



Guidance Document

Release of Fish or Fish Product Detained or Recalled for Marine Biotoxin Reasons

20 December 2017

Title

Guidance Document: Release of Fish or Fish Product Detained or Recalled for Marine Biotoxin Reasons

About this document

This document provides guidance for the release, by an animal product officer, of fish product detained or recalled due to the potential presence of marine biotoxins.

Related Requirements

[Animal Products Act 1999](#)

[Animal Products Notice: Specifications for Products Intended for Human Consumption 2016](#)

[Animal Products \(Specifications for Bivalve Molluscan Shellfish\) Notice 2006](#)

Document history

| Version Date | Section Changed | Change(s) Description |
|--------------|-----------------|---|
| January 2012 | | |
| January 2018 | All | New format and branding. No content change. |

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1 Purpose

This document sets out the guidance conditions for the release, by an animal product officer, of fish product detained or recalled due to the potential presence of marine biotoxins.

2 Background

Since the 1993 marine biotoxin event, various fish products have been detained, recalled or had their movement restricted due to their potential to contain unacceptable levels of marine biotoxins.

Before release of detained fish product it must be demonstrated that sufficient random samples have been taken of the product to provide a reliable insight into whether the total consignment is in compliance with the standards. For marine biotoxin levels in shellfish, the standards are those prescribed in the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.

3 Definitions

MPI

Ministry for Primary Industries

RMP

Risk Management Programme

4 Legislation

- (1) Clause 14.15 (4) of the Animal Products Notice: Specifications for Products Intended for Human Consumption requires that:

“The operator must have a documented procedure in the risk management programme for sampling and testing bivalve molluscan shellfish product detained or recalled for marine biotoxin reasons”. This guide can be referenced by the operator in their RMP as a documented procedure.

- (2) Animal Products Act 1999 Section 90 Power to condemn and require disposal of animal products that are diseased, contaminated, etc.

“(1) An animal product officer may condemn, and require the owner or person in control to destroy, dispose of, or otherwise rectify,—

(c) any animal material or animal product which in the opinion of the officer, reasonably formed in the light of any relevant standards and specifications for the time being in force, is contaminated or diseased or otherwise not in compliance with this Act.”

- (3) Clause 45(1) of the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006 states:

“An animal product officer, in consultation with the shellfish industry, must develop and implement a marine biotoxin management plan for each growing area, in accordance with the requirements of this Notice.”

5 Sampling Procedure

- (1) Each sample of each lot must be analysed for the biotoxin(s) of concern as determined by the animal product officer.

- (2) The lot must be rejected if any sample exceeds the maximum level for any of the biotoxins prescribed in Table 6B of the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.

6 Sampling

6.1 Approvals

- (1) The sampling plan and sampling procedure (including the detailed description of the lot) must be approved in writing by an animal product officer prior to sampling commencing.

6.2 Sampling plan

- (1) All detained product for each toxin group of concern must be sampled using a two class attribute plan, $n = 60$, $c = 0$, for each lot for toxin group of concern. This will provide 95% confidence of detecting at least one case where the incidence level in the lot is 5%.

- a) "n" = the number of samples to be taken
"c" = the acceptable number of defective samples.

An example of a lot is described in Appendix I.

- (2) The operator may propose to the animal product officer what constitutes a "lot", but the operator needs to be aware that the animal product officer may not accept different species of shellfish/different regional growing areas within a "lot" and the animal product officer may limit the definition to that in Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.
- (3) A tiered sampling plan, as described below, may be used.

6.3 Sampling system

- (1) All samples must be selected using a random sampling system, e.g. the total number of cartons in the lot must be known prior to computing the sampling plan. It is important to identify cartons down to individual cartons within a large box. Each carton in the lot is then issued with a sequential number and the required numbered cartons selected using random number tables.
- (2) Any carton which fits the parameters of the lot but which was not included in the lot at the time of sampling must not, under any circumstances, be considered to be part of that lot (i.e. as a late entry) for the purposes of release.
- (3) No carton may be removed from the lot between the allocation of sequential numbers and the taking of samples. Cartons may only be removed after the samples have been taken from the lot and an animal product officer provides written agreement prior to the removal.

6.4 Tiered sampling

- (1) Tiered sampling may be used so that highly contaminated lots can be disposed of early in the sampling plan without incurring unnecessary expense. Where tiered sampling is used, all 60 samples are to be drawn from the lot before the first tier is analysed.
- (2) The tier option for the sampling plan should be discussed with the laboratory because lab resources may dictate sample sizes and timing of analysis. An example is:
 - a) first tier - 15 samples, then if all comply,
 - b) second tier - a further 15 samples, then if all comply,
 - c) third tier - a further 15 samples, then if all comply,

- d) fourth tier - a further 15 samples.
- (3) If any sample is contaminated with any of the biotoxins at or greater than the prescribed maximum permissible levels, at any tier, all cartons comprising the lot must be rejected.
- (4) Retesting of the lot is not permitted. Retesting of a part of the lot may be permitted providing it is in accordance with the full procedures described in this guide for a lot.

6.5 Supervision

- (1) Samples must be taken under the direct supervision of the animal product officer.

7 Testing

7.1 Laboratories and Methods

- (1) The laboratory and methods used must meet the requirements of part 15 of the Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006.

7.2 Results

- (1) A copy of all analytical results from each lot must be provided to the animal product officer.

7.3 Release of Product

- (1) No product may be released after sampling without the written approval of the animal product officer.

7.4 Variations

- (1) In exceptional circumstances, variations from all or part of this guide may be provided by the regional shellfish specialist in writing after agreement from the principal adviser (animal products). Applications for variations must be made in writing and be stand-alone documents containing all the supporting evidence. Variations are unlikely to be provided for sampling plans and analytical methods that have not been approved by MPI.

Appendix I: Deciding What Constitutes a Lot

- (1) It is recommended that operators consult with their animal product officer about what may constitute a lot.
- (2) The operator may propose to the animal product officer what it believes constitutes a lot, but the operators need to be aware that the animal product officer will be guided by the definition in the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations. The animal product officer should consult with the regional shellfish specialist on the acceptability of what constitutes a lot, as there may be other factors to be considered.

Example of sampling protocol

- (1) Take as a lot, all Greenshell mussels harvested in the Coromandel growing area 615 Motukopake Island on a particular day in the backdated closure period.
- (2) Ascertain where this product is held and document the total number of cartons of mussels being held and their location.
- (3) Assign each carton in the lot a sequential number.
- (4) Using random number tables, generate 60 random numbers.
- (5) A sample must be taken from each of the 60 cartons corresponding to the random numbers (e.g. one packet from the carton). These samples must be stored separately to the lot.