31 December 2014**. After this date, the EC will not accept results generated by the biological method.

Division V of the *Export Control (Fish and Fish Products) Orders 2005*, states:

‘If a statement as to a particular condition of fish and fish products is made on a government certificate, the analysis, inspection or examination required for the certificate must be carried out in a laboratory accredited by NATA or IANZ to perform the analysis, inspection or examination.’

In accordance with this requirement, AQIS encourages all Australian laboratories wishing to undertake LCMS testing for bivalves exported to the European Union to contact Slava Zeman on 02 6272 5027 or at Slava.Zeman@aqis.gov.au to discuss the development and correct application of validated testing methodology.

Alternatively, accredited laboratories in New Zealand which undertake LCMS techniques which have been appropriately validated through IANZ for the range of biotoxins of concern to the EU may be used for Australian testing purposes.

In accordance with Regulation (EC) No 853/2004, bivalve molluscs must not contain marine biotoxins in total quantities (measured in the whole body or any edible part separately) that exceed the following limits:

- a) paralytic shellfish poison (PSP), 800 micrograms per kilogram;
- b) amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;
- c) okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
- d) yessotoxins, 1 milligram of yessotoxin equivalent per kilogram; and
- e) azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

Important Note: biotoxin testing for bivalve molluscs being exported to the EU, with the exception of scallops harvested from the open ocean, is conducted under the Australian Shellfish Quality Assurance Program (ASQAP) as presence of biotoxins results from environmental contamination not from post-harvest handling. Scallops harvested from open oceans are not monitored under ASQAP and therefore export registered establishments are required to test product periodically to verify the source of the product as indicated in product standards at the following web address: <http://www.daff.gov.au/aqis/export/fish/guidelines>.

Relevant state or territory Shellfish Quality Assurance Program managers should ensure that samples are sent to laboratories which utilise testing methodology in compliance with the above requirements.

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