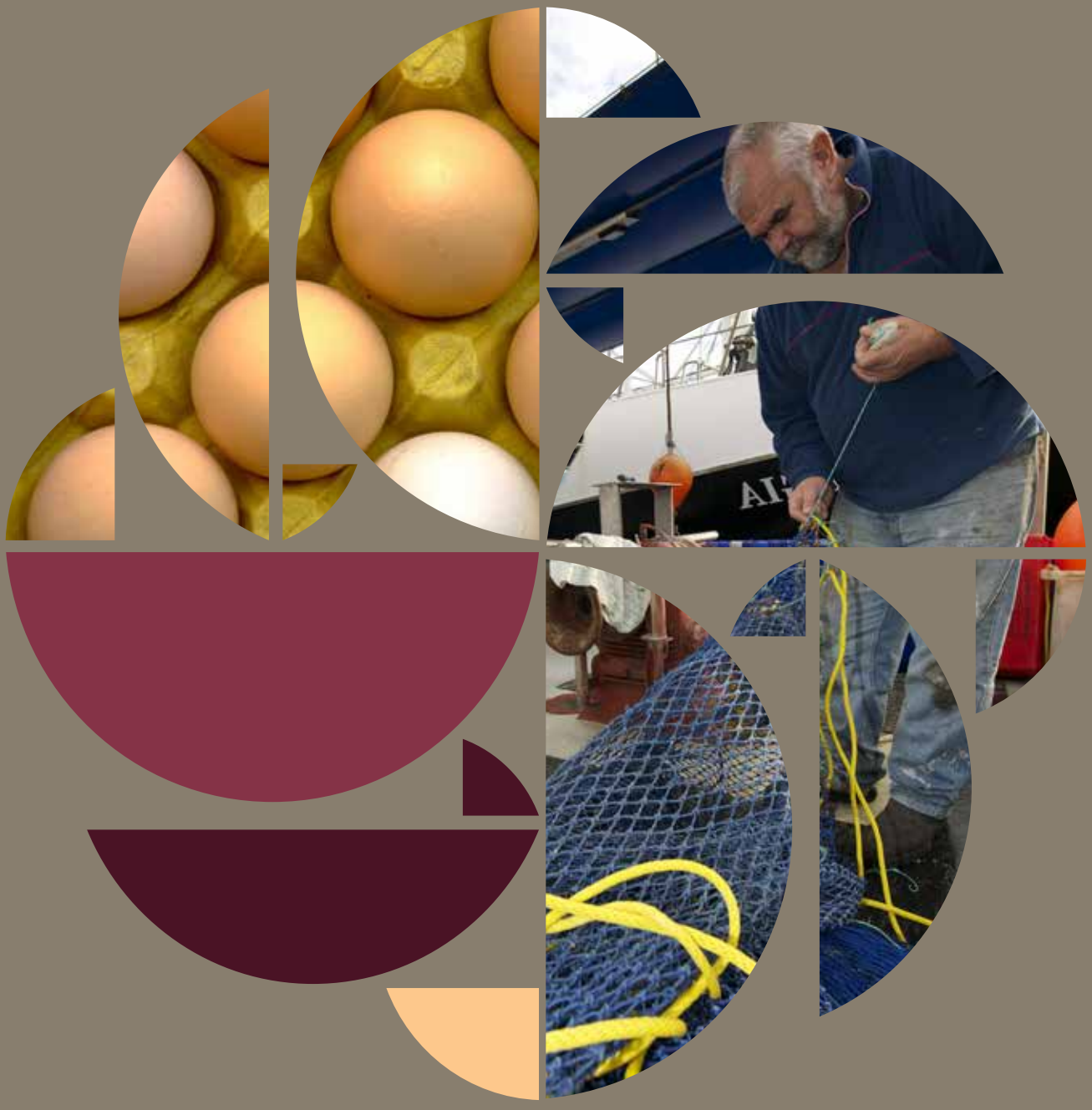
Australian Government

Department of Agriculture and Water Resources

# Dairy, egg and fish exports guideline for export registered establishments: product standards guideline—fish exports



**The Australian Government Department of Agriculture and Water Resources has created this set of guidelines to assist those wishing to prepare dairy, egg and fish products in Australia for export, as well as those wishing to export the final products.**

**This guideline sets out mandatory minimum testing requirements for export establishments that prepare fish products. The document also contains EU-specific requirements for fish products exported to the European Union. The requirements are mandatory, must be incorporated into the manufacturing establishment's Approved Arrangement and will be verified through regular export audits.**

## Background

Product testing assesses the performance of an export registered establishment's food management system (Approved Arrangement) in producing compliant fish and fish products. A regular programme of product testing provides the Australian Government with a level of assurance, which allows them to issue export health certification. See the Department of Agriculture and Water Resources' website for more information on registration, Approved Arrangements and government export health certification.

Where the importing country has a different food standard to Australia, establishments must demonstrate compliance with this standard for all fish intended for export to that market.

## Additional testing

This guideline mandates minimum testing requirements for some fish and fish products. Additional product testing may be required to verify that controls documented in your Approved Arrangement are effective in producing compliant fish and fish products. Accurate product descriptions and thorough hazard analysis of all product lines for the potential presence of contaminants, natural toxicants (for example, ciguatoxin) and residues will assist in determining where additional product testing is required to verify the adequacy of your Approved Arrangement.

Additional testing may also be required:

- when food additives that may have regulated limits are used (for example, sulphur dioxide in crustacea)
- to verify that product complies with the relevant regulatory levels as detailed in the Australian New Zealand Food Standards Code (FSC) or as set by importing country authorities
- to verify that action taken to address non-compliance has been effective
- to verify that a specific shipment meets importing country requirements
- as a result of sanctions.

Minimum testing requirements for export to the European Union are provided at Appendix A. Known requirements of other importing countries can be found in the Manual of Importing Country Requirements (MICoR).

## When the department must be notified

Under Australia's export legislation a registered establishment must notify the department when product has been found to be or is suspected of being unsafe and an export permit has been issued. Procedures for this must be covered in the export registered establishment's Approved Arrangement.

## Testing requirements

The minimum testing required for export is outlined in Tables 1 to 4. Table 1 outlines specific testing for contamination that may occur before harvest (sourcing requirements). Tables 2 to 4 outline specific testing for contamination that may occur post harvest and during manufacture (HACCP verification).

The testing requirements can be integrated into other testing that the establishment undertakes for domestic or commercial arrangements.

### Who conducts testing

If required by an importing country or if declarations relating to test results are required on certification, all testing must be carried out in a NATA or IANZ accredited laboratory. If not required for these purposes, testing can be conducted in-house or at non NATA-accredited laboratories.

### What testing methods can be used

Alternate test methods are permitted for sourcing and HACCP verification in Tables 1, 3 and 4 only where the laboratory has determined equivalence to the test methods prescribed by the FSC (if one is prescribed), but may not be allowable for confirming specific declarations on certification.

### Chemical and micro testing notes

The FSC (Standard 1.1.1) requires that foods comply with the prescribed microbiological limits at any stage of their manufacture or sale. Consideration should be given to sampling product at intervals that can verify shelf life and where 'use by' labelling is applied to packaging.

Testing may be minimised for certain environmental or sourcing hazards where valid technical data can be provided that supports the likelihood that fish taken from particular areas will contain levels of environmental contaminants within acceptable limits. For example, data from the Department of Agriculture and Water Resources' Fisheries Branch or National Residue Survey can be used to reduce the minimum testing tabled in this document on a case-by-case basis after consultation with the Dairy, Egg and Fish Export Programme.

Where the test is a presence/absence test for a specific food pathogen, the testing laboratory may composite the sub-samples and conduct one test. You should discuss your product testing needs with the laboratory before sending samples for analysis.

### Antibiotic testing

Documented evidence of nil use of antibiotics, including in feed, may be used to justify minimum testing of one sample per year per supplier for antibiotic testing of product. National test results for antibiotics can be substituted for this test (if they are within 12 months) or where the supplier provides laboratory test results.

## Product testing: supplier assurance verification testing

Tables 1 to 4 detail fish products that require testing, according to risk, and provides corresponding minimum testing frequencies.

**TABLE 1** Testing requirements to verify the source of fish and fish products

| Product type | Test required | Frequency of sampling | Sample size | Regulatory levels | Notes |
|---|---|---|---|---|---|
| Scallops exported roe-on and whole | Amnesic Shellfish Poison (ASP)<br>Diarrhoeic Shellfish Poison (DSP)<br>Paralytic Shellfish Poison (PSP) | At least once per year for each area/ zone (relevant to the state fishery) that scallops are sourced from. | One 100g sample per lot [a] | ASP maximum level of 20 mg/kg<br>DSP maximum level of 0.2 mg/kg<br>PSP maximum level of 0.8 mg/kg<br>As per Australia New Zealand Food Standards Code (FSC) Standard 1.4.1 | Whenever there are indications, such as severe storms and algal blooms, that increase the potential for contamination with biotoxins, additional biotoxin testing should be considered. The test results must identify the area/zone of the fishery.<br>Biotoxin testing is not required for scallops harvested under an export approved Australian Shellfish Quality Assurance Program (ASQAP) management plan that includes biotoxin management. |
| Aquaculture fish (including crocodile, crustacea and gastropods but excluding bivalve molluscs) | Antibiotics—general screen | A minimum of one annual test per aquaculture farm is required. | One 100g sample per lot | As per FSC Standard 1.4.2 | |
| Finfish of the following families: *Scrombridae* (tuna and mackerels), *Clupeidae* (including herrings and sardines), *Engraulidae* (anchovy), *Coryphaenidae* (dolphin fish) | Histamine | At least once per year per catcher vessel/aquaculture farm. | One (5 x 100g sub-sample) per lot | Maximum level of 200 mg/kg<br>As per FSC Standard 1.4.1 (for all fish) | When there is an indication that temperature control has not been maintained, additional histamine testing should be considered.<br>Additional finfish species should be considered for testing where there have been previous known incidents with histamine levels.<br>This testing is only required if finfish are exported as whole (whether gilled and gutted or not). |

[a] A 'lot' is declared as a quantity of processed food of the same type, processed or packed under essentially the same conditions, during a particular period of time (not generally exceeding 24 hours) and usually from a particular processing or packing line. For shellfish, a 'lot' means a single species of shellfish harvested from a particular harvest area and designated by a single harvest record number.

## Product testing: Verification testing of processing conditions (i.e. HAACP)

The frequency for testing of fish products will depend on whether the establishment prepares the product types detailed and the intended use of these products.

**TABLE 2** Frequency of testing for product types specified in Tables 3 and 4

| | Product type | Test frequency |
|---|---|---|
| **Low** | Live fish and crustacea | 6 monthly |
| **Medium** | Fish and fish products intended to be cooked or further processed before consumption | 4 monthly |
| **High** | Ready-to-eat fish and fish products | 3 monthly |

**TABLE 3** Minimum testing regime of fish and fish products to verify HACCP—microbiological

| Product type | Micro-organisms | Sampling plan (1) | | Regulatory levels (Food Standards Code, Standard 1.6.1) | |
|---|---|---|---|---|---|
| | | n | c | m (cfu/g) | M (cfu/g) |
| Raw crustacea | Coagulase positive staphylococci/g | 5 | 2 | 100 | 1000 |
| | SPC/g | 5 | 2 | 500 000 | 5 000 000 |
| Cooked crustacea | Coagulase positive staphylococci/g | 5 | 2 | 100 | 1000 |
| | Salmonella/g | 5 | 0 | not detected in 25g | – |
| | SPC/g | 5 | 2 | 100 000 | 1 000 000 |
| Ready-to-eat food in which growth of *Listeria monocytogenes* will not occur | *Listeria monocytogenes*/g | 5 | 0 | 0 | 100 |
| Ready-to-eat food in which growth of *Listeria monocytogenes* can occur | *Listeria monocytogenes*/g | 5 | 0 | not detected in 25g | 0 |
| Bivalve molluscs (does not include scallops) | *Escherichia coli*/g | 5 | 1 | 2.3 | 7 |
| Bivalve molluscs (including scallops) that have undergone processing other than depuration, shucking or freezing. | *Listeria monocytogenes*/g | 5 | 0 | not detected in 25g | – |

**c** The maximum allowable number of defective sample units. **m** The acceptable microbiological level in a sample unit. **M** The level that when exceeded in one or more samples would cause the lot to be rejected.



**TABLE 4** Minimum testing regime of fish and fish products to verify HACCP—other standards

| Food category | Contaminant or chemical | Sample size | Regulatory level | Notes |
|---|---|---|---|---|
| Finfish of the families: *Scrombridae* (tuna and mackerels), *Clupeidae* (including herrings and sardines), *Engraulidae* (anchovy), *Coryphaenidae* (dolphin fish) | Histamine | One (5 x 100g sub-sample) per lot | Maximum level of 200 mg/kg | Additional finfish species should be considered for testing where there have been previous known incidents with histamine levels.<br><br>This testing is not applied where the finfish being exported are whole (whether gilled and gutted or not) and testing to verify the source of the product is in place. |

## Product testing: sourcing requirements

Table 5 details the minimum testing requirements for the sourcing of fish and fish products to be eligible for the European Union and may be in addition to requirements for testing in Table 1.

**TABLE 5** Biotoxin and contaminants testing for the European Union

| Food category | Micro-organisms /their toxins, metabolites | Sample size | EU regulatory levels | Frequency of testing | When the criterion applies | Analytical reference method | Sampling—plan |
|---|---|---|---|---|---|---|---|
| **Scallops** (including both roe-on and roe-off) harvested in the open ocean (i.e. off-shore areas).<br><br>**Abalone** (regardless of whether from aquaculture or wild origin) | Amnesic Shellfish Poison (ASP) (Domoic acid) | 100g | Maximum level of 20mg/kg of Domoic acid | once every 10 shipments | End of the manufacturing process | High-performance liquid chromatography (HPLC) or equivalent | A biotoxin test must be carried out at least once per year for each area/zone (relevant to the state fishery) and whenever there are indications, such as algal blooms that increase the potential for contamination with biotoxins.<br><br>Testing methodology: liquid chromatography mass spectrometry (LCMS). This test must be covered under the laboratory's NATA/IANZ scope of accreditation. |
| | Paralytic Shellfish Poison (PSP) | 100g | Maximum PSP level 0.8mg/kg | once every 10 shipments | End of the manufacturing process | Pre-column HPLC (Lawrence method) or equivalent | |
| | Okadaic acid, dinophysistoxis and pectenotoxins together | 100g | Okadaic acid maximum level 0.16mg equivalents/kg | once every 10 shipments | End of the manufacturing process | Liquid Chromatography Mass Spectrometry (LC-MS/MS) or equivalent | |
| | Yessotoxins | 100g | Maximum level 1mg equivalents/kg | once every 20 shipments | End of the manufacturing process | | |
| | Azaspiracids | 100g | Maximum level 0.16mg equivalents/kg | once every 20 shipments | End of the manufacturing process | | |
| Prawns | Cadmium | 100g | Maximum level 0.5mg/kg | One sample every 6 months | End of the manufacturing process—as packaged for export | – | As the European Union may test product from each vessel on arrival you are strongly advised to discuss what test results are required with your agent or buyer before the consignment is consolidated for export. |

## Product testing: HACCP verification

Tables 6 and 7 detail the minimum testing requirements for fish and fish products to be eligible for export to the European Union and may be in addition to requirements for testing in Tables 3 and 4.

**TABLE 6** Microbiological criteria for the European Union

| Food category | Micro-organisms, their toxins, metabolites | Sampling plan (1) n | Sampling plan (1) c | EU regulatory levels | Analytical reference method | When the criterion applies | Frequency of testing |
|---|---|---|---|---|---|---|---|
| 1.2. Ready to eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes | *Listeria monocytogenes* | 5 | 0 | Absence in 25g | EN/ISO 11290-2 or AS 5013.24.1-2009 | Before the food has left the immediate control of the food business operator who has produced it | As per Table 2 |
| 1.16. Cooked crustacea and cooked molluscan shellfish | Salmonella | 5 | 0 | Absence in 25g | EN/ISO 6579 or AS 5013.10.2009 | Products placed on the market during their shelf life | As per Table 2 |
| 1.17. All live bivalve molluscs, echinoderms, tunicates and gastropods | Salmonella | 5 | 0 | Absence in 25g | EN/ISO 6579 or AS 5013.10.2009 | Products placed on the market during their shelf life | As per Table 2 |
| 1.24. All live bivalve molluscs, echinoderms, tunicates and gastropods | *E.coli* | 1 (min. 10 individual animals) | 0 | 230 MPN/100g of flesh and intra-valvular liquid | ISO TS 16649-3 or AS 5013.15.2006 | Products placed on the market during their shelf life | As per Table 2 |
| 1.25. Fishery products from fish species associated with a high amount of histamine (—*Scrombridae* (tuna and mackerels), *Clupeidae* (including herrings and sardines), *Engraulidae* (anchovy), *Coryphaenidae* (dolphin fish), *Pomatomidae* (tailor), *Scombresosidae* (sauries)) | Histamine | 9 | 2 | m 100mg/kg | M 200mg/kg | High performance liquid chromatography or AS 4884.2008 | Products placed on the market during their shelf life | As per Table 2 |
| 1.26. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histamine | Histamine | 9 | 2 | m 200mg/kg | M 400mg/kg | High performance liquid chromatography or AS 4884.2008 | Products placed on the market during their shelf life | As per Table 2 |

**c** The maximum allowable number of defective sample units. **m** The acceptable microbiological level in a sample unit. **M** The level that when exceeded in one or more samples would cause the lot to be rejected.

**TABLE 7** Process hygiene criteria for the European Union

| Food category | Micro-organisms | Sampling plan (1) | | EU regulatory levels | | Analytical reference method | When the criterion applies | Action in case of unsatisfactory results | Frequency of testing |
|---|---|---|---|---|---|---|---|---|---|
| | | n | c | m | M | | | | |
| 2.4.1. Shelled and shucked products of cooked crustacea and cooked molluscan shellfish | *E.coli* | 5 | 2 | 1 MPN or cfu/g | 10 MPN or cfu/g | ISO TS 16649-3 or AS 5013.15.2006 | End of the manufacturing process | Investigation to identify where the breach is occurring, then corrective action | As per Table 2 |
| | Coagulase-positive staphylococci | 5 | 2 | 100 cfu/g | 1 000 cfu/g | EN/ISO 6888-1 or 2 or AS 5013.12 | End of the manufacturing process | Investigation to identify where the breach is occurring, then corrective action | As per Table 2 |

**c** The maximum allowable number of defective sample units. **m** The acceptable microbiological level in a sample unit. **M** The level that when exceeded in one or more samples would cause the lot to be rejected.

## Appendix 1: Testing requirements for products intended for export to the European Union

The information in this appendix is from Commission Regulation No. 853/2004 laying down the specific hygiene rules for food of animal origin; Commission Directive No 22/2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs; and Commission Regulation No 2073/2005 on microbiological criteria for foodstuff. Commission Regulation No. 2074/2005, 1664/2006 and 15/2011 are also referenced. Commission Regulations and directives are available from the European Union's official website.

Information on EU requirements for additives and flavourings is available from the EU Foods system application.

## Useful links

**Approved Arrangements and registration**
agriculture.gov.au/dairy-egg-fish-export-guidelines

**Audit fees**
agriculture.gov.au/fees/charging-guidelines

**EU Commission Regulations**
europa.eu/eu-law/legislation/index_en.htm

**EU Foods system application**
webgate.ec.europa.eu/sanco_foods/main/?event=display

**Export Documentation system (EXDOC)**
agriculture.gov.au/biosecurity/export/exdoc

**Export fees and charges**
agriculture.gov.au/fees/charging-guidelines

**Export legislation**
agriculture.gov.au/biosecuritylegislation

**Manual of Importing Country Requirements (MICoR)**
agriculture.gov.au/micor

## Other guidelines for Australian export registered establishments and exporters

The department's website has further information on:

- Approved Arrangements
- becoming export registered
- department audit regime
- government issued export permits and certificates.

**agriculture.gov.au/dairy-egg-fish-export-guidelines**

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