

A Guide to Hazard Analysis Critical Control Point Systems in the Seafood Industry

**Fishing Industry Inspection and Certification Council
MAF Regulatory Authority (Meat and Seafood)
Wellington
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Preface

This document is produced on behalf of the Fishing Industry Inspection and Certification Council (FIICC) and the MAF Regulatory Authority (Meat and Seafood) to assist the Seafood Industry in the application of the hazard analysis critical control point (HACCP) system to seafood product and processes. However, it is essential that the Industry establish good manufacturing practices (GMP) prior to the introduction of HACCP and, on an ongoing basis, to support successful HACCP implementation.

HACCP identifies, evaluates and controls food safety hazards. It is internationally recognised as the best system currently available for assuring food safety.

The contents of this document reflect New Zealand's current approach to HACCP and will be further updated as new information and research becomes available.

The document is based on the Codex Alimentarius Commission's HACCP guidelines. The Codex guidelines will play a pivotal role in providing an internationally standardised approach to HACCP, harmonising food safety in the global market place.

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Amendments

Suggestions are welcomed for alterations, deletions or additions to these guidelines to improve them or to make them better suited to the needs of the fishing industry and inspection staff. Suggestions should be forwarded to the co-ordinator, together with reasons for the change and any relevant experimental or documentary data.

Amendments to these guidelines can be identified by the issue number in the page header and a background screen over the changes which have been made. Deletions are marked by a background screen appearing where the entry has been deleted, e.g. .

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Amendment Record

It is important that these guidelines are kept up-to-date by the prompt incorporation of amendments.

To update these guidelines when you receive an amendment, remove the appropriate outdated pages, destroy them, and replace them with the pages from the new issue. Complete instructions will be given on the covering letter accompanying the amendment. File the covering letter at the back of the guidelines and sign off and date this page.

If you have any queries, please ask your local Inspector.

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1. Introduction

- 1.1 This document has been produced by the Fishing Industry Inspection and Certification Council (FIICC) to provide:
- background information from which an understanding of the hazard analysis critical control point (HACCP) approach to food safety can be obtained;
 - guidance in the design and implementation of a HACCP plan for food safety;
 - a template for seafood applications;
 - generic models for the application of the template to selected products;
 - guidance on other HACCP-based applications.
- 1.2 HACCP is a widely used and an internationally recognised science-based control system for assuring food safety. This is achieved by systematically identifying hazards, evaluating them and developing effective control systems, focusing on preventive measures rather than end product testing.
- 1.3 HACCP was developed by the Pillsbury Company in the United States of America in consultation with the US Army and the US National Aeronautics and Space Administration to ensure food safety for astronauts. The system was used to manufacture food products with a high degree of assurance that they were safe, and this resulted in minimal reliance on end product testing.
- 1.4 Over the last 10 years, several detailed methods for the application of HACCP have been documented, primarily for processed and canned foods. Some of these documents involve extensive analysis and result in a complex application to a particular process. In comparison, the development of HACCP plans for raw seafood is a far less complex process.
- 1.5 The Codex Committee on Food Hygiene has been actively promoting the use of HACCP for food safety in conjunction with the revision of Codex codes of hygienic practice. The current HACCP document provided by Codex is annexed to the *International Code of Practice – General Principles of Food Hygiene*. It is strongly recommended as background reading.
- 1.6 HACCP is widely recognised by New Zealand's trading partners. Countries such as Canada and USA are particularly proactive in developing generic models to make use of HACCP within the food industry. The US Food and Drug Administration (FDA) have published its final rule on the "Seafood HACCP Program". The European Commission also recognises the benefits of HACCP and have incorporated HACCP principles into the Food Hygiene Directive, and revised directives for fish, meat products, poultry and milk.
- 1.7 HACCP will continue to receive increasing recognition internationally. It has already been mandated into legislation by some countries and will influence future market access for New Zealand seafood products.

- 1.8 HACCP is compatible with quality systems such as ISO 9000 series. It is a particularly useful tool for the process control section of any quality system taken up by the Industry. HACCP also has considerable overlap with other quality system components such as management review, internal audit, product non-conformance, corrective action procedures and verification.
- 1.9 HACCP focuses inspection activities on the critical areas of food safety and will ensure a scientific basis for controls operating in the Seafood Industry. It requires a long-term commitment by industry management in each seafood premises and fishing vessel.
- 1.10 HACCP can be applied throughout the food chain from producer to consumer. Wherever possible, the whole food processing and distribution system should be evaluated for possible HACCP application.
- 1.11 HACCP principles can be applied to areas other than food safety. Where alternative applications occur, consideration should be given to using different terminology.
- 1.12 The development of HACCP will inevitably extend back from processing premises into the catching and harvesting areas of the Seafood Industry. Already, some fishing vessels and marine farms have introduced quality management systems to provide food safety and quality information to processors on shore. HACCP can also be applied to these harvest areas. Similarly, it is the long term expectation that HACCP will also be applied to post-processing areas, i.e. to storage and distribution, and eventually through to preparation for consumption. This will result in HACCP being integrated throughout the entire food chain from harvest to table. This integration will provide the most benefit to the consumer in terms of food safety.
- 1.13 FIICC's strategic plan provides a clear direction for the Industry to develop and implement HACCP in recognition of increasing food safety concerns from consumers both nationally and internationally.

2. The Role of FIICC and Other Parties in the Implementation of HACCP in the Seafood Industry

2.1 FIICC

The strategic plan of the FIICC (available from the Fishing Industry Board, Private Bag 24901, Wellington) recognises that there are many pressures on seafood producers today to provide assurance that the products they produce are safe. These pressures come not only from government regulators, but also from consumers worldwide who are being exposed to increasing rates of food borne illness.

FIICC strongly supports the principles of the HACCP system for food safety and is actively promoting its adoption and implementation by the Seafood Industry.

There are positive reasons for all sectors of the Industry to implement HACCP voluntarily. These include:

- producing a safer product,
- gaining a better understanding and control of operations,
- actively encouraging raw material suppliers (e.g. those in the catching and harvesting sector) to adopt a similar approach,
- providing a firm base for the application of quality management systems,
- improving product quality,
- improving production efficiency and decreasing wastage,
- becoming a more competitive supplier,
- participating in changes to current regulatory requirements.

2.2 HACCP Steering Group

MAF Regulatory Authority (Meat and Seafood) (MAF RA (M&S)) is providing support to FIICC and the Seafood Industry in many aspects of HACCP development and implementation. A HACCP Steering Group, comprising representatives from a number of food producing industries as well as MAF RA, MAF Quality Management (MQM) and the Ministry of Health, has been formed with the following goals:

- to involve the Industry and regulators in ensuring a common approach to all aspects of HACCP,
- to provide appropriate and current information on HACCP to all interested parties,
- to promote the philosophy that the Industry owns and is responsible for HACCP and associated outcomes,
- to develop and update generic HACCP manuals in association with specific industry groups,

- to assist the Industry to develop their own HACCP plans.

More information on the HACCP Steering Group can be obtained from MAF RA (M&S), Wellington.

2.3 MAF RA (M&S)

MAF RA (M&S) promotes HACCP uptake by the Seafood Industry. In addition to the HACCP Steering Group, MAF RA (M&S) is also involved in other aspects of HACCP, namely:

- the development of technical skills which are continually expanded as more information is gathered about the application and implementation of HACCP;
- providing technical support and review of industry-designed HACCP systems for food safety;
- applied research to determine the most practical application of HACCP, especially to raw seafood production;
- auditing HACCP plans and systems when required.

2.4 The Industry

The Industry has the primary responsibility for developing and implementing specific HACCP plans to assure food safety. This guide aims to provide a strong basis from which any company wishing to take up HACCP can begin.

The Industry must also ensure that development of the technical skills relating to HACCP is provided for on an ongoing basis. They must be aware of future developments with regard to HACCP, both on a domestic and international level.

3. Principles of HACCP

3.1 Source

For the purposes of this document, the following seven principles, which are the basis of the HACCP system, have been sourced from the Codex Alimentarius Commission Report of the 29th Session of the Codex Committee on Food Hygiene (Alinorm 97/13A) Appendix II, *Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application (1996)*.

3.2 Principles

The HACCP system consists of the following seven principles:

- **Principle 1:** Conduct a hazard analysis.
- **Principle 2:** Determine the critical control points (CCPs).
- **Principle 3:** Establish critical limits
- **Principle 4:** Establish a system to monitor control of the CCP.
- **Principle 5:** Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- **Principle 6:** Establish procedures for verification to confirm that the HACCP system is working effectively.
- **Principle 7:** Establish documentation concerning all procedures and records appropriate to these principles and their application.

3.3 Definitions

The following definitions are used in these guidelines.

Control, when used as a verb, means to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control, when used as a noun, means the state wherein correct procedures are being followed and criteria are being met.

Control measures means actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action means any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical control point (CCP) means a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit means a criterion which separates acceptability from unacceptability.

Food safety objective means the expected food safety outcome for the product as a result of implementing the HACCP plan. It may have a qualitative or quantitative association with a level of risk to the consumer.

GMP means good manufacturing practice.

Hazard analysis critical control point (HACCP) is a system which identifies, evaluates and controls hazards which are significant for food safety.

HACCP audit means a systematic and independent examination of an applied HACCP plan to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are achieving set objectives on an ongoing basis.

HACCP co-ordinator is an appropriately trained person responsible for co-ordinating the application and implementation of HACCP at a premises.

HACCP plan is a document prepared in accordance with the principles of HACCP analysis to ensure the control of hazards which are significant for food safety in the segment of the food chain under consideration.

HACCP plan summary spreadsheet is a summary of the seven HACCP principles as they apply to the product and process under consideration.

Hazard means a biological, chemical or physical agent or condition with the potential to cause an adverse health effect.

Hazard analysis is the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Input means incoming materials such as consumable or non-consumable items added to the product during the process. Consumable items include raw materials, ingredients and food additives. Non-consumable items include wrapping, packaging and containers.

ISO is the International Organization for Standardization.

Monitor means the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Prerequisite programme is a documented programme covering an activity which may interact within and across various processes and which has the potential to influence the food safety outcome. It may also be referred to in other documents as good hygienic practices, good manufacturing practices, standard operating procedures, umbrella programmes or satellite programmes.

Revalidation means a reconfirmation that the HACCP plan is complete and can deliver the expected food safety outcomes after changes (modification) have taken place.

Risk means a function of the likelihood and severity of an adverse health effect on the consumer as a result of exposure to a hazard.

SOP means standard operating procedure.

Step is a point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.

Task description is a description of the expected operational activities at a process step. Examples of presentation include a written description, photos or a video presentation. This may also be known as a job description or work instruction.

TQM means total quality management.

Validation of HACCP plan means initial confirmation that the HACCP plan is complete and can deliver the expected food safety outcomes

Verification means the application of methods, procedures and tests in addition to those used in monitoring to determine:

- compliance with the HACCP plan;
- the ongoing effectiveness of the HACCP plan in delivering expected outcomes (food safety objectives), i.e. validation and revalidation;
- whether the HACCP plan, or its application, needs modification.

4. Prerequisite Programmes

- 4.1 Before developing a HACCP plan, it is essential to have a sound base of good hygienic and manufacturing practice. This means that all basic hygienic practices, encompassing facilities and operations, need to be in place and operating effectively. These practices include programmes currently required under the Fishing Industry Agreed Implementation Standards (IAISs) and current New Zealand legislation. In relation to the implementation of HACCP the documented procedures are referred to as prerequisite programmes.
- 4.2 Prerequisite programmes cover all those activities which interact within and across various processes, that may influence the food safety outcomes of the product. Confirmation that effective prerequisite programmes are in place means that the HACCP team can focus on the application of HACCP to the product and process selected, without repeating the analysis of hazards from the processing and surrounding environment. The prerequisite programmes may be generic to all processes at an individual premises.
- 4.3 Prerequisite programmes relevant to a seafood process should include the following:
- cleaning and sanitation (hygiene of facilities and equipment, including both pre-operational and operational),
 - hygiene of personnel (training, health, personal habits and protective clothing),
 - *reception of fish,
 - *incoming materials (ingredients, food additives, wrapping and packaging),
 - **Listeria* management (for specific processes),
 - product recall,
 - repairs and maintenance,
 - *storage and transport, including temperature controls,
 - training,
 - vermin control,
 - potability of water and ice (including clean seawater),
 - waste management (inedible product management and dropped product).
- * Aspects of fish reception, incoming materials, *Listeria* management, and storage and transport will also probably be in the HACCP plan.

5. Designing the HACCP Plan

5.1 Introduction

5.1.1 The aim of this section is to provide a guide to designing a comprehensive plan which focuses on control of significant hazards at identified CCPs in the process in order to prevent or minimise food safety risk to the consumer. The HACCP plan requires an in-depth evaluation of the product and the process to determine where specific control is required.

5.1.2 This section explains the necessary steps which should be followed in order to design a product-specific HACCP plan. A template and generic models are available for further guidance in Appendixes I and II. Note that the template begins with suggested prerequisite programmes and then moves to Step 3: Scope of the HACCP plan. The template assumes that the issues relating to management commitment and the assembly of the HACCP team have been addressed.

5.1.3 The following steps should be followed when designing the HACCP system:

- Step 1: Obtain management commitment and involvement
- Step 2: Assemble the HACCP team
- Step 3: Describe the scope of the HACCP plan
- Step 4: Describe the product and its intended use
- Step 5: Set food safety objectives for the product
- Step 6: Construct and confirm the process flow diagram
- Step 7: Write and confirm task descriptions
- Step 8: Identify hazards
- Step 9: Determine the critical control points (CCPs)
- Step 10: Establish critical limits for each CCP
- Step 11: Establish a monitoring system
- Step 12: Establish corrective actions
- Step 13: Establish verification procedures
- Step 14: Establish documentation requirements

5.2 Management Commitment (Step 1)

5.2.1 Management commitment is essential to underpin the development and implementation of HACCP with the provision of appropriate resources, responsibilities and authorities. Management need to understand the philosophy of the HACCP process and its role in food safety assurance, and to be proactive in driving the cultural changes that often accompany its introduction. In this respect, HACCP is essentially a self-assessment system, whereby the company takes primary

responsibility for and controls the food safety outcomes of the product(s), ensuring food safety objectives are being met and nonconformances are addressed. The programme will not succeed if management does not support this approach.

5.2.2 Management must also ensure that appropriate product- and process-specific knowledge and expertise is available for the development of an effective HACCP plan. The successful development and implementation of HACCP requires the involvement of all people associated with the process. These people should clearly understand the rationale behind HACCP and the likely impact on the business.

5.2.3 It is strongly recommended that management identifies:

- the scope of HACCP for the company,
- the timetable for development and implementation, allowing review of progress and modifications where necessary,
- presentation (e.g. documentation style and control, in line with existing company systems),
- key personnel required to progress HACCP, including the HACCP co-ordinator.

5.3 Assembly of the HACCP Team (Step 2)

5.3.1 Ideally, a HACCP team should be formed because a team approach offers the benefit of a range of expertise, different perspectives and experience. This team should be under the guidance of the HACCP co-ordinator and be selected on the basis of:

- their responsibilities,
- their knowledge and experience of the company, products, processes and hazards relevant to the scope of the HACCP plan,
- their knowledge of the principles and practice of food safety.

For small companies it may not be possible to establish such a team, e.g. only one person may be available with the required expertise. In these cases, external advice, such as that provided by consultants and/or regulatory agencies, should be obtained as necessary to assist in the development of the HACCP plan.

5.3.2 The HACCP team should develop the HACCP plan for each product at the individual premises. This development will periodically require the involvement and consultation of all personnel involved in the process. This also helps to ensure that the programme is jointly owned and operated by the people who do the work, as well as quality control and supervisory personnel. Outside expertise may be needed from time to time and generic models may be available as guidelines.

5.3.3 An action plan is strongly recommended to outline the tasks, responsibilities and timetable for each team member where appropriate.

5.4 Scope of the HACCP Plan (Step 3)

5.4.1 The scope must be determined to define the accepted boundaries of each HACCP plan.

5.4.2 Components to consider should include:

- a list of documented prerequisite programmes in operation at the premises,
- whether HACCP will be extended to activities other than food safety,
- the start and endpoint of the process covered by the HACCP plan.

5.5 Description of the Product and its Intended Use (Step 4)

5.5.1 A full description of the product or product group (a product group would have similar processing characteristics and expected food safety outcomes) is required. This description provides the HACCP team with a “picture” of the product which is necessary to assist with the setting of food safety objectives and the hazard analysis.

5.5.2 It should encompass:

- product name(s),
- important product characteristics,
- how it is to be used,
- packaging,
- shelf life and storage,
- where it will be sold,
- labelling instructions,
- distribution.

5.5.3 It is important to consider the expected use of the product outside the premises, e.g. by a processor and, ultimately, the consumer. Unusual use or abuse may create a greater food safety risk than is generally the case and in some cases, specific “high risk” consumers may have to be considered. The description of the intended use should identify:

- normal usage conditions, e.g. appropriate storage temperatures, any consumer limitations with regard to eating the product and how it is likely to be eaten;
- potential for abuse of the product (e.g. the likelihood of any situation in the distribution chain where the product could be incorrectly stored or handled, resulting in unacceptable growth of micro-organisms).

5.5.4 This information will be used to create a “risk profile” for the product and will help to analyse the impact of potential food safety hazards. For example, consider a microbiological hazard and a final product with the following intended end uses and potential outcomes:

- wet fish which is frozen and known to be cooked prior to consumption,
- compared with
- wet fish which is chilled and is known to be eaten raw as sashimi,
- compared with
- wet fish which is chilled, but the final preparation is unknown.

5.6 Setting Food Safety Objectives for the Process (Step 5)

5.6.1 Having established the product characteristics and likely use, the HACCP team needs to determine what the company wishes to achieve in terms of food safety outcomes for each product. Food safety objectives (FSOs) assist this process by stating these outcomes in a measurable way and may relate to individual hazards or a group of hazards.

5.6.2 Food safety objectives offer the following benefits:

- a quantitative target for the design of a HACCP plan, allowing effective measurement of the expected food safety outcomes, thus assisting in the verification process;
- provision of a means for assessing equivalence of food safety systems, e.g. for market access;
- achievement of the “due diligence” expected for seafood products in international trade;
- clear identification of the limitations of a HACCP plan.

5.6.3 For raw products, food safety objectives will often be closely associated with those outcomes achievable by good hygienic practices (GHP) and may only be qualitatively associated with food safety as it relates to the consumer. In time, more data will become available to better determine the links between the level of hazards in the final product and risks to human health in the consumer population.

5.6.4 Examples of food safety objectives for raw product could be:

- to achieve a specified microbiological target according to a specified sampling plan,
- to be free from parasites that pose a food safety hazard,
- to be free from hazardous levels of chemical residues associated with a particular fish species, according to a specified sampling plan,
- to be free from any physical hazards (bones) according to a specified sampling plan.

5.6.5 For canned fish, the food safety objectives for the product could be:

- to achieve commercial sterility under normal storage conditions;
- to have no sample unit containing histamine that exceeds 20 mg/100 g (this would apply only to species of the families Scombridae, Clupeidae, Coryphaenidae, Scombrotoxicidae and Pomatomidae, e.g. mackerel, tuna),
- to be free from hazardous levels of other substances (including substances derived from micro-organisms) in accordance with established standards (e.g. sodium nitrite),
- to achieve nil container integrity defects that compromise the hermetic seal,
- to be free from any physical hazards that pose a food safety risk to the consumer according to a specified sampling plan.

5.6.6 Food safety objectives are meant to link initial food safety expectations of the product with measurable achievements resulting from the implementation of the HACCP plan. They should not limit a full hazard analysis taking place and should in fact be reviewed after that step and confirmed as appropriate for the product before determining CCPs.

5.7 Constructing and Confirming a Process Flow Diagram (Step 6)

5.7.1 The HACCP team should construct a flow diagram based on their knowledge of the process. This flow diagram provides the foundation for the hazard analysis and control and lists consecutive steps for the complete process.

5.7.2 The inputs must be described. These include raw materials, ingredients, food additives, and wrapping and packaging materials or containers that come into direct contact with the product, e.g. plastic liners. Inputs are sourced from outside the premises and can introduce contaminants such as micro-organisms, vermin, chemicals or physical hazards. Incoming materials such as water and ice, which are already covered in effective prerequisite programmes, need not be included as inputs.

5.7.3 Edible outputs should also be shown. Each of these may initiate a separate process flow diagram of its own and form part of another HACCP plan with a different end product.

5.7.4 It is important that the process flow diagram reflects what is actually happening with the process. On completion, the process flow diagram should be confirmed by the following means:

- discussing the process flow diagram with each operator in the process to ensure it accurately describes the process steps and all inputs and edible outputs;
- observing the work that is carried out at each process step and confirm that the process flow diagram is correct.

5.8 Writing and Confirming Task Descriptions (Step 7)

5.8.1 A task description should be written for each process step, containing a detailed account of the operation (e.g. what the operator is required to do and/or what the equipment is expected to achieve). It should also contain the relevant food safety responsibilities for that operator. Task descriptions provide excellent training tools for companies to use with new employees.

5.8.2 The task description should be confirmed by:

- observation,
- discussion with the operator.

There is flexibility as to when the task descriptions are confirmed. This may be left until the HACCP plan is completed.

5.9 Identification of Hazards (Step 8)

5.9.1 Hazard identification will highlight those food safety hazards reasonably expected to be associated with the selected product and process.

5.9.2 Before starting hazard identification, background information on potential food safety hazards associated with the product and the process should be collected, e.g. from personal experience, MAF, seafood consultants, and libraries and research organisations such as Crop and Food Research (Seafood Division), National Institute for Water and Atmospheric Research (NIWA), Cawthron Institute and the Communicable Diseases Centre (part of Environmental and Scientific Research). You should also refer to Appendix VI.

#

5.9.3 The identification of hazards requires a sound understanding of the raw material, the process, product specifications, type of processing equipment, the processing environment, and operator activities (e.g. personnel and product flow paths) within a process. A team approach to identify hazards is very useful to ensure all sources of hazards are considered. The food safety hazards that must be considered are:

- **Biological**

These are agents that have the potential to cause food poisoning, e.g. *Salmonella* spp. *Listeria monocytogenes*. *Vibrio* spp. *Clostridium botulinum*. Hepatitis A virus, Norwalk virus, marine biotoxins, histamine and parasites.

- **Chemical**

These are chemical residues and contaminants that could cause food to be unsafe, e.g. residues of heavy metals such as cadmium and mercury. Food additives may also be hazardous if included at greater than acceptable levels.

- **Physical**

This is any material that could constitute a human health risk when eaten, e.g. bones, shell fragments and metal filings.

- 5.9.4 Hazard identification should take place using the process flow diagram and task descriptions, and by considering the appropriate hazards at each process step. Expertise in seafood hazard identification should be sought to help with this exercise. The hazards associated with the incoming raw material should be initially identified and listed. Then additional hazards which could occur at each process step, including those associated with any other inputs (e.g. ingredients, wrapping/packaging), should be considered.
- 5.9.5 Identified hazards must be documented.
- 5.9.6 Food safety objectives should now be reviewed to ensure that all identified food safety hazards expected to be under the processor's control are covered.
- 5.9.7 Unaddressed hazards (i.e. those not under the processor's control) should be noted so they can be considered elsewhere in the food chain, e.g. by further processing or by preparation prior to consumption.

5.10 Determining Critical Control Points (Step 9)

- 5.10.1 CCPs can be points, steps or procedures at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level. **The most practical designation of a CCP is as a process step.**
- 5.10.2 The identified hazards are now analysed for significance in relation to the product. Consideration is given to the following points when determining significance:
- the food safety objectives for that product,
 - the level of occurrence of the hazard,
 - the frequency of occurrence of the hazard,
 - whether transfer/redistribution of the hazard occurs,
 - the severity of the effects the hazard has on the consumer.
- 5.10.3 Control measures must be available for all those hazards which are considered significant. Where these measures are not available within the process, then the product or process may need to be redesigned to accommodate a control measure. This designates a CCP.
- 5.10.4 CCPs can be identified using a decision tree or by another means, as long as meaningful evaluation of each identified hazard is carried out at each process step. An example of a decision tree can be found in Appendix I, Figure I.1.
- 5.10.5 All hazards that **may be appropriate** for each process step and which the processor is responsible for controlling must be considered when applying the decision tree.

5.10.6 Some hazards may have more than one CCP. Similarly, more than one hazard may be controlled at a CCP.

5.10.7 The rationale behind selection of the CCP(s) must be documented.

5.11 Establishing Critical Limits (Step 10)

5.11.1 Critical limits are criteria separating acceptable and unacceptable observations or measurements. They initiate corrective action when they are exceeded.

5.11.2 Critical limits must be specified for each CCP as they define the acceptable activities and operations to control hazards and achieve established FSOs. The critical limits must be clearly defined and measurable.

5.11.3 Criteria often used include:

- ranking systems for the type and level of grossly detectable contamination,
- temperature and time combinations,
- moisture level,
- pH,
- water activity,
- free available chlorine,
- visual appearance.

5.11.4 Establishing critical limits for food safety hazards may be a difficult task in some processes, e.g. in raw fish products, where further information or research may be needed to establish baseline data on microbiological hazards before meaningful critical limits can be determined.

5.11.5 In some circumstances, critical limits may need to be considered in relation to regulatory requirements, i.e. the regulator may set the critical limit.

5.11.6 Critical limits must be documented.

5.12 Monitoring Critical Control Points (Step 11)

5.12.1 Monitoring is the planned sequence of observations or measurements to assess whether a CCP is under control relative to its critical limits.

5.12.2 Monitoring of CCPs will rarely be continuous in raw seafood processes. Monitoring must be at a frequency that ensures that the CCP is under control and should be statistically based.

5.12.3 Where calibrated automatic monitoring equipment is available, monitoring will be able to be carried out on a continuous basis, e.g. continuous temperature recording of a chiller.

The accuracy of this monitoring equipment should be guaranteed by an appropriate system.

5.12.4 The person allocated the monitoring task must be fully trained and have appropriate responsibility for the position. This should include responsibilities for taking corrective action.

5.12.5 When the monitoring results indicate a trend towards loss of control at the CCP, corrective action should be initiated. This will bring the process back in control before the deviation leads to a safety hazard and possibly alters the way the product can be used.

5.12.6 Monitoring procedures must be documented. All findings must be recorded.

5.13 Requirements for Corrective Action (Step 12)

5.13.1 Specific corrective actions must be developed for each CCP when the critical limits are exceeded. The corrective actions must be designed to rapidly regain control at the CCP and also have the objective of preventing recurrence. In addition, corrective action should include retention of the product and if necessary, changing the way it can be used. This may include rejection.

5.13.2 The person initiating the corrective action must be fully trained and have appropriate responsibility for the position.

5.13.3 Corrective action procedures must be documented. All corrective actions taken, including the subsequent disposition of the product, must be recorded.

5.14 Procedures to Verify the HACCP Plan (Step 13)

5.14.1 Verification activities involve the application of methods, procedures and tests in addition to those used in monitoring to determine:

- compliance with the HACCP plan,
- the ongoing effectiveness of the HACCP plan in delivering expected outcomes (food safety objectives), i.e. validation and revalidation,
- whether the HACCP plan or its application, needs modification.

5.14.2 Verification procedures should include:

- validation of the HACCP plan (initial confirmation that the plan delivers the expected food safety outcomes as laid down by the objectives set); refer to Appendix VII for additional guidance on validation,
- review of all components of the HACCP system, its documentation and records
- (internal and external audit), including review of deviations, customer complaints, corrective actions and any product dispositions; the review period needs to be determined and documented,

- calibration,
- end product and microbiological testing where relevant,
- revalidation where necessary (when product and/or process changes occur or new food safety information requires modifications to the HACCP plan).

5.14.3 Verification procedures, including the expected frequency, must be documented to ensure that the HACCP plan is complete and functioning to specifications. All findings must be recorded.

5.15 Documentation and Record Keeping (Step 14)

5.15.1 All components of the HACCP plan need to be documented as noted in the preceding steps.

5.15.2 The HACCP plan summary spreadsheet is a useful way of presenting an overview of the HACCP plan for a particular product/process.

5.15.3 The following records must be kept to provide evidence that the HACCP plan is working according to documented procedures:

- CCP monitoring results,
- corrective action results,
- verification results.

5.15.4 These records must be kept according to current regulatory requirements.

6. Implementing the HACCP Plan

6.1 General Requirements

6.1.1 The aim during implementation of HACCP is to ensure that food safety hazards associated with the product and the process are controlled effectively and on a continual basis. The company will require an ongoing commitment to ensure that staff are given adequate empowerment to guarantee the plan's success.

6.1.2 There are a number of ways that HACCP can be implemented. This will be influenced by a number of factors, such as the scope and size of the plan, type and complexity of the process and whether it is to be in parallel with the development phase.

6.1.3 Several issues must be addressed before the plan can be implemented. These are:

- **Training**

- Specific HACCP training will be required for the co-ordinator, supervisors and key operators involved at CCPs.
- HACCP awareness training will be essential for all staff.

Note: A staff HACCP training programme should also be established in accordance with the ongoing expectations of the company. See Appendix III for further details on training.

- **Responsibilities need to be defined and understood**

- Everyone involved in the implementation must have clearly defined and documented responsibilities.

- **Resources**

These will include but are not limited to:

- sampling plans, CCP worksheets, checklists, reference material on products;
- equipment (e.g. calibrated thermometers, meters and timing devices for CCP monitoring).

6.2 Validation of the HACCP Plan

6.2.1 The initial phase of validation is the formal assessment of the documentation followed by assessment of the application against that documentation. Food safety hazards identified for the product and process must be controlled effectively on an ongoing basis. Validation of the plan will have been achieved when it can be shown that this is the case and food safety objectives (FSOs) are being met. This is done by comparing the outcomes or end results with the FSOs originally set for the product and process.

6.2.2 Where the outcomes of the plan do not match the objectives, a review will be required to determine the problem. This means that a re-evaluation of the HACCP plan, including the FSOs, is required. On completion of validation, when the FSOs are met, management should sign off the HACCP plan.

6.2.3 Documented evidence of conformance to the HACCP plan over time is required. How well organised the implementation process is will determine how quickly HACCP settles into place, and how well process stability is achieved with consistent process outcomes.

6.2.4 For more information on validation of HACCP plans, see Appendix VII.

6.3 Ongoing Management and Verification of the HACCP Programme

6.3.1 Successful HACCP implementation will require a continuous commitment from the company. Maintenance tasks include:

- ongoing verification activities, as documented in the plan, including revalidation where necessary (when product and/or process changes occur or new food safety information requires modifications to the HACCP plan);
- maintenance of training according to the requirements of the premises;
- retention of records according to regulatory requirements;
- continual support by effective prerequisite programmes.

6.3.2 Access to the company's HACCP plan, including all supporting documentation and records, may be required by the following:

- company personnel to enable informed decisions to be made,
- regulatory agencies,
- clients,
- external auditors.

The needs of the above parties will vary, and therefore consideration should be given as to how the relevant information can be identified and retrieved (e.g. regulatory agencies will only be concerned with food safety, market access and compliance issues).

6.3.3 The established HACCP plan(s) for a premises must remain dynamic.

6.3.4 HACCP may be used in conjunction with systems being developed or already in place on a premises, e.g. ISO 9000 series quality system. For more information, see Appendix IV.

As records are collated over a period of time, the company may wish to re-evaluate its expected outcomes associated with the HACCP plan. For example, it may result in:

- an awareness of the need to change the food safety objectives,
- knowledge and experience giving confidence to change other components of the HACCP plan.

7. Auditing HACCP Plans

7.1 Introduction

Once the HACCP plan has been implemented, the company will want to periodically assess actual performance against the documented system and desired food safety objectives. This forms part of the verification procedures outlined in the HACCP plan and is likely to involve both independent internal and external assessment at some stage. These assessments are best carried out in a systematic way with written evidence of the outcomes. The HACCP Steering Group has produced an audit protocol designed to provide guidance for internal and external auditors in assessing whether a HACCP plan is working effectively.

7.2 Aims of the Audit of the HACCP Plan

The audit of the HACCP plan focuses on effective control of food safety hazards. However, the intent of the audit will vary depending on the type (see Appendix V.I).

Generally the following outcomes are sought:

- to determine whether all required elements are present in the HACCP plan and that they are addressed adequately;
- to determine whether the procedures are effective with respect to achieving acceptable food safety outcomes for the product/process on an ongoing basis;
- to determine whether actual events comply with the validated documented procedures.

7.3 Audit Approach

The recommended audit approach, based on ISO Standards 10011.1:1992; 10011.3:1992, is:

- decide the type of audit, **including the standard** against which the HACCP plan is to be assessed (see Appendix V.1);
- notify the auditee;
- obtain information prior to the premises audit (see Appendix V.2);
- assess the pre-audit information and, if necessary, target specific concerns to be addressed prior to the audit or for further evaluation on-site;
- select the audit team (see Appendix V.3);

- brief the audit team;
- visit the premises and carry out the entry meeting;
- carry out the audit (see Appendix V.4); all observations and nonconformances should be acknowledged by the auditee;
- carry out the exit meeting and deliver the conclusions of the audit, deciding how to accept corrective actions (if required) and how to verify those corrective actions;
- write the formal report (see Section 5.4.2 of ISO 10011.1 for the main headings);
- follow the appeal procedures, where provided, if the auditee disagrees with the conclusions of the audit;
- follow up on nonconformances as agreed.

Pre-audit information may be assessed off-site or on-site. The practicalities of this will be determined by the auditor and auditee.

7.4 Outcome of the Audit

7.4.1 Assessment of conformance

The findings should be evaluated using all information available (both pre-audit information and that gathered during the audit). The questions in Appendices V.2 and V.4 provide guidance for this. The aims of the audit should be considered and then whether the HACCP plan is effective should be determined.

The HACCP plan is deemed to be conforming (effective) when all the following have been met:

- All necessary prerequisite programmes are in place and are operating without any deficiencies which are likely to compromise the food safety outcome of the HACCP plan.
- It can be demonstrated that acceptable food safety objectives (FSOs) are being met on an ongoing basis (with deficiencies addressed promptly followed by appropriate and documented review).
- In relation to the seven HACCP principles, all components are met to the satisfaction of the auditor.
- Actual events substantially match documented HACCP procedures.

A conforming HACCP plan may mean that some or all of the following may occur:

- Audit frequency may decrease.

- Regulatory overview and audits may decrease.
- A change in the type of audit may occur.
- Customised process changes may be sanctioned.
- Market access is granted.

7.4.2 Assessment of nonconformances

All nonconformances should be identified according to the specific parts of the related standard.

7.4.2.1 Prerequisite programme nonconformances

The HACCP plan auditor, if carrying out a separate role to that of a compliance auditor, should only be concerned about the presence of prerequisite nonconformances which have the potential to adversely affect the food safety outcome expected from application of the HACCP plan, and which have not been effectively addressed by the auditee (or the represented licensee). However, deficiencies outside the scope of the HACCP audit should still be drawn to the attention of the appropriate person.

Corrective action may include one or more of the following:

- action by the processor to immediately correct the deficiencies in the prerequisite programme(s);
- notification by the HACCP plan auditor to the service provider who has responsibility for verifying the ongoing compliance of the prerequisite programme with statutory requirements and industry agreed standards;
- notification by the HACCP plan auditor to the auditee that the effectiveness of the HACCP plan is seriously compromised, with additional corrective actions being applied as in Section 7.4.2.2.

There is the option of aborting the HACCP plan audit at this stage or progressing the audit with the intention of providing additional feedback to the auditee even though the outcome may have been affected.

7.4.2.2 HACCP plan nonconformances

Nonconformances are any activities that do not meet the given standard and/or what is documented in the HACCP plan. The auditee will be expected to act on the outcomes of the audit to correct nonconformances within the agreed timeframe. The urgency and scope of the corrective actions will depend on the seriousness of the nonconformances and may include one or more of the following actions:

- action by the processor to correct deficiencies in the HACCP plan,
- increase in audit frequency,

- increase in depth of audit,
- recognition that the HACCP plan has failed to achieve FSOs with a review required of the entire plan,
- immediate remedial action by the processor,
- recall of product immediately by the processor according to the recall procedures,
- suspension of production by the processor,
- other actions that the regulatory authority may deem necessary, e.g:
 - notification to the regulatory authority,
 - recall of product immediately according to the conditions outlined by the regulatory authority,
 - suspension of market access by the regulatory authority.

Regulatory action for nonconformances can only be applied with respect to mandatory requirements.

The auditor will confirm that the proposed corrective actions are satisfactory and how they will be verified.

Any standard procedures in the industry-agreed implementation standards concerning non-compliances need to be followed.

7.4.3 Close-out of nonconformances

The auditee will ensure all corrective actions are addressed according to the agreed timeframe.

The auditor will verify that all corrective actions have been taken by the auditee and are effective.

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Appendix I. Template for a HACCP Plan

I.1 Introduction

The following template has been developed to assist the seafood industry in the development of their HACCP plans. It must be remembered that it is a guide only, and industry must carry out a detailed study of their own products and processes in order to ensure that resultant HACCP plan is tailored specifically for their premises. All explanatory notes in the template can be expanded by consulting the relevant part of Section 5.

I.2 Prerequisite Requirements

Prior to starting the HACCP plan, the HACCP team should ensure that all the relevant prerequisite programmes are documented and that they are substantially in compliance with specifications for GMP as covered in the IAISs. The prerequisite programmes should be ticked off on the Prerequisite Requirements form.

I.3 Scope of the HACCP Plan

The HACCP team should determine the scope of the HACCP plan (e.g. food safety), the product name and the process, including the segment of the food chain it relates to, and document these at the beginning of the HACCP plan.

I.4 Describe the Product and Its Intended Use

The final product and its intended use should be described on Form 1, with particular food safety requirements for the product. Any sections not applicable should also be noted.

Form 1 can be used for the overall product description, not just food safety.

I.5 Set Food Safety Objectives for the Product

Food safety objectives represent the food safety outcomes expected for the final product. For raw products, these objectives will often be limited to those outcomes achievable by good hygienic and manufacturing practices and may only be qualitatively associated with food safety. The reason for this at present is the lack of data to allow a formal risk assessment to determine quantitative associations between the level of hazards in the final product and risks to human health.

In the development of the HACCP plan, food safety objectives should be initially formulated when discussing and documenting the desired outcomes for the final product and its intended use. These objectives should be confirmed as appropriate after the hazard identification is completed. This ensures that control of all identified hazards is covered by appropriate food safety objectives.

The initial food safety objectives should be listed for the product and process.

I.6 Construct a Process Flow Diagram

A process flow diagram should be constructed which shows relevant inputs for each process step. These include raw materials, ingredients and non-recyclable items which enter the process and contact the product. Edible outputs should also be shown. Forms 2 and 3 provide a template for information on raw materials, other inputs and the process flow diagram.

I.7 Write Task Descriptions

Task descriptions should be written for each process step. Form 4 provides a template for this information and particularly highlights food safety responsibilities.

I.8 Identify Hazards

All biological, chemical and physical hazards relating to raw materials and other inputs should be identified at each process step. Hazards should be identified according to the following:

- **Raw material hazards**

Raw material is the initial input into the process.

The potential hazards associated with the raw material should be inserted on Form 5a.

- **Other input hazards**

Other inputs consist of consumable and non-consumable food contact materials that are added during the process to form part of the end product. Hazards relating to these inputs may be effectively controlled by an existing prerequisite programme. If this is the case, the hazard and its control measure need not be repeated in the HACCP plan. The potential input hazards should be inserted in Form 5A.

- **Process step hazard identification and control measures**

Process step hazards are hazards **appropriate** to each process step shown in the process flow diagram, considering raw material and other inputs.

Hazards should be identified and listed on Form 5b, along with their respective control measures, where applicable.

Note that some hazards might not be able to be controlled at the end of the process and should be highlighted for consideration elsewhere in the food chain, e.g. on the fishing vessel or by the consumer.

I.9 Confirm the Food Safety Objectives (FSOs) for the Process

The FSOs should be reviewed in light of what hazards can be controlled, by you as a processor, and confirmed FSOs listed.

I.10 Determine the Critical Control Points (CCPs)

The CCPs should be determined using a decision tree (Figure I.1) or other methods, considering those identified hazards that the processor is primarily responsible for controlling. An example of a decision tree is given on Form 6. CCPs must be determined for each hazard at each process step.

I.11 Establish Critical Limits (CLs)

For each CCP, clearly defined and measurable critical limits must be determined for each hazard. Form 7 provides a template for summarising these.

I.12 Monitor CCPs

Monitoring parameters for each CCP should be established. The monitoring parameters to be covered include responsibilities for monitoring, what is monitored, where monitoring is done and how frequently it should be done. Form 7 provides a template for summarising these.

I.13 Set Corrective Actions

Specific corrective actions for each CCP must be established for when the critical limits are exceeded. These corrective actions must be designed to rapidly regain control at the CCP and should also have the objective of preventing recurrence. In addition, corrective actions may mean retaining and, if necessary, altering disposition of affected product. Form 7 provides a template for summarising these.

I.14 Verify the HACCP Plan

Verification procedures must be established that will confirm whether the HACCP plan is operating effectively and according to documented procedures. Verification will include validation of the HACCP plan. Form 7 provides a template for summarising these.

I.15 Documentation and Record Keeping

Appropriate documentation for the HACCP plan has been referred to throughout this template. Records also need to be kept for monitoring, corrective actions and verification results. Form 7 provides a template for documenting the records relevant to the HACCP plan.

Prerequisite Requirements

(tick boxes if the premises complies)

Programme	Complies with IAISs ✓	Documented ✓
Cleaning and sanitation of facilities and equipment, including both pre-operational and operational)		
Hygiene of personnel (training, health, personal habits, protective clothing)		
*Reception of fish		
*Incoming materials (ingredients, food additives, wrapping and packaging)		
* <i>Listeria</i> management		
Product recall		
Repairs and maintenance		
*Storage and transport, including temperature controls		
Training		
Vermin control		
*Water and ice potability (including clean seawater)		
Waste management (inedible product management, dropped product)		

* Aspects of these prerequisite programmes are also considered in the HACCP plan.

Form 1: Product Description and Intended Use

1. Product name(s)	
2. Important product characteristics	
3. How is it to be used? (a) By a further processor (b) By the consumer	
4. Intended consumer	
5. Packaging	
6. Shelf-life and storage requirements	
7. Where it will be sold (a) Exported (<i>state countries</i>) (b) Local market	
8. Labelling instructions	
9. Special distribution controls required	

Form 2: Description of Raw Materials and Other Inputs

Product name:

Raw material/Other inputs

Description/Specifications

Form 3: Process Flow Diagram

Process:

Inputs	Process steps	Outputs

Form 4: Task Description

Task description:

Process step no.:

List of food safety responsibilities for the operator: *(confirm after HACCP plan completed)*

Reference:

Form 5a: Raw Material Hazard Identification

Raw material	Hazard	Processor-controlled?	Control measure

Appendix II. Generic Models

II.1 Introduction

The following generic models have been developed to assist the Seafood Industry with their own HACCP plans. It must be remembered that they are examples only, and that each company must carry out a detailed study of their own products and processes in order to ensure that the resultant HACCP plan is tailored specifically for their premises.

II.2 Generic Model for Half-Shell Mussels

Prerequisite Requirements		
<i>(tick boxes if the premises complies)</i>		
Programme	Complies with IAISs	Documented
Cleaning and sanitation of facilities and equipment, including both pre-operational and operational)		
Hygiene of personnel (training, health, personal habits, protective clothing)		
*Reception of fish		
*Incoming materials (ingredients, food additives, wrapping and packaging)		
* <i>Listeria</i> management		
Product recall		
Repairs and maintenance		
*Storage and transport, including temperature controls		
Training		
Vermin control		
*Water and ice potability (including clean seawater)		
Waste management (inedible product management, dropped product)		

* Aspects of these prerequisite programmes are also considered in the HACCP plan.

Scope

HACCP Application	Food Safety
Product	Half-shell mussels
Process	Receipt of live shellstock through to freezer storage of packaged half-shell mussels

Form 1: Product Description and Intended Use	
1. Product name(s)	Half-shell mussels (<i>Perna canaliculus</i>).
2. Important product characteristics	Heat shocked, shucked, frozen.
3. How is it to be used? (a) By a further processor (b) By the consumer	 (b) Ready-to-eat/further cooked
4. Intended consumer	General public
5. Packaging	Boxes with plastic liners.
6. Shelf-life and storage requirements	12 months at -18 °C.
7. Where it will be sold (a) Exported (<i>state countries</i>) (b) Local market	 (a) United States of America (b) New Zealand
8. Labelling instructions	In accordance with IAIS 002 and IAIS 004 – USA requirements.
9. Special distribution controls required	Maintain frozen temperature at -18 °C or colder. Documentation to accompany product for recall requirements.

Food Safety Objectives

1. To ensure that all mussel product sampled and tested as per IAIS 003.9 meets the current requirements for *Listeria monocytogenes*.
2. To ensure that all shellstock meets the current requirements of IAIS 005 for microbes, marine biotoxins and toxic substances by only sourcing shellstock from approved growing areas which are open at the time of harvest.

Form 2: Description of Raw Materials and Other Inputs	
Product name: Half-shell mussels (<i>Perna canaliculus</i>)	
Raw material/Other inputs	Description/Specifications
Shellstock	Accepted according to IAIS 005.1
Ice and water	Refer to water monitoring programme
Packaging	Letter of guarantee from supplier

Form 3: Process Flow Diagram		
Process: Heat shocked, shucked and frozen half-shell mussels		
Inputs*	Process steps	Edible Outputs
Shellstock ▶ Ice Glazing solution ▶ Packaging ▶	1. Receive 2. Chill/store 3. Grade 4. Heat shock 5. Chill 6. Shuck 7. Grade 8. Freeze 9. Glaze 10. Pack 11. Store (frozen)	▶ Mussel meat ▶ Mussel meat ▶ Frozen half-shell mussels

* Inputs are restricted to those consumable or non-consumable items added to the product during the process.

Form 4: Task Descriptions

No examples of task descriptions are given as these are considered specific for each process and facility.

Form 5a: Raw Material Hazard Identification			
Raw material	Hazard	Processor-controlled?	Control measure
Mussels	Biological		
	B1 - Internal microbiological hazards e.g. Faecal coliforms, <i>Vibrio</i> spp, pathogenic viruses	Yes	Sourcing from approved growing areas, Heat shocking Temperature control
	B2 - External microbiological hazards associated with seabird, rodent excreta and other extraneous materials e.g. <i>Salmonella</i> spp, <i>Campylobacter jejuni</i> , <i>Listeria monocytogenes</i> *	Yes	See prerequisite requirements for receipt of incoming material "Reception of Fish Programme"
	B3 - Marine biotoxins	Yes	Sourcing from approved growing areas
	Chemical		
	C1 - Pollutants derived from harvest areas, harvest operations or transporation, e.g. fuel oil, heavy metals and other chemical residues	Yes	Sourcing from approved growing areas See prerequisite requirements for receipt of incoming material "Reception of Fish Programme"
	Physical		
	Nil		

* Published work indicates that *Listeria monocytogenes* is more likely to be external contaminant of shellstock from harvesting onwards, rather than an internal contaminant of the raw material in the marine environment.

Form 5b: Process Step Hazard Identification				
Process Step	Raw material hazards*	Other input/ process step hazards#	Processor-controlled? (Input/step hazards)	Control measure (Input/step hazards)
1. Receive	B1, B2, B3, C1	Nil		
2. Chill/store	B1, B2	Pathogen growth (temperature abuse)	Yes	Via prerequisite programme with time/temperature control and production control.
3. Grade	B1, B2	Nil		
4. Heat shock	B1, B2	Nil		
5. Chill		Pathogen growth (temperature abuse)	Yes	Via prerequisite programme with time/temperature control and production control.
6. Shuck		Nil		
7. Grade		Nil		
8. Freeze		Pathogen growth (temperature abuse)	Yes	Via prerequisite programme with time/temperature control and production control.
9. Glaze		Nil		
10. Pack		Nil		
11. Freezer store		Pathogen growth (temperature abuse)	Yes	Via prerequisite programme with time/temperature control and production control.

* See explanatory text for hazard types in Form 5a.

Note that other food safety hazards such as those associated with cross contamination from personnel to product should be addressed in the appropriate prerequisite programme.

Form 6: CCP Determination					
Process step	Identified hazard	Q1. Could the hazard be present in or on the product* at unacceptable** levels at this step? If yes – give reasons and go to Q2 If no – not a CCP. Proceed to next identified hazard	Q2. Is there a control measure available at this step that would prevent unacceptable** levels of the hazard? If yes – this step is a CCP. Answer Q3 If no – not a CCP. Answer Q3.	Q3. Is there a control measure available at a previous step which would significantly contribute to preventing unacceptable** levels of the hazard at this step? If yes – retrospectively assign the previous step as a CCP If no – if the answer to Q2 also was also no, consider whether any subsequent steps can control the hazard or whether redesign of the process /product is necessary to ensure a control measure is available Proceed to the next identified hazard	CCP No:
1. Receive	B1	Yes – product could be from closed harvest area, shellstock temperature - abused, causing pathogen growth	Yes – source; time/temperature controls for shellstock from harvesting	No	CCP 1
	B2	Yes – contamination from transport, containers	Yes – cleanliness check	No	CCP 1
	B3	Yes – product could be from closed harvest area	Yes – source	No	CCP 1
	C1	Yes – pollution within harvest area	Yes – source	No	CCP 1
2. Chill/store	B1	No – level of pathogens acceptable as shellstock only accepted from areas open for harvest			
	B2	Yes – shellstock may be contaminated with <i>L. monocytogenes</i> externally	No	Yes – cleanliness of incoming shellstock at process step 1	
3. Grade	B1	No – level of pathogens acceptable as shellstock only accepted from areas open for harvest			
	B2	Yes – shellstock may be contaminated with <i>L. monocytogenes</i> externally	No	Yes – cleanliness of incoming shellstock at process step 1	

Form 6: CCP Determination Continued

Process step	Identified hazard	Q1. Could the hazard be present in or on the product* at unacceptable** levels at this step? If yes — give reasons and go to Q2 If no — not a CCP. Proceed to next identified hazard	Q2. Is there a control measure available at this step that would prevent unacceptable** levels of the hazard? If yes — this step is a CCP. Answer Q3 If no — not a CCP. Answer Q3.	Q3. Is there a control measure available at a previous step which would significantly contribute to preventing unacceptable** levels of the hazard at this step? If yes — retrospectively assign the previous step as a CCP If no — if the answer to Q2 also was also no, consider whether any subsequent steps can control the hazard or whether redesign of the process /product is necessary to ensure a control measure is available Proceed to the next identified hazard	CCP No:
4. Heat shock	B1	No — level of pathogens acceptable as shellstock only accepted from areas open for harvest			
	B2	Yes — shellstock may be contaminated with <i>L. monocytogenes</i> externally	Yes — size, speed, temperature/time requirements	Yes — cleanliness of incoming shellstock at process step 1	CCP 2
5. Chill					
6. Shuck					
7. Grade					
8. Freeze					
9. Glaze					
10. Pack					
11. Freezer store					

* Product is the edible component of final product.

** Unacceptable should be demonstrated by data (scientific literature, applied research or on-site experience) associated with achieving the FSOs established for the process. In determination of unacceptability, hazards should be considered in terms of frequency of occurrence, level of occurrence, transfer and redistribution and severity of effect on consumer.

Form 7: HACCP Plan Summary Spreadsheet – Mussels

Process step	Hazard Identification	CCP no:	Critical limits	Monitoring procedures/tools (consider, who, what, when and how)	Corrective action procedures	Verification procedures*	HACCP records
1. Receive	B1,B2, B3, C1	1	Accept shellstock only as per IAIS 005.1 Accept shellstock only if time/temperature parameters of shellstock from harvest to packhouse are met (IAIS 005) including $\leq 16\text{ }^{\circ}\text{C}$ / $>24\text{hrs}$ after harvest. Accept “clean” shellstock (as defined in IAIS 005).	100% of all incoming lots Check all incoming lots	Retain affected product until info available Reject from process if from closed harvest area Reject if temperature controls are not met. Pre-wash (B2)	Validation of FSOs Internal audit External audit HACCP review	Validation report Harvest declarations Labels CCP monitoring sheet Audit report Review report
2. Chill/store							
3. Grade							
4. Heat shock	B2	2	Time/temperature parameters with reference to mussel size and speed of conveyor	Time/temp checks (auto/manual)	Retain affected product Adjust time/temperature parameters to suit mussel size and speed of conveyor Reprocess (undercooked) Regrade for mussel meat/marinated product	Validation of FSOs Calibration checks on equipment Internal audit External audit HACCP review Product test	Validation report CCP monitoring sheet CATR record Calibration record Audit report Review report Product test results
5. Chill							
6. Shuck							
7. Grade							
8. Freeze							
9. Glaze							
10. Pack							
11. Freezer store							

* Includes food safety objectives being met on a regular basis.

II.3 Generic Model for Oysters

Prerequisite Requirements		
<i>(tick boxes if the premises complies)</i>		
Programme	Complies with IAISs ✓	Documented ✓
Cleaning and sanitation (Hygiene of facilities and equipment including both pre-operational and operational)		
Hygiene of personnel (training, health, personal habits, protective clothing)		
*Reception of fish		
*Incoming materials (ingredients, food additives, wrapping and packaging)		
Product recall		
Repairs and maintenance		
*Storage and transport, including temperature controls		
Training		
Vermin control		
*Water and ice potability (including clean seawater)		
Waste management (inedible product management, dropped product)		

* Aspects of these prerequisite programmes are also considered in the HACCP plan.

Scope

HACCP application

Food Safety

Product

Pottled oysters

Process

Receipt of live shellstock through to chilled storage of pottled oysters.

Form 1: Product Description and Intended Use	
1. Product name(s)	Pottled pacific oysters (<i>Crassostrea gigas</i>).
2. Important product characteristics	Shucked, chilled, pottled in brine.
3. How is it to be used? (a) By a further processor (b) By the consumer	 (b) Eaten raw/further cooked.
4. Intended consumer	General public
5. Packaging	Plastic pottles
6. Shelf-life and storage requirements	7 days under chilled conditions at 4 °C or cooler
7. Where it will be sold (a) Exported (<i>state countries</i>) (b) Local market	 (a) Australia (b) New Zealand
8. Labelling instructions	In accordance with IAIS 004 and IAIS 002 — Australian requirements.
9. Special distribution controls required	Maintain chill temperature at 4 °C.

Food Safety Objectives

1. To minimise microbiological hazards associated with pottled oysters by application of a HACCP plan that achieves specified microbiological targets for:
 - aerobic plate count per g @ $n=5$, $c=1$, $m=10^5$ and $M=5 \times 10^5$
 - *E.coli* per gram @ $n=5$, $c=1$, $m=2.5$, $M=7$
2. To ensure that all shellstock are sourced from approved growing areas which are open at the time of harvest (covering microbiological, biotoxin and chemical hazards).
3. To ensure no sample of final product has shell pieces present, where shell pieces are considered significant enough to formulate an objective.

Form 2: Description of Raw Materials and Other Inputs	
Product name: Pottled pacific oysters (<i>Crassostrea gigas</i>)	
Raw material/Other inputs	Description/Specifications
Shellstock	Accepted according to IAIS 005.1
Salt	Refer to prerequisite programme Guaranteed food grade
Packaging	Letter of guarantee from supplier

Form 3: Process Flow Diagram		
Process: Shucked, chilled and pottled oysters		
Inputs*	Process steps	Outputs
Shellstock ▶ Pottles ▶ Salt ▶	1. Receive 2. Wash/grade 3. Chill 4. Shuck 5. Pack 6. Chill/store	▶Shells ▶Chilled pottled oysters

* Inputs are restricted to those consumable or non-consumable items added to the product during the process.

Form 4 should be completed for each step in the particular process.

Form 5a: Raw Material Hazard Identification for Oysters

Raw material	Hazard	Processor-controlled?	Control measure
Oysters	Biological B1 - Intrinsic microbiological hazards e.g. <i>Salmonella</i> spp, <i>Vibrio</i> spp, <i>Listeria monocytogenes</i> *, pathogenic viruses	Yes	Sourcing from approved growing areas, temperature control
	B2 - Microbiological hazards associated with seabird, rodent excreta and other extraneous materials e.g. <i>Salmonella</i> spp, <i>Campylobacter jejuni</i> , <i>Listeria monocytogenes</i>	Yes	See prerequisite requirements for receipt of incoming material "Reception of Fish Programme"
	B3 - Marine biotoxins	Yes	Sourcing from approved growing areas
	Chemical C1 - Pollutants derived from harvest areas, harvest operations or transporation, e.g. fuel oil, heavy metals and other chemical residues	Yes	Sourcing from approved growing areas See prerequisite requirements for receipt of incoming material "Reception of Fish Programme"
	Physical P1 - Shell #	Yes	Shucking

* *Listeria monocytogenes* has been found in the raw material sampled at growing sites.

Shell should be considered by the premises and a decision made as to whether it is relevant for that specific process.

Form 5b: Process Step Hazard Identification				
Process Step	Raw material hazards*	Other input/process step hazards[#]	Processor-controlled? (Input/step hazards)	Control measure (Input/step hazards)
1. Receive	B1, B2, B3, C1	Nil		
2. Wash/grade	B1, B2	Nil		
3. Chill/store	B1, B2	Pathogen growth (temperature abuse)	Yes	Under prerequisite programme with time/temperature control and production control.
4. Shuck	B1, B2, P1	Nil		
5. Pack	B1, B2	Nil		
6. Chill/store	B1, B2	Pathogen growth (temperature abuse)	Yes	Under prerequisite programme with time/temperature control and production control.

* See explanatory text for hazard types in Form 5a.

Note that other food safety hazards such as those associated with cross contamination from personnel to product should be addressed in the appropriate prerequisite programme.

Form 6: CCP Determination

Process step	Identified hazard	Q1. Could the hazard be present in or on the product* at unacceptable** levels at this step? If yes — give reasons and go to Q2 If no — not a CCP. Proceed to next identified hazard	Q2. Is there a control measure available at this step that would prevent unacceptable** levels of the hazard? If yes — this step is a CCP. Answer Q3 If no — not a CCP. Answer Q3.	Q3. Is there a control measure available at a previous step which would significantly contribute to preventing unacceptable** levels of the hazard at this step? If yes — retrospectively assign the previous step as a CCP If no — if the answer to Q2 also was also no, consider whether any subsequent steps can control the hazard or whether redesign of the process /product is necessary to ensure a control measure is available Proceed to the next identified hazard	CCP No:
1. Receive	B1	Yes — product from closed harvest area; Intrinsic pathogens, product temperature - abused	Yes — source; time/temperature controls for shellstock from harvesting	No	CCP 1
	B2	Yes — contamination from transport/containers	Yes — cleanliness check		CCP 1
	B3	Yes — product from closed harvest area	Yes — source	No	CCP 1
	C1	Yes — pollution within harvest area	Yes — source	No	CCP 1
2. Wash/grade	B1	No — product only accepted from open areas			
	B2	No — product accepted as clean at receipt			
3. Chill/store	B1	No — level of pathogens acceptable as not considered unacceptable for raw product			
	B2	No — not considered unacceptable for raw product			
4. Shuck	B1	No — level of pathogens acceptable as not considered unacceptable for raw product			
	B2	Yes — not considered unacceptable for raw product			
	P1	No — shell pieces not considered unacceptable level			
5. Pack	B1	No — not considered unacceptable for raw product			
	B2	No — not considered unacceptable for raw product			

Process step	Identified hazard	Q1. Could the hazard be present in or on the product* at unacceptable** levels at this step? If yes — give reasons and go to Q2 If no — not a CCP. Proceed to next identified hazard	Q2. Is there a control measure available at this step that would prevent unacceptable** levels of the hazard? If yes — this step is a CCP. Answer Q3 If no — not a CCP. Answer Q3.	Q3. Is there a control measure available at a previous step which would significantly contribute to preventing unacceptable** levels of the hazard at this step? If yes — retrospectively assign the previous step as a CCP If no — if the answer to Q2 also was also no, consider whether any subsequent steps can control the hazard or whether redesign of the process /product is necessary to ensure a control measure is available Proceed to the next identified hazard	CCP No:
6. Chill/store	B1	No — level of pathogens acceptable as not considered unacceptable for raw product			
	B2	No — not considered unacceptable for raw product			

* Product is the edible component of final product.

** Unacceptable should be demonstrated by data (scientific literature, applied research or on-site experience) associated with achieving the FSOs established for the process. In determination of unacceptability, hazards should be considered in terms of frequency of occurrence, level of occurrence, transfer and redistribution, and severity of effect on consumer.

Form 7: HACCP Plan Summary Spreadsheet – Oysters

Process step	Hazard identification	CCP no:	Critical limits	Monitoring procedures (consider who, what, when and how)	Corrective action procedures	Verification* procedures	HACCP records
1. Receive	B1, B2, B3, C1	1	Accept shellstock only as per IAIS 005.1. Accept shellstock only if time/temperature parameters of shellstock from harvest to packhouse are met (IAIS 005) including $\leq 16^{\circ}\text{C}$ / $>24\text{hrs}$ after harvest. Accept "clean" shellstock (as defined in IAIS 005).	100% of all incoming lots Check all incoming lots	Retain affected product until information available Reject from process if from closed harvest area Reject if temperature controls are not met Rewash (B2)	Validation FSOs Internal audit External audit HACCP review Product test	Validation report CCP monitoring sheet Audit report Review report Product test results
2. Wash/grade							
3. Chill/store							
4. Shuck							
5. Pack							
6. Chill/store							

* Food safety objectives met on a regular basis.

II.4 An Example of a HACCP Plan for Hot Smoked Mussel Meat

1. Prerequisite Programmes

The following are documented prerequisite programmes likely to be present in conjunction with a HACCP plan for hot smoked mussel meat:

- cleaning and sanitation (hygiene of facilities and equipment including both pre-operational and operational);
- personal hygiene (health, personal habits, protective clothing);
- reception of fish;
- incoming materials (ingredients, food additives, wrapping and packaging, storage and handling);
- *Listeria* management (note that parts are included in the HACCP plan);
- raw/cook separation policy (includes product and personnel flow);
- nonconforming product, product recall;
- repairs and maintenance;
- storage and transport including refrigeration management;
- training;
- vermin control;
- water/ice potability (including clean seawater);
- waste management (inedible product management, dropped product).

2. Scope of HACCP Plan

HACCP application: Food safety

Product: Chilled/frozen vacuum-packed hot smoked mussel meat

Process: Shucked mussel meat is hot smoked, flavoured, vacuum-packed, chilled/frozen and dispatched in chilled/frozen form.

3. Product Description and Intended Use

Form 1: Product description and intended use

1.	Product name(s)	Chilled/frozen vacuum packed hot smoked mussel meat
2.	Important product characteristics	Mussel meat sourced from a licenced export premises. Cooked, ready-to-eat Vacuum-packed Chilled/frozen
3.	How is it to be used? a. By a further processor or retailer b. By the consumer	a. Not applicable b. Ready to eat
4.	Intended consumer	General public ("high-risk" groups not specified)
5.	Packaging	Company/regulatory specification
6.	Shelf life and storage requirements	Company/regulatory specification
7.	Where it will be sold a. Export market b. Local market	a. List countries, if applicable b. Local supermarkets, hospitality trade, catering
8.	Labelling instructions	Company/regulatory specification
9.	Special distribution controls required	Company/regulatory specification

4. Initial Food Safety Objectives

(To be confirmed after hazard analysis and CCP determination. See Section 8 for confirmed objectives.)

- To achieve a *Listeria monocytogenes*-free product by application of a validated process and the product testing requirements of IAIS 003.9.
- To ensure that temperature controls less than 3.3 °C are met to prevent *Clostridium botulinum* toxin production taking place.
- To minimise the presence of shell pieces to specified targets.

5. Process Flow Diagram

Form 2: Description of incoming materials /other inputs

Product name: Chilled vacuum-packed hot smoked mussel meat	
Incoming material/other inputs	Description/specifications
Heat shocked mussel meat	From export licensed premises operating under a HACCP plan
Smoke	From non-tanalised wood. Meets NZ Food Regulations 1984
Oil mixture ¹	Meets requirements for additives and ingredients as in IAIS 003.1 and company specifications for preparation and storage
Other inputs ² – food contact packaging materials ³	Suitable for use as food contact materials

1. The preparation of the oil mixture is subject to a separate HACCP plan.
2. Inputs are defined as materials such as consumable or non-consumable items added to the product during the process. These inputs and their hazards may be addressed by a prerequisite programme, have their own HACCP plan or be specifically considered during hazard identification in this HACCP plan.
3. Specifications and hygienic handling of these materials are covered by the premises' prerequisite programme for food contact materials.

Form 3: Process flow diagram

Process: Chilled/frozen vacuum-packed hot smoked mussel meat		
Inputs	Process steps	Edible outputs
Shocked mussel meat ▶	1. Receipt of chilled/frozen cartons of shucked mussel meat ▼	
	2. Storage of mussel meat in chiller/freezer ▼	
	3. Decartoning and thawing frozen mussel meat ▼	
	4. Loading smoker ▼	
Smoke ▶	5. Smoking and cooking mussel meat ▼	
Plastic bags ▶	6. Removing mussel meat from smoker, bagging and placing in chiller ▼	
	7. Chilling ▼	
Barrier bags/trays ▶	8. Packing mussel meat ▼	
Prepared oil mixture ▶	9. Addition of oil mixture ▼	
Barrier film ▶	10. Vacuum sealing and labelling ▼	
	11. Chilling/freezing ▼	
	12. Dispatch	▶ Chilled/frozen vacuum-packed hot smoked mussel meat

7. Hazard Analysis and CCP Determination

7.1 Incoming material hazard identification

Form 5a: Hazard identification for heat shocked mussel meat

Incoming material	Biological hazard	Chemical hazard	Physical hazard ²
Heat shocked mussel meat	B1 ¹ – Microbiological hazards associated with incoming material, e.g. <i>Listeria monocytogenes</i>	Not applicable	P1 – Shell pieces

1. *Listeria monocytogenes* has been found in the incoming material, even though it has previously been heat shocked.

There is currently no published evidence of *Clostridium botulinum* type E being found in New Zealand seafood. Other relevant *Clostridium botulinum* types are not considered reasonably likely to occur. See background information attached.

2. When customising this HACCP plan, individual premises may wish to add other physical hazards, such as plastic fragments, if these hazards are relevant to their incoming material.

7.2 Hazard analysis and CCP determination (incoming material, other inputs and process steps)

Hazard analysis may result in changes to the initial food safety objectives set in Section 4. See Section 8 for confirmed objectives.

Form 5b: Hazard analysis and CCP determination (incoming material, other inputs and process steps)¹

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product ¹ at unacceptable levels ² at this step? If yes, answer Q2 and Q3. If no, then GMP is controlling the hazard in a satisfactory manner.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs			Yes/No	Justification			
	Component	Hazards	Component	Hazards						
1. Receipt	Mussel meat	B1				Yes	Presence of <i>L. monocytogenes</i> unacceptable in relation to expected FSO. Refer to Annex, Section 1.2.	No	No	
		P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	
2. Storage	Mussel meat	B1				Yes	Presence of <i>L. monocytogenes</i> unacceptable in relation to expected FSO. Refer to Annex, Section 1.2.	No	No	

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product ¹ at unacceptable levels ² at this step? If yes, answer Q2 and Q3. If no, then GMP is controlling the hazard in a satisfactory manner.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs			Yes/No	Justification			
	Component	Hazards	Component	Hazards						
					(ii) Pathogen growth	No				
		P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	
3. Decartoning /thawing	Mussel meat	B1				Yes	Presence of <i>L. monocytogenes</i> unacceptable in relation to expected FSO. Refer to Annex, Section 1.2.	No	No	
					(ii) Pathogen growth	No				
		P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product ¹ at unacceptable levels ² at this step? If yes, answer Q2 and Q3. If no, then GMP is controlling the hazard in a satisfactory manner.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs			Yes/No	Justification			
	Component	Hazards	Component	Hazards						
4. Loading smoker	Mussel meat	B1				Yes	Presence of <i>L. monocytogenes</i> unacceptable in relation to expected FSO. Refer to Annex, Section 1.2.	No	No	
		P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	
5. Smoking and cooking	Mussel meat	B1				Yes	Presence of <i>L. monocytogenes</i> unacceptable in relation to expected FSO. Refer to Annex, Section 1.2.	Yes - heat treatment	No	1
		P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product ¹ at unacceptable levels ² at this step? If yes, answer Q2 and Q3. If no, then GMP is controlling the hazard in a satisfactory manner.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs			Yes/No	Justification			
	Component	Hazards	Component	Hazards						
			Smoke	None						
6. Removing, bagging and placing in chiller	Mussel meat	P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	
					(i) B3 - Recontamination of cooked product with pathogens	No				
			Plastic bags	None						
7. Chilling	Mussel meat	P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	No	No	
		B3				No				
					(ii) Pathogen growth	No				

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product ¹ at unacceptable levels ² at this step? If yes, answer Q2 and Q3. If no, then GMP is controlling the hazard in a satisfactory manner.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs			Yes/No	Justification			
	Component	Hazards	Component	Hazards						
8. Packing	Mussel meat	P1				Yes	Shell pieces in mussel meat unacceptable if exceeding the expected FSO. Refer to Annex, Section 2.1.	Yes - inspection for shell pieces	No	2
		B3				No				
					(i) B3 - Recontamination of cooked product with pathogens	No				
			Barrier bags/trays	None						
9. Addition of oil mixture	Mussel meat	B3				No				
					(i) B3 - Recontamination of cooked product with pathogens	No				
			Prepared oil mixture	None						

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product ¹ at unacceptable levels ² at this step? If yes, answer Q2 and Q3. If no, then GMP is controlling the hazard in a satisfactory manner.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs			Yes/No	Justification			
	Component	Hazards	Component	Hazards						
10. Vacuum sealing and labelling	Mussel meat	B3				No				
			Barrier film	None						
11. Chilling /freezing	Mussel meat	B3				No				
12. Dispatch	Mussel meat	B3				No				

1. B – Biological
 - B1 – Microbiological hazards associated with incoming material, e.g. *Listeria monocytogenes*
 - B2 – Microbiological hazards associated with inputs, e.g. *Listeria monocytogenes*, *Staphylococcus aureus* (none found in this plan)
 - B3 – Microbiological hazards associated with contamination due to a process step deficiency, e.g. *Listeria monocytogenes*, *Staphylococcus aureus*
 - C – Chemical
 - C1 – Chemical hazards associated with incoming material (none found in this plan)
 - C2 – Chemical hazards associated with inputs (none found in this plan)
 - C3 – Chemical hazards associated with process step (none found in this plan)
 - P – Physical
 - P1 – Physical hazards associated with incoming material
 - P2 – Physical hazards associated with inputs (none found in this plan)
 - P3 – Physical hazards associated with process step (none found in this plan)
2. Product – edible component of final product
3. Unacceptable – as demonstrated by data (scientific literature, applied research or on-site experience) associated with achieving the FSOs established for the process. In determination of unacceptability, hazards should be considered in terms of frequency of occurrence; level of occurrence; transfer and redistribution; and severity of effect on consumer.

8. Confirmed Food Safety Objectives (FSOs)

FSO 1: To achieve a *Listeria monocytogenes*-free product by application of a validated process and the product testing requirements of IAIS 003.9.

FSO 2: To minimise recontamination of cooked smoked product to within specified microbiological targets.

FSO 3: To minimise the presence of shell pieces to specified targets.

9. Completion of the HACCP Plan

Full documentation is required for each of the remaining elements of the HACCP plan:

- critical limit setting;
- monitoring procedures;
- corrective action procedures;
- verification procedures including validation;
- documentation and recordkeeping procedures.

Form 6 is intended to provide a **summary** of the HACCP plan. References to documented procedures should be shown in this form.

10. Critical Limits

The rationale for the critical limits should be fully documented as part of the HACCP plan.

Example: CCP1: Internal core temperature minimum: e.g. 72 °C for 4.41 seconds (Bremer 1998) for a 9D reduction process

CCP2: All visible shell pieces greater than 5 mm removed (customer complaint file, premises trial data)

11. Monitoring Procedures

Monitoring procedures should be fully documented as part of the HACCP plan. Monitoring parameters should include information on who is responsible for monitoring, what method is to be used, where monitoring is done and how frequently it should be performed.

11.1 Responsibilities

Example: CCP1: Operator — monitoring cook/smoke process parameters.

CCP2: Operator — inspecting the product during packing.

11.2 Method

Example: CCP1: What: Core temperature/time.

How: Temperature recorder.

Where and when: Each batch.

CCP2: What: Mussel meat

How: Visual observation of all product for shell pieces.

Where and when: At packing. Each batch.

11.3 Records

Results to be recorded immediately on the record sheet. Time, date and initials/signature of person recording the results to be entered on the sheet.

Example: CCP1: CCP monitoring sheet

CCP2: CCP monitoring sheet.

12. Corrective Action Procedures

Corrective action responsibilities and procedures should be fully documented as part of the HACCP plan.

12.1 Responsibilities

Example: CCP1: Operator — monitoring cook/smoke process parameters

CCP2: Operator — monitoring packing step

12.2 Actions

Example: CCP1: Reprocess to correct temperature and time.

CCP2: Remove shell pieces. Reinspect product. Feedback to supplier through Supervisor/QA Manager.

Actions to be recorded immediately on the record sheet. Time, date and initials/signature of person recording the results to be entered on the sheet. Any follow up activities to be noted.

12.3 Records

Example: CCP1 and CCP2: Corrective action/comment section of CCP monitoring sheet.

13. Verification of the HACCP Plan

Verification responsibilities and procedures should be fully documented as part of the HACCP plan.

13.1 Responsibilities

Example: Internal verification: Supervisor or QA Manager

13.2 Validation of the HACCP plan

Validation of the HACCP plan involves the initial confirmation that the HACCP plan is complete and will achieve each of the food safety objectives. Identified CCPs should be evaluated to ensure that the control measure applied at that particular process step will achieve or contribute to the achievement of the relevant food safety objective (FSO).

An example of how this generic HACCP plan may be validated is given below:

FSO 1: To achieve a *Listeria monocytogenes*-free product by application of a validated process and the product testing requirements of IAIS 003.9.

FSO1 is expected to be achieved by CCP 1 (smoking and cooking) and effective prerequisite programmes (e.g. personal hygiene, cleaning and sanitation, *Listeria* management programme, storage and transport). Prerequisite programmes are to be validated in accordance with IAIS requirements.

CCP1 (Smoking and cooking)

Considerations for validation of the smoke/cook process are described in detail by Bremer (1998), and focus on the following critical factors:

- the number of contaminating bacteria expected to be present in the incoming material;
- the core temperatures obtained by the product during processing;
- the temperature variations in different parts of the kiln;
- the thermal death point of *L. monocytogenes*;
- the addition of smoke.

This means establishing a thorough knowledge of smokehouse performance (including temperature capability and possible variation) in conjunction with the nature of the incoming material. Microbiological sampling of final product will confirm the expected outcome of an individual smoke/cook process (given effective prerequisite programmes as above).

Where smokehouse validation has been achieved prior to implementing HACCP, historical data may be used for evaluating this CCP, provided no significant changes have occurred (e.g. changes to premises, product, process, intended use of the product) with the application of HACCP. Companies that do not have a relevant database should implement an appropriate standardised microbiological sampling programme and collect new data from the time the HACCP plan is implemented.

The following is an example of an appropriate design for microbiological validation in the absence of benchmark or historical data:

Sample size: 25 samples or as many samples as determined by statistical techniques. (Under most New Zealand situations, a sample size of 25 will provide a basis for statistical comparison.)

Sample time frame: Two week period. Random selection of five sampling days, random selection of five samples per day.

Methodology: As per requirements of IAIS 003.9.

FSO2: To minimise recontamination of product to within specified microbiological targets.

FSO2 is expected to be achieved by effective prerequisite programmes (e.g. personal hygiene, cleaning and sanitation, *Listeria* management programme, storage and transport). Prerequisite programmes are to be validated in accordance with IAIS requirements and should consider guidelines with respect to cooked, ready-to-eat product, e.g. MOH, Codex.

FSO3: To minimise the presence of shell pieces to specified targets.

FSO 3 is expected to be achieved by CCP2 (packing). Historical data may be used for evaluating this CCP, as long as no change has occurred to product/ process with the application of HACCP. Data obtained before the HACCP plan implementation (i.e. historical data) should be compared to data obtained after HACCP implementation to ensure that the HACCP plan is at least equivalent to GMP-based controls at the premises.

Guidance on establishing sampling regimes for validation using visual observation may be obtained from publications on statistical process control. The sampling programme for validation (whether considering historical or new data) should be based on application of statistical techniques which take into consideration, the prevalence of the hazard, the level of confidence expected and the accuracy the processor wants to achieve.

13.3 Ongoing verification

Example:

Internal audit/reviews of CCP monitoring and corrective action taking shall be carried out as necessary to verify compliance with the HACCP plan requirements. This will change, according to HACCP plan performance.

Initial frequency: Once per day.

Next frequency: Once per week (when programme can demonstrate consistent compliance, e.g. two weeks satisfactory results).

Product sampling frequency for shell shall be determined according to the prevalence of the hazards, i.e. suppliers' performance.

Product shall be sampled on an ongoing basis for *L. monocytogenes* as per current IAIS 003.9 requirements.

Calibration of instruments associated with the temperature and time measuring devices of the smoker/cooker will be carried out annually and in accordance with the manufacturers' recommendations.

Feedback from all extrinsic audits/reviews of the HACCP plan will be considered. Action will be taken as necessary and recorded in a written report. Changes to the HACCP plan will be documented.

13.4 Revalidation

Revalidation of the HACCP plan is required, whenever changes are made (e.g. changes to premises, product, process, intended use of the product) or when process failure that may compromise product safety occurs.

Example:

A full HACCP plan review will occur at least once per annum or sooner if required by events such as audit findings, changes to the product or process and new food safety hazards.

13.5 Records

Records will be kept of all verification activities mentioned above.

14. Documentation and Recordkeeping Procedures

Documentation must be available to support all aspects of the HACCP plan.

Example:

Background rationale for hazard identification and CCP selection are to be appended to this HACCP plan as Annex 1. Rationale for critical limits are supported by scientific papers or data files referenced in this plan.

Blank copies of selected record sheets for CCP monitoring, corrective action taking and verification activities may be appended to the HACCP plan (not available in this generic plan). All completed HACCP records (monitoring, corrective actions, verification) will be maintained for three years.

Form 6: HACCP plan summary spreadsheet for hot smoked mussel meat

Process step	Hazard ID	CCP no:	Critical Limits	Monitoring procedures/tools (consider who, what, when, how)	Corrective actions	Verification procedures	HACCP records
1. Receipt							
2. Storage							
3. Decartoning /thawing							
4. Loading smoker							
5. Smoking / cooking	B1 - pathogens (<i>Listeria monocytogenes</i>)	1	Core temperature and time measurements as appropriate to the required "D" reduction of <i>L. monocytogenes</i> (see Bremer, 1998)	<p>Who: Operator</p> <p>What: Core temperature /time measurements</p> <p>When: Every batch</p> <p>How: Temperature recorder/timer</p>	<p>Who: Operator</p> <p>What: Re-heat to correct temperature and time</p>	<p>Who: Supervisor/ QA Manager</p> <p>What: FSO validation Product sampling Internal audit Calibration of instruments HACCP review</p> <p>Other: Extrinsic audit</p>	<p>CCP monitoring sheet</p> <p>Corrective action report</p> <p>Validation report</p> <p>Internal audit report</p> <p>Microbiological report</p> <p>Calibration record</p> <p>HACCP review records</p> <p>Extrinsic audit report</p>
6. Removing mussels from smoker to chiller							
7. Chilling							

Process step	Hazard ID	CCP no:	Critical Limits	Monitoring procedures/tools (consider who, what, when, how)	Corrective actions	Verification procedures	HACCP records
8. Packing	P1 – shell	2	No shell pieces > target size	Who: Operator What: All product How: Visual observation When: Each batch	Who: Operator What: Remove shell and reinspect. Feedback to supplier via Supervisor/QA Manager	Who: Supervisor/QA Manager What: FSO validation Internal audit Consumer feedback Extrinsic audit Product sampling HACCP review Others: Extrinsic audit	CCP monitoring sheet Corrective action report Validation report Internal audit report Consumer feedback report Product test report HACCP review records Extrinsic audit report
9. Addition of oil mixture							
10. Vacuum sealing and labelling							
11. Chilling/freezing							
12. Dispatch							

Annex to the Example of a HACCP Plan for Hot Smoked Mussel Meat

1. Biological and chemical hazards

1.1 Incoming material

Shucked mussel meat from New Zealand fish packhouses onsold as incoming material for further processing (e.g. for hot smoked mussel meat) has some clear food safety expectations associated with it. Hazards associated with shellstock are discussed in some detail in the current Industry Agreed Implementation Standards (FIICC, 1995). This includes the fact that the shellstock are to be sourced and processed in accordance with the current requirements of these standards which should minimise incoming material hazards such as marine biotoxins and pathogenic organisms associated with polluted shellfish growing waters.

1.2 Pathogenic Bacteria

Listeria monocytogenes

Whether *Listeria monocytogenes* is a natural contaminant of the incoming mussel or arises as a contaminant during processing is unresolved (Bremer and Osborne, 1996). Current opinion, however, supports cross-contamination during processing as the major source of *Listeria* for processed product (Bremer and Osborne, 1996).

After application of a heat shock process step, the product standard for *Listeria monocytogenes*, as per the Fishing Industry Agreed Implementation Standards (FIICC, 1995), is that on a monthly basis, five samples of each type of product in its final packaging, randomly selected from the same batch, are to be free from *L. monocytogenes* ($n = 5$, $c = 0$, $m = 0$). Although assumptions are readily made that heat-shocked product is free from *L. monocytogenes*, this is not always the case (Baker and Wilson, 1993). Processors of value-added product using heat-shocked mussel meat as incoming material, and setting their own food safety objective of zero *L. monocytogenes* in final product, therefore have to ensure that they have effective prerequisite programmes and a validated listericidal step (Bremer, 1998) within their own process, in order to achieve this objective.

Clostridium botulinum

The non-proteolytic strains of *Clostridium botulinum* are most commonly associated with the marine environment (Hauschild, 1989; Fletcher, 1996; USFDA, 1998) and are of most concern to the seafood industry. Critical growth conditions for these non-proteolytic strains have been highlighted (Fletcher, 1996; USFDA, 1998).

Clostridium botulinum has been found in New Zealand waters (Gill and Penney, 1982) but no evidence of types toxic to man was found. To date, only two (related) cases of botulism have been recorded in New Zealand (Flacks, 1985) and the associated toxin type was type A. Home-preserved mussels and watercress were implicated in these cases.

2. Physical hazards

2.1 Incoming material

Shell pieces and polyentrapment (plastic retention) can be a problem for some processors when using frozen blocks of shucked mussel meat (pers. comm.). Control measures for shell pieces include selection of appropriate suppliers and on-line observation of product. Control measures for polyentrapment include careful observation for plastic remnants amongst mussel meat after thawing.

References

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Bremer, P. (1998) Guidelines for the safe preparation of hot-smoked seafood in New Zealand. In press.

Bremer, P. and Osborne, C. (1995) Thermal-death times of *Listeria monocytogenes* in green shell mussels (*Perna canaliculus*) prepared for hot smoking. *J Food Prot* 58:(6) 604-608.

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Hauschild, A.H.W. (1989) Chapter 4: *Clostridium botulinum* In *Foodborne Bacterial Pathogens*. (Ed. Doyle, M.P) Marcel Dekker, Inc. New York.

Ministry of Health (1995) Microbiological Reference Criteria for Food. Ministry of Health, Wellington.

USFDA (1998) Fish and Fishery Products Hazards and Controls Guide. Second edition. Food and Drug Administration. Washington, D.C.

Appendix III. Training Programmes

Introduction

Training guidelines have been developed by the HACCP Steering Group in response to an urgent need by both industry and regulators for a meaningful HACCP training package that will clearly show personnel involved in the provision and receipt of HACCP training expected outcomes for participants/trainees. However, the guidelines are not meant to assess these training outcomes.

Using these guidelines as a base, HACCP unit standards will also be developed and registered with the New Zealand Qualifications Authority. These standards will have associated assessment criteria which will be used to determine whether a person has met the standard. Assessing the outcomes of prior learning against the standard is also possible.

Briefing Executive Managers about HACCP

Purpose

This briefing is designed for senior managers and executives of food businesses planning to introduce HACCP-based food safety systems. It provides a broad overview of HACCP and the context in which HACCP should be utilised.

Suggested Duration

Two hours.

Pre-requisite Requirements for Participants

Not applicable.

Items for the Trainer to Consider

Use examples of:

- success and failure relating to food safety,
- application of HACCP principles,
- each category of hazard,
- market access requirements,
- other benefits.

Learning Objectives

After attending this briefing, the participant should be able to:

1. Recognise the food industry's role in managing food safety issues:
 - understand the importance of HACCP to the Food Industry,
 - understand the benefits and costs to the Industry,
 - understand how the Industry and Government can work together to effectively ensure food safety.
2. Understand what HACCP is and why the Food Industry should embrace it:
 - be aware of the history of HACCP and its food safety core,
 - be able to generally compare HACCP to other systems, including sanitation, GMP and quality systems, e.g. ISO, TQM,
 - have a basic understanding of the seven principles of HACCP.

3. Recognise the threats to food safety and where they can be found:
 - appreciate all potential sources of hazards “from preharvest to table”,
 - understand the categories of hazards (biological, chemical, physical).
4. Recognise the relationship between current regulatory and legislative requirements and HACCP:
 - understand the New Zealand regulatory agencies’ approach to HACCP,
 - understand the position of HACCP in the international market place,
 - appreciate the role of the Codex Alimentarius Commission in ensuring the consistency HACCP worldwide,
 - be aware of current variations in the interpretation and promotion of HACCP around the world.
5. Recognise the role of on-going management in the implementation of the HACCP plan:
 - appreciate the importance of on-going management commitment,
 - appreciate the need to identify and provide resources (including obtaining help on HACCP elsewhere, e.g. industry codes of practice),
 - realise the associated implementation costs compared to benefits,
 - understand the need for specific employee training.

Training of the HACCP Co-ordinator

Purpose

This training guideline is designed for the person who would become the primary co-ordinator of the development and implementation of the HACCP system at a food premises.

Suggested Duration

24 hours.

Pre-requisite Requirements for Participants

Background — a minimum or equivalent of:

- Unit No 167 — Food Handling — Produce Safe Food.
- Unit No 168 — Food Handling — Prevent Food Contamination.

Participants will need:

- relevant industrial experience,
- understanding of GMP/SOP (essential),
- quality systems experience (desirable).

Items for the Trainer to Consider

- Present the Codex HACCP guideline as the baseline standard (see bibliography).
- Use case studies relevant to the course participants.
- Some on-site training would be desirable.
- Participants should receive a theoretical and practical assessment of their understanding of HACCP as it pertains to this course. This assessment should include a HACCP plan.

Learning Objectives

After completing this course, and in association with the Codex HACCP guideline and other expertise available within the HACCP team, the participant should be able to:

1. Recognise the relationship between the HACCP system and food safety:
 - explain the relationship between HACCP, food safety and quality management systems,

- discuss the benefits of implementing a HACCP system, which include motivating and selling HACCP to the Industry and reviewing case studies,
 - discuss HACCP and basic food safety principles.
2. Review SOPs and GMP which are not a part of the HACCP plan:
- define SOP,
 - define GMP,
 - discuss the importance of SOPs and GMP,
 - describe how SOPs and GMPs support HACCP plans.
3. Identify product and how hazards relate to it:
- identify types of food items that are produced,
 - discuss the significance of food composition, distribution controls and intended use,
 - define a hazard,
 - understand definitions and principles relative to hazard identification,
 - explain control measures that prevent, reduce, or minimise hazards associated with different types of foods,
 - develop food safety objectives relating to the production of particular foods.
4. Present the principles of HACCP and apply them:
- develop a detailed flow chart of a process and product;
 - discuss the usefulness of task/job descriptions for each process step;
 - conduct and document a hazard analysis of the process and product which includes the following factors:
 - evaluation of the rationale for hazard selection,
 - evaluation of the occurrence of hazards associated with raw material, ingredients and other significant inputs at each process step,
 - evaluation of the significance of hazards in relation to the product, process and end use,
 - evaluation of the preventive/control measures available,
 - awareness of the need to evaluate the nature and severity of the risk (risk assessment) in relation to the consumer, wherever possible;
 - identify critical control points (CCPs) in the process:
 - define a CCP,
 - identify CCPs by using valid scientific criteria and risk assessment where appropriate;

- establish critical limits for preventive measures associated with each CCP:
 - define and determine critical limits,
 - set critical limits that are relevant to product safety (noting the limitations for raw end product),
 - document the rationale for critical limit selection and its relationship to the food safety status of the end product (noting the limitations for raw end product),
 - ensure critical limits are documented and measurable;
- establish CCP monitoring procedures:
 - define monitoring and explain monitoring requirements,
 - recognise the importance of monitoring,
 - identify critical limits to be monitored,
 - identify where measurements will be taken,
 - explain how monitoring is to be conducted,
 - determine the frequency for taking measurements;
- identify who is responsible for monitoring,
 - describe monitoring procedures, sampling plans and the methodology used;
- establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit:
 - define corrective action,
 - develop corrective actions,
 - document corrective actions,
 - identify the personnel responsible for taking correction action;
- establish procedures for verification that the HACCP system is effective:
 - define verification and understand how it differs from monitoring,
 - recognise the importance of verification to support and assure the long term viability of the HACCP plan,
 - discuss the range of activities that can be conducted as part of verification,
 - understand what validation of the HACCP plan means,
 - conduct a HACCP plan review at regular intervals or when significant changes in equipment, ingredients or operating procedures occur,
 - understand what revalidation of the HACCP plan means;
- establish effective documentation and record keeping procedures that fully support the HACCP system:
 - discuss the importance of documentation of all components of the HACCP plan,
 - discuss the importance of record keeping, detailing monitoring outcomes, corrective action taken, verification steps;
- document HACCP plan details:
 - identify what information should be included in records,
 - develop simple, user-friendly records with clear instructions,
 - recognize the importance of reviewing records as part of the verification process;
- understand and be able to use generic HACCP plans for different types of food/end uses.

- compare and contrast HACCP plans for products from different risk categories, e.g. raw frozen; cooked, chilled ready-to-eat; canned product.
5. Implement a HACCP plan:
- describe the commitment from upper management necessary for HACCP to succeed,
 - determine the key factors for successful HACCP implementation, including formulation of the HACCP team,
 - discuss the steps for developing and implementing HACCP in the food premises, including validation of the plan,
 - develop implementation steps supported by GMP/SOPs,
 - determine and convey realistic expectations of time and commitment to the HACCP system,
 - establish a staff training program in accordance with the expectations of the establishment.
6. Understand the factors essential to maintenance and ongoing improvement of the HACCP plan:
- recognise that the establishment is responsible for producing and maintaining the HACCP plan;
 - maintain a staff training programme in accordance with the expectations of the establishment;
 - establish HACCP plan maintenance and measurement procedures:
 - recognise that HACCP systems are dynamic and subject to change/updating,
 - identify factors that significantly impact on a HACCP plan and require review of the system and possible revalidation of the plan,
 - recognise the need for support systems for key personnel (supervisors/operators),
 - recognise the need for ongoing measurement of the effectiveness of the HACCP plans (food safety objectives),
 - evaluate the appropriateness of different measurement tools that are operation/process specific for HACCP systems,
 - evaluate data collected from implementation of HACCP for future improvement.
7. Recognise regulatory issues impacting on the implementation of HACCP systems:
- understand the role of the regulatory authority in a non-mandatory environment,
 - understand the role of the regulatory authority in a mandatory environment.
8. Recognise market access issues impacting on the design and implementation of HACCP systems.

Introduction to HACCP for Supervisors

Purpose

This training guideline is designed to give supervisors in food premises an appreciation of HACCP and their role in supporting a HACCP system.

Suggested Duration

Eight hours.

Pre requisite Requirements for Participants

Not applicable.

Items for the Trainer to Consider

In relation to the learning objectives outlined below:

- Use examples of food-borne illness.
- Use group participation.
- Cover the steps in developing a HACCP plan without being too specific. Use the CCP decision tree as an example only.
- Use a video to reinforce what has been discussed.

Learning Objectives

After attending this introductory course, the participant should be able to:

1. Understand the history of HACCP:
 - know what all the fuss is about,
 - appreciate the rise of reported food-borne related illness/problems,
 - know what HACCP is, where it came from and why.
2. Recognise the benefits of HACCP:
 - understand the need for assurance that food safety hazards are controlled and food safety is enhanced,
 - understand HACCP in relation to market access requirements,
 - have a general understanding of the cost-benefit issues in relation to HACCP.

3. Understand the basic concepts of HACCP:
 - explain what is meant by the scope of HACCP and, where applicable, its relationship to existing quality systems, e.g. ISO, TQM,
 - define and give examples of food safety hazards (biological, chemical and physical), CCPs and critical limits,
 - know what monitoring, corrective action taking, verification and documentation/records means with respect to HACCP.
4. Understand the need for management's commitment to HACCP:
 - know the HACCP policy for the premises.
5. Recognise what makes HACCP work:
 - understand the general responsibilities and commitment of everybody in making HACCP work,
 - understand the importance of prerequisite programmes,
 - be aware of the steps involved in developing a HACCP plan,
 - understand the supervisor's specific role (with prerequisite programmes/good manufacturing practice, specific involvement in monitoring CCPs, taking corrective action and recording).
6. Recognise the expected outcomes of HACCP and what it will mean as a supervisor:
 - understand the meaning of HACCP to different individuals (companies, public, customers, markets),
 - appreciate the advantages and disadvantages associated with the development and implementation of HACCP,
 - understand the wider perspective of HACCP, i.e. it is not just going to impact on procedures, monitoring and records,
 - appreciate the importance of every individual in the organisation,
 - appreciate the need to work closely with the regulator (e.g. regulators in a monitoring or verification role).

Introduction to HACCP for Operators

Purpose

This training guideline is designed to give operators in food premises an appreciation of HACCP and their role in supporting a HACCP system.

Suggested Duration

Two hours.

Prerequisite Requirements for Participants

Not applicable.

Items for the Trainer to Consider

In relation to the learning objectives below:

- Use examples of food-borne related illness.
- Use group participation where appropriate.
- Use a video to reinforce what has been discussed.

Learning Objectives

After attending this introductory course, the participant should be able to:

1. Understand the history of HACCP:
 - know what all the fuss is about,
 - appreciate the rise of reported food-borne related illness/problems,
 - know what HACCP is, where it came from and why.
2. Recognise the benefits of HACCP:
 - understand the need for assurance that food safety hazards are controlled,
 - understand HACCP in relation to market access requirements.
3. Understand the basic concepts of HACCP:
 - know what is meant by the scope of HACCP and, where applicable, its relationship to existing quality systems, e.g. ISO, TQM,

- know what food safety hazards (biological, chemical and physical), their critical control points and critical limits are,
 - know what monitoring, corrective action taking, verification and documentation/records means with respect to HACCP.
4. Understand the need for management's commitment to the HACCP system:
 - know the HACCP policy for the premises.
 5. Recognise what makes HACCP work:
 - appreciate the general responsibilities and commitment of everybody in making HACCP work,
 - understand the operator's specific role (with prerequisite programmes/good manufacturing practice, specific involvement in monitoring CCPs, taking corrective action and recording).
 6. Understand the expected outcomes of a HACCP programme for the business.

Appendix IV. Integration of ISO and HACCP Systems

IV.1 Introduction

Hazard analysis critical control point (HACCP) is a scientifically based process control system for ensuring food safety. It is based on a systematic assessment of hazards, focusing on preventive measures, critical areas of food safety and subsequently developing control systems. This moves process control away from the traditional approach of endpoint testing of product.

ISO 9000 series standards are designed with two objectives in mind:

- to provide a customer with the assurance that a product or service of a specified quality will be supplied;
- to give the supplier the minimum guidelines to allow the development of an appropriate quality management system which can demonstrate product or service quality assurance to the customer.

The ISO 9000 series standards make it quite clear that the users need to tailor the quality system to their individual needs. Practically, this means that a company wishing to achieve ISO certification has a wide choice of scopes of application and this is reflected by the wide variation in certified ISO quality systems seen at present.

There are real benefits in combining HACCP and ISO requirements. HACCP adds detail to some key areas (especially that of food safety) for which the ISO standard provides the “minimum guidelines”. This is particularly useful where, after companies have established a formal quality system, they then require a HACCP plan for their product. This may be the result of a contractual requirement, a regulatory requirement, or a voluntary need to add specific detail to their existing quality system as it applies to a particular product.

Both systems add the following advantages to a company’s business:

- a rational approach to control of production parameters, including food safety and quality,
- a collective discipline over all levels of the company’s organisation,
- motivation of the workforce,
- increased assurance of conformity to set specifications (food safety and others).

Note that HACCP applications usually avoid covering food safety hazards associated with those activities which may interact within and across various processes. These hazards are expected to be addressed in prerequisite programmes which substantially comply with good manufacturing practice on an ongoing basis.

IV.2 Comparison of the Components of ISO 9002 and HACCP Systems

The seven principles of HACCP are:

- analyse hazards,
- determine critical control points,
- set critical limits for those critical control points,
- establish a monitoring programme for the critical control points to ensure control,
- establish corrective actions for when the critical control points are out of control,
- establish a verification programme that HACCP is effective,
- establish documentation and records to support HACCP.

These principles overlap with several components of the ISO 9000 series standards and this is demonstrated in Table IV.1.

Table IV.1 A comparison of ISO 9002 and HACCP components

ISO 9002	HACCP
4.1 Management responsibility	Steps 1, 2, 3, 5, 6, 7, 13, 14
4.2 Quality system	HACCP principles
4.3 Contract review	Step 13
4.5 Document and data control	Step 14
4.6 Purchasing	Steps 4, 8, 10, 11, 12, 13, 14
4.7 Control of customer-supplied product	Steps 4, 8, 10, 11, 12, 13, 14
4.8 Product identification and traceability	Steps 4, 7, 8, 9, 12, 13, 14
4.9 Process control	Steps 5, 6, 7, 8, 9, 10, 11, 12, 13, 14
4.10 Inspection and testing	Steps 13, 14
4.11 Control of inspection, test and measuring equipment	Steps 13, 14
4.12 Inspection and test status	Steps 13, 14

ISO 9002	HACCP
4.13 Control of nonconforming product	Steps 12, 14
4.14 Corrective and preventive action	Steps 12, 14
4.15 Handling, storage, packaging, etc.	Steps 3, 4, 5, 8, 9, 10, 11, 12, 13, 14
4.16 Control of quality records	Step 14
4.17 Internal quality audits	Step 13
4.18 Training	Prerequisite requirement
4.19 Servicing	Not applicable
4.20 Statistical techniques	Step 11

Note: The number of the ISO headings is the same as the numbering in the standard. Section 4.4 “Design Control” of the ISO 9001 standard does not apply to ISO 9002.

When HACCP is used to cover the food safety requirements of a process, it focuses on and provides essential elements which incorporate clearly defined requirements for the implementation of process control to achieve food safety. This fits easily into a company’s ISO quality system, particularly expanding the section on “Quality in production (process control)”.

A detailed comparison of the HACCP system and the ISO 9002 standard follows.

IV.3 Management Responsibility

ISO 9002

The quality policy is defined, including objectives and company commitment, documented and applied to all levels of the organisation. The scope for the quality policy can be wide-ranging. Responsibilities, authority and interrelationships of the organisation are defined and documented. Resource requirements must be identified and provided. A responsible representative for the quality system must be appointed to overview its implementation and maintenance. Management review (with records) of the quality system must occur at defined intervals for assurance of continuing suitability and effectiveness.

HACCP

Step 1 in designing the HACCP plan is obtaining senior management commitment and involvement in the HACCP programme. The HACCP team must be agreed upon and assembled (step 2). Resources for the HACCP plan’s design and implementation need to be agreed upon (steps 1 and 2). Responsibilities for food safety need to be outlined for all appropriate staff. The scope of the HACCP plan (step 3) needs to be clearly defined and will be primarily limited to food safety (although there is the potential to

expand into other activities). Food safety objectives need to be set for the product and process (step 5). The interrelationships affecting the process and the responsibilities for the process steps are evaluated and verified (steps 6 and 7). Ongoing verification of all components of the HACCP plan is essential (step 13). Documentation and record keeping are also required (step 14).

IV.4 Quality System

ISO 9002

A quality system must be established, documented, implemented and maintained, including a quality manual, procedures and structure of documentation consistent with the ISO standard. Quality planning must be included for all components of the quality system.

HACCP

Seven principles are defined which are essential to the application of HACCP and its implementation (steps 8-14 inclusive).

IV.5 Contract Review

ISO 9002

Documented procedures must be established, maintained and co-ordinated for contract review.

HACCP

All review requirements where they relate to food safety, including contract review, are considered as a component of the verification procedures of the HACCP plan (step 13).

IV.6 Document and Data Control

ISO 9002

Documents and data must be established and maintained relating to the requirements of the standard. Document control procedures must be in place, identifying the current revision status. Pertinent issues must be available and obsolete documents removed from use. Changes to documents and data must be reviewed and approved.

HACCP

Documentation and record keeping procedures are essential to the application of HACCP (step 14). Document control requirements are not stipulated.

IV.7 Purchasing

ISO 9002

The quality system must ensure that purchased product conforms to specified requirements.

HACCP

Purchased products (where applicable to the scope of the HACCP plan) are considered in several parts of the HACCP design. These include step 4 which evaluates components of a product and associated food-contact materials; step 8 which analyses the hazards (some of which may be associated with purchased product), step 9 which determines whether a purchased product is a critical control point, step 10 which will set the critical limits for the purchased product, step 11 which monitors the purchased product, and step 13 which verifies that the purchased product is meeting the requirements of the HACCP plan. Documentation and record keeping will be required (step 14).

IV.8 Control of Customer-Supplied Product

ISO 9002

Documented procedures must be in place to demonstrate control of verification, storage and maintenance of customer-supplied product. Unsuitable product must be notified to the customer.

HACCP

Customer-supplied product (where applicable to the scope of the HACCP plan) is evaluated according to Section IV.7: Purchasing. Feedback to the customer is not stipulated.

IV.9 Product Identification and Traceability

ISO 9002

Where appropriate, documented procedures must be established and maintained for identification of product at all stages from receipt through to installation. Where traceability is a specified requirement, unique identification of batches or individual product is required and is to be recorded. This is essential for product recall situations, as well as in process retain and rework of non-conforming product.

HACCP

Initial product description and intended use (step 4) may consider the requirements (if applicable) for identification and traceability. Hazard analysis (step 8) would also consider the impact of lack of positive identification of the product in relation to food safety. Corrective action procedures (step 12) incorporate product identification requirements where applicable (e.g. for retained or reworked product). Verification that both complying and non-complying product is identified and traceable is expected (step 13) and the findings recorded (step 14).

IV.10 Process Control

ISO 9002

Production, installation and servicing shall be identified, planned and controlled. Components must include:

- documented procedures,
- use of suitable equipment and environment,
- compliance with reference standards and codes, quality plans and/or documented procedures,
- monitoring and control,
- approval of processes/equipment,
- criteria for workmanship,
- suitable maintenance of equipment,
- suitable records.

HACCP

Designing and implementing a HACCP plan covers all process control requirements (see steps 5, 6, 7, 8, 9, 10, 11, 12, 13 and 14).

IV.11 Inspection and Testing

ISO 9002

Inspection and testing activities must be carried out to verify that specified requirements are met for the product. Documentation and record keeping requirements must be met.

HACCP

Verification of the HACCP plan for each process and particular product must occur (step 13). Appropriate documentation and record keeping (step 14) are expected.

IV.12 Control of Inspection, Test and Measuring Equipment

ISO 9002

Documented procedures must be available to control, calibrate and maintain inspection, test and measuring equipment used to demonstrate conformance of the product.

HACCP

Verification procedures (step 13) would ensure appropriate calibration of equipment used in demonstrating food safety conformance. Documentation and record keeping (step 14) supports this activity.

IV.13 Inspection and Test Status

ISO 9002

Identification and maintenance of the inspection and test status of product is required by suitable means, indicating conformance or non-conformance.

HACCP

Initial product description and intended use (step 4) may consider the requirements (if applicable) for identification and traceability. Hazard analysis (step 8) would also consider the impact of lack of positive identification of the product in relation to food safety. Corrective action procedures (step 12) incorporate product identification requirements where applicable (e.g. for retained or reworked product). Verification that both complying and non-complying product is identified and traceable is expected (step 13) and the findings recorded (step 14).

IV.14 Control of Non-conforming Product

ISO 9002

Documented procedures are required to ensure that product not conforming to specified requirements is prevented from unintended use.

HACCP

Control of non-conforming product is an integral component of the HACCP principle (step 12) covering corrective actions. Documentation of corrective actions to be taken and subsequent record-keeping of actions taken are expected (step 14).

IV.15 Corrective and Preventive Action

ISO 9002

Documented procedures for implementing appropriate corrective and preventive action are required.

HACCP

HACCP requires that corrective actions are documented for each process and the actions taken are recorded (steps 12 and 14).

IV.16 Handling, Storage, Packaging, Preservation and Delivery

ISO 9002

Documented procedures are required for handling, storage, packaging, preservation and delivery of product to ensure the integrity and quality of the product.

HACCP

Depending on the scope of the HACCP plan, the ISO 9002 components would be addressed under steps 4, 5, 8, 9,10, 11, 12, 13 and 14 where relevant to food safety. The scope (step 3) would have to include delivery of product.

IV.17 Control of Quality Records

ISO 9002

Documented procedures are required for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records. Quality records shall demonstrate ongoing conformance to specified requirements and the effective operation of the quality system.

HACCP

While not as specific in the requirements for quality records as ISO 9002, Principle 7 (step 14) stipulates that documentation is established and records are kept which are appropriate to the application of the principles and the HACCP plan.

IV.18 Internal Quality Audits

ISO 9002

Documented procedures are required for planning and implementing internal quality audits, verifying the effectiveness of the quality system.

HACCP

Internal audits are an accepted component of application of Principle 6 (step 13) covering verification activities.

IV.19 Training

ISO 9002

Documented procedures are required to identify and provide for training of all personnel performing tasks relating to the quality system. Records are to be kept.

HACCP

Training is not covered specifically in the HACCP principles or design steps for HACCP plans. However, it is accepted as an essential prerequisite to HACCP implementation.

IV.20 Servicing

ISO 9002

Servicing activities shall be covered by the quality system where it is a specified requirement.

HACCP

Servicing requirements are not covered specifically by HACCP.

IV.21 Statistical Techniques

ISO 9002

Documented procedures shall be provided to cover application of statistical techniques where appropriate to the product and process.

HACCP

HACCP principles do not specify particular tools for use in establishing, monitoring and verifying product characteristics and process capability. However, statistical techniques are frequently used in HACCP applications as a monitoring tool (step 11).

Appendix V. Auditing HACCP Plans

V.1 Types of Audit

Audit

A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Audits are carried out against standards. An audit against the HACCP Guide would have to be clearly agreed to by both parties prior to the audit.

Recognition of validity

An initial full audit carried out by the Inspector in order to recognise the validity of the HACCP plan.

Review of Validity

A full or partial audit by the Inspector in order to recognise the validity of changes to a HACCP plan.

Compliance audit

An audit carried out by the Inspector to determine whether actual practices comply with the documented procedures in the validated HACCP plan.

Internal audit

An audit carried out by the licensee to evaluate the implementation of the HACCP plan. The person or persons carrying out the audit should be independent of the system under consideration.

Extrinsic audit

An audit carried out by a customer, regulator or third party on a company to assess company compliance with the HACCP plan.

Full audit

An audit covering all aspects of the HACCP plan and selected prerequisites (selected by the auditor). A full audit would be necessary on the following occasions:

- initial audit (e.g. licensee audit, Inspector's initial audit recognising validity),
- where substantial changes have been made to the product or process,

- according to a minimum frequency as stipulated by a standard or a regulatory authority,
- where the last audit indicated a need for it.

Partial audit

An audit covering selected components of a HACCP plan.

Voluntary audit

An audit determined by:

- the processor,
- the processor's customers as per supply arrangements.

The processor would decide who performs the audit and agree on the frequency of such audits with the auditor.

Mandatory audit

An audit required where:

- a HACCP plan is a component of market access,
- a HACCP plan is specifically required by the legislation or an industry-agreed implementation standard.

The regulatory authority would set the frequency and scope of mandatory audits in conjunction with appropriate industry consultation and in consideration of market access requirements.

V.2 Pre-audit Checklist

This checklist provides detailed guidelines to assist the auditor in assessing preaudit information.

Preaudit checklist	Comments
<p>1. Quality system</p> <ul style="list-style-type: none"> • Is there a quality system? • What is the scope of the quality system? • How does the HACCP plan link with the quality system? • Is there an external audit of the quality system? 	
<p>2. Prerequisite programmes</p> <ul style="list-style-type: none"> • What are the prerequisite programmes? • Are they addressed separately from the HACCP plan? • Is there evidence of authorisation by a responsible company person? • Is there evidence of an ongoing acceptable level of compliance (as per industry/regulatory standard)? <p>For an initial audit, check:</p> <ul style="list-style-type: none"> • internal review/audit reports, • external review/audit reports, • nonconformance records, • documentation and records for selected sample of prerequisite programmes. <p>For subsequent audit, check:</p> <ul style="list-style-type: none"> • information for the above since the last HACCP plan audit, • information on any changes to prerequisite programmes 	
<p>3. Submitted HACCP plan</p> <p>(See Appendix V.4 for an HACCP plan audit questionnaire.)</p> <ul style="list-style-type: none"> • Are previous HACCP plan audit reports available? 	

<p>4. Responsibilities</p> <ul style="list-style-type: none"> • HACCP-trained individual (as defined by the industry-agreed standard or regulatory agency) for review of the initial plan, review of records and any subsequent modifications. 	
<p>5. Other information most likely to be accessed on-site:</p> <ul style="list-style-type: none"> • Are HACCP training records available? • Have layout plans for product and personnel flowpaths been considered? • Are suppliers guarantees/validations available? • Are job descriptions/work instructions available? • Are hazard ID resources available? 	
<p>Other comments</p>	

V.3 Audit Team Qualifications

V.3.1 Auditor qualifications are outlined in *Guidelines for Auditing Quality Systems* ISO 10011.1:1992 and ISO 10011.2:1992.

V.3.2 The team leader should have:

- qualifications and experience as appropriate to the audit, i.e. internal (according to company requirements) or external (recognised audit qualification by JASANZ or its equivalent).

V.3.3 The team also should have:

- experience in HACCP programmes, indicating competence in meeting the expected outcomes of the HACCP co-ordinator guidelines (see Appendix III) or as per industry agreed or regulatory standards;
- technical expertise and industry knowledge.

The audit team may consist of only one person if that person meets all the requirements.

V.3.4 The auditor(s) need to be free from bias and influences which could affect objectivity. All persons and organisations involved with an audit should respect and support the independence and integrity of the auditors.

V.4 HACCP Plan Audit Questionnaire

Note: This questionnaire is a guide only. A status has been given to each question to assist the auditor in evaluating the outcome of the audit. The final judgment rests with the auditor.

Key

Recommended means considered of value in developing, implementing and maintaining a HACCP plan but not essential for a successful outcome to the HACCP plan audit. May be mentioned in the audit report to assist the auditee.

Required means part of the HACCP standard. Nonconformance is serious and is likely to result in actions taken as per Section 7.4.2.2.

FS means New Zealand Fishing Industry Agreed Implementation Standard IAIS 003.5.

FHG means FIICC HACCP Guide.

HACCP plan audit questionnaire	Comments
<p>1. Is there commitment by Management to HACCP ? [State whether informal or formal.]</p> <p>Has the HACCP plan been signed off by Management?</p> <p>Ref: FS 2.3A.5 FHG 5.2; 6.2</p> <p>Status: Required</p>	
<p>2. Was an HACCP team established?</p> <p>Ref: FHG 5.3</p> <p>Status: Recommended</p>	
<p>3. Was the team composition and responsibilities documented?</p> <p>Ref: FHG 5.3</p> <p>Status: Recommended</p>	

<p>4. Is the scope of the HACCP plan defined and documented?</p> <p>Ref: FS 2.3A.1 FHG 5.4</p> <p>Status: Required</p>	
<p>5. Is there a description or specification for the product?</p> <p>Ref: FS 2.3A.3 FHG 5.5</p> <p>Status: Required</p>	
<p>6. Does the description cover intended use?</p> <p>Ref: FS 2.3A.3 FHG 5.5</p> <p>Status: Required</p>	
<p>7. Were food safety objectives formulated for the HACCP plan?</p> <p>Ref: FS 2.3A.3 FHG 5.6</p> <p>Status: Required</p>	
<p>8. Is there a process flow description?</p> <p>Ref: FS 2.3A.1 FHG 5.7</p> <p>Status: Required</p>	
<p>9. Does it reference relevant inputs and outputs at each process step? [If not, have the inputs and outputs been considered elsewhere?]</p> <p>Ref: FHG 5.7</p> <p>Status: Recommended</p>	
<p>10. Has the process flow information been confirmed as accurate?</p> <p>Ref: FHG 5.7</p> <p>Status: Recommended</p>	

Review actual process against process flow information

11. Was background information obtained on hazards appropriate to the product?

Ref: FS 2.3A.1
FHG 5.9

Status: Required

12. Was effective hazard identification carried out and documented for all raw materials, inputs and for each process step?

Ref: FS 2.3A.1
FHG 5.9, 5.15

Status: Required

13. Did the hazard identification consider the variability of the process/operators?

Ref: FHG 5.9

Status: Recommended

14. CCP determination — was the significance/level of unacceptability of each identified hazard/ generic group of hazards at each process step determined?

Ref: FS 2.3A.3
FHG 5.10

Status: Required

Review hazard significance against selected food safety objectives

15. CCP determination — was a control measure(s) identified for each significant/unacceptable hazard/generic group of hazards?

Ref: FS 2.3A.3
FHG 5.10

Status: Required

16. Is there documentation to support the CCP determination?

Ref: FS 2.3A.3
FHG 5.10, 5.15

Status: Required

<p>17. Were unaddressed hazards identified and recorded?</p> <p>Ref: FS 2.3A.3 FHG 5.9</p> <p>Status: Required</p>	
<p>18. Were unaddressed hazards highlighted for further consideration?</p> <p>Ref: FHG 5.9</p> <p>Status: Recommended</p>	
<p>19. Were measurable critical limits determined and documented for all hazards covered by a CCP?</p> <p>Ref: FS 2.3A.3 FHG 5.11, 5.15</p> <p>Status: Required</p>	
<p>20. Are the critical limits scientifically valid for the hazard?</p> <p>Ref: FS 2.3A.3 FHG 5.11</p> <p>Status: Required</p>	
<p>21. Are the critical limits achievable, (practical) given the process?</p> <p>Ref: FS 2.3A.3 FHG 5.11</p> <p>Status: Required</p>	
<p>Review critical limits against food safety objectives</p>	
<p>22. Is responsibility for monitoring defined and documented?</p> <p>Ref: FS 2.3A.3 FHG 5.12, 5.15</p> <p>Status: Required</p>	

Check responsibilities with selected staff	
<p>23. Does monitoring supply enough information to ensure that the CCPs are under control? [Consider when, how and what, including relationship to prevalence of hazard.]</p> <p>Ref: FS 2.3A.3 FHG 5.12</p> <p>Status: Required</p>	
<p>24. Are monitoring procedures documented?</p> <p>Ref: FS 2.3A.3 FHG 5.12, 5.15</p> <p>Status: Required</p>	
<p>26. Are monitoring results recorded?</p> <p>Ref: FS 2.3A.3 FHG 5.12, 5.15</p> <p>Status: Required</p>	
Review monitoring activities and records against documented procedures	
<p>27. Are responsibilities for taking corrective action defined and documented?</p> <p>Ref: FS 2.3A.3 FHG 5.13, 5.15</p> <p>Status: Required</p>	
Check responsibilities with selected staff	
<p>28. Are the corrective action procedures documented ?</p> <p>Ref: FS 2.3A.3 FHG 5.13, 5.15</p> <p>Status: Required</p>	
View corrective actions taken against documented procedures	
<p>29. Do corrective actions take place when monitoring trends indicate that the process is heading towards a critical limit?</p> <p>Ref: FHG 5.13</p> <p>Status: Recommended</p>	

<p>30. Do the corrective actions incorporate all the necessary components?</p> <p>Ref: FS 2.3A.3 FHG 5.13</p> <p>Status: Required</p>	
<p>31. Are corrective actions followed up by appropriate rechecks?</p> <p>Ref: FS 2.3A.3 FHG 5.13</p> <p>Status: Required</p>	
<p>32. Are corrective actions implemented as per documented procedures and the outcomes recorded?</p> <p>Ref: FS 2.3A.3 FHG 5.13</p> <p>Status: Required</p>	
<p>33. Are corrective actions signed off as completed?</p> <p>Ref: FS 2.3A.3 FHG 5.13</p> <p>Status: Required</p>	
<p>Review corrective action records against documented procedures</p>	
<p>34. Are there adequate documented verification procedures? [Consider what, when, how, including validation, internal and external checks, calibration of equipment, HACCP plan review, product tests where relevant.]</p> <p>Ref: FS 2.3A.3 FHG 5.14, 5.15</p> <p>Status: Required</p>	
<p>Review actual verification activities against documented procedures</p>	
<p>35. Are verification responsibilities defined?</p> <p>Ref: FS 2.3A.3; 2.3A.6 FHG 5.14</p> <p>Status: Required</p>	

Check responsibilities with selected staff

36. Are the verification findings recorded?

Ref: FS 2.3A.3
FHG 5.14, 5.15

Status: Required

Review verification records against documented procedures

37. Are documented control provisions in place?

Ref: FS 2.3A; 2.5A

Status: Required

38. Is a retention period for records defined?

Ref: Regulation 10, Fish Export Processing
Regulations 1995
FHG 5.15

Status: Required

Other comments:

Appendix VI. Seafood Hazard Identification Guide

VI.1 Introduction

This guide has been prepared by New Zealand MAF Food Assurance Authority to provide New Zealand seafood processors with information on species-related hazards. The format of the guide has been adapted from the US Food and Drug Administration (FDA) *Fish and Fisheries Products Hazards and Controls Guide: Chapter 3*, with their permission.

The primary purpose of this guide is to assist processors in the development and ongoing review of their HACCP plans. The information given in the tables provides guidance for determining which hazards are likely to occur in the raw material. The information has been obtained from scientific literature and reports specific to seafood available in New Zealand waters. Appropriate information about potential raw material hazards should be sought when processing seafood from outside New Zealand waters.

New Zealand seafood species are listed in the tables alphabetically, by common name (as per IAIS 004). Commonly fished species also have a species code listed under their name. Hazards associated with that particular species are indicated by a tick in the appropriate column. **Note that the lack of a tick does not mean that the hazard is not associated with that species, only that there is no documented or published information available to categorically link the hazard with the species.** References cited in the tables are listed and summarised at the end of the guide.

It should be noted that the guide does not provide a judgement on whether the raw material hazards may be present at “unacceptable” levels (i.e. to determine whether a critical control point is required). This responsibility lies with the HACCP co-ordinator at individual premises. The hazards identified are those that are of general concern to the New Zealand seafood industry. Therefore the hazards identified may not necessarily be appropriate to specific products of individual premises, but all those listed should be considered. Raw material hazards should not be restricted to those given in this guide. Careful thought must be put into the relevance or applicability of information given in this guide before it is adopted. When available, other sources of relevant information, such as company records and unpublished reports, should be used by processors to assist them in hazard identification and analysis. Processors should also be alert to new or emerging problems (e.g. the occurrence of natural toxins in fish not previously associated with that toxin).

MAF Food intends to revise and reissue this guide from time to time as more information becomes available. It is anticipated that the guide may be expanded at a later date to include process-related hazards and methods of control. In the meantime, useful information for these areas can be found in the USFDA *Fish and Fisheries Products Hazards and Controls Guide*.

VI.2 Potential Raw Material Hazards in Vertebrate Species

Note that the lack of a tick does not mean that the hazard is not associated with that species, only that there is no documented or published information available to categorically link the hazard with the species. Careful thought must be given to the relevance or applicability of information given in this guide before it is adopted. Raw material hazards should not be restricted to those given in this guide, but all those listed should be considered. When available, other sources of relevant information such as company records and unpublished reports should be used by processors to assist them in hazard identification and analysis.

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Albacore tuna (ALB)	<i>Thunnus alalunga</i>		✓		✓		7, 13
Alfonsino (BYS, BYX)	<i>Beryx splendens</i> <i>Beryx decadactylus</i>					✓	17
Anchovy	<i>Engraulis australis</i>						
Atlantic salmon	<i>Salmo salar</i>						
Barracouta (BAR)	<i>Thyrsites atun</i>		✓				7
Bass groper (BAS)	<i>Polyprion americanus</i>						
Bigeye tuna (BIG)	<i>Thunnus obesus</i>						
Black cod	<i>Paranotothenia angustata</i>		✓				7
Black flounder (BFL)	<i>Rhombosolea retiaria</i>						
Black marlin	<i>Makaira indica</i>						
Black oreo dory (BOE)	<i>Allocyttus niger</i>						
Black sharks	<i>Apristurus</i> spp. <i>Centrophorus squamosus</i> <i>Scymnodon plunketi</i> <i>Centroscymnus crepidater</i> <i>Centroscymnus owstonii</i> <i>Etmopterus</i> spp.		✓			✓	7, 17
Black stingrays	<i>Dasyatis thetidis</i> <i>Dasyatis brevicaudatus</i>						
Blue cod (BCO)	<i>Parapercis colias</i>		✓				7

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Blue mackerel (EMA)	<i>Scomber australasicus</i>						
Blue maomao	<i>Scorpius violaceus</i>						
Blue marlin	<i>Makaira mazara</i>						
Blue moki (MOK)	<i>Latridopsis ciliaris</i>						
Blue shark (BWS)	<i>Prionace glauca</i>		✓				7
Blue warehou (WAR)	<i>Seriola brama</i>		✓		✓		7, 16
Bluenose (BNS)	<i>Hyperoglyphe antarctica</i>					✓	17
Brill (BRI)	<i>Colistium guntheri</i>						
Broadbill swordfish (SWO)	<i>Xiphias gladius</i>						
Bronzewhale shark	<i>Carcharhinus brachyurus</i>						
Butterfish (BUT)	<i>Odax pullus</i>						
Butterfly perch	<i>Caesioperca lepidoptera</i>						
Butterfly tuna (BTU)	<i>Gasterochisma melampus</i>						
Cardinal fish (CDU)	<i>Epigonus telescopus</i>					✓	23
Catfish	<i>Ameiurus nebulosus</i>						
Conger eel	<i>Conger verreauxi</i>		✓				7
Dolphin fish	<i>Coryphaena hippurus</i>						
Eagle ray	<i>Myliobatis tenuicaudatus</i>						
Elephant fish (ELE)	<i>Callorhynchus milii</i>						
Frostfish (FRO)	<i>Lepidopus caudatus</i>		✓				7
Garfish (GAR)	<i>Hyporhamphus ihi</i>						
Gemfish (SKI)	<i>Rexea solandri</i>		✓				7

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Ghost sharks (GSH, OSD)	<i>Hydrolagus novaezelandiae</i> <i>Hydrolagus</i> spp. <i>Chimaera</i> spp.					✓	17
Giant boarfish	<i>Paristiopterus labiosus</i>		✓				7
Greenback flounder (GFL)	<i>Rhombosolea tapirina</i>		✓				7
Grenadiers	<i>Caelorinchus</i> spp. <i>Coryphaenoides</i> spp. <i>Macrourus</i> sp. <i>Trachyrinchus</i> spp. <i>Lepidorhynchus</i> sp.		✓				7
Grey mullet (GMU)	<i>Mugil cephalus</i>						
Grey spiny dogfish	<i>Squalus mitsukurii</i>						
Hake (HAK)	<i>Merluccius australis</i>		✓			✓	7, 17
Hammerhead shark	<i>Sphyrna zygaena</i>						
Hapuku (HAP)	<i>Polyprion oxygeneios</i>		✓			✓	7, 17
Hoki (HOK)	<i>Macruronus novaezelandiae</i>		✓				7
Jack mackerels (JMN, JMD, JMM)	<i>Trachurus novaezelandiae</i> <i>Trachurus declivis</i> <i>Trachurus murphyi</i>		✓		✓		7, 13, 16
John dory (JDO)	<i>Zeus faber</i>		✓				7
Kahawai (KAH)	<i>Arripis trutta</i>		✓		✓		7, 13, 14, 15, 16
Kelpfish	<i>Chironemus marmoratus</i>						
Koheru	<i>Decapterus koheru</i>						
Lamprey	<i>Geotria australis</i>						
Leatherjacket (LEA)	<i>Parika scaber</i>						
Lemon sole (LSO)	<i>Pelotretis flavilatus</i>						

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Ling (LIN)	<i>Genypterus blacodes</i>		✓			✓	7, 17
Longfin eel (LFE)	<i>Anguilla dieffenbachii</i>		✓				7
Longfinned boarfish	<i>Zanclistius elevatus</i>						
Longnosed chimaera	<i>Harriotta raleighana</i>						
Lookdown dory (LDO)	<i>Cyttus traversi</i>						
Mako shark	<i>Isurus oxyrinchus</i>		✓			✓	7, 17
Marblefish	<i>Aplodactylus arctidens</i>						
Mirror dory	<i>Zenopsis nebulosus</i>		✓				7
Monkfish (STA)	<i>Kathetostoma giganteum</i> <i>Kathetostoma</i> spp.		✓				7
Moonfish (MOO)	<i>Lampris guttatus</i>		✓				7
Northern bluefin tuna (NTU)	<i>Thunnus thynnus</i>						
Orange perch	<i>Lepidoperca aurantia</i>						
Orange roughy (ORH)	<i>Hoplostethus atlanticus</i>		✓			✓	7, 17
Parore (PAR)	<i>Girella tricuspidata</i>						
Pigfish	<i>Congiopodus leucopaecilus</i>		✓				7
Pilchard (PIL)	<i>Sardinops neopilchardus</i>		✓				7
Pink maomao	<i>Caprodon longimanus</i>						
Porae (POR)	<i>Nemadactylus douglasi</i>		✓				7
Porbeagle shark	<i>Lamna nasus</i>						
Quinnat salmon (SAM)	<i>Oncorhynchus tshawytscha</i>		✓				7
Ray's bream (RBM)	<i>Brama brama</i>						
Red baitfish	<i>Emmelichthys nitidus</i>						

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Red cod (RCO)	<i>Pseudophycis bachus</i>		✓				7
Red gurnard (GUR)	<i>Chelidonichthys kumu</i>		✓				7
Red moki	<i>Cheilodactylus spectabilis</i>						
Red mullet	<i>Upeneichthys lineatus</i>						
Red pigfish	<i>Bodianus vulpinus</i>						
Red snapper (RSN)	<i>Centroberyx affinis</i>						
Ribaldo (RIB)	<i>Mora moro</i>		✓			✓	7, 17
Rig (SPO)	<i>Mustelus lenticulatus</i>		✓			✓	7, 17
Rock cod	<i>Lotella rhacinus</i>		✓				7
Roughy	<i>Paratrachichthys trailli</i>		✓				7
Ruby fish (RBY)	<i>Plagiogeneion rubiginosus</i>		✓				7
Rudderfish	<i>Centrolophus niger</i>						
Sand flounder (SFL)	<i>Rhombosolea plebeia</i>						
Saury	<i>Scomberesox saurus</i>						
Scarpee (SPE)	<i>Helicolenus percoides</i>						
School shark (SCH)	<i>Galeorhinus galeus</i> <i>G. australis</i>		✓			✓	7, 17
Scorpionfishes	<i>Scorpaena cardinalis</i> <i>Scorpaena papillosus</i>		✓				7
Sea horse	<i>Hippocampus abdominalis</i>						
Sea perch (SPE)	<i>Helicolenus barathri</i>						
Seal shark (BSH)	<i>Dalatias licha</i> <i>Scymnodalatias licha</i>		✓			✓	7, 17
Shortfin eel (SFE)	<i>Anguilla australis</i>						
Shovelnose spiny dogfish	<i>Deania calcea</i>		✓			✓	7, 17

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Silver dory (SDO)	<i>Cyttus novaezealandiae</i>		✓				7
Silver drummer	<i>Kyphosus sydneyanus</i>						
Silver roughy	<i>Hoplostethus mediterraneus</i>						
Silver warehou (SWA)	<i>Seriola punctata</i>		✓		✓		7, 16
Silverside	<i>Argentina elongata</i>		✓				17
Skates (SKA, RSK)	<i>Raja innominata</i> <i>Raja nasuta</i>		✓				7
Skipjack tuna (SKJ)	<i>Katsuwonus pelamis</i>		✓				7
Slender tuna (STU)	<i>Allothunnus fallai</i>						
Slickheads	<i>Alepocephalus</i> spp. <i>Roulenia</i> spp.						
Smelt	<i>Retropinna retropinna</i>		✓				7
Smooth oreo dory (SSO)	<i>Pseudocyttus maculatus</i>						
Snapper (SNA)	<i>Pagrus auratus</i>		✓				7
Sockeye salmon	<i>Oncorhynchus nerka</i>						
Sole (ESO)	<i>Peltorhamphus novaezeelandiae</i>		✓				7
Southern blue whiting (SBW)	<i>Micromesistius australis</i>		✓				7
Southern bluefin tuna (STN)	<i>Thunnus maccoyii</i>					✓	17
Southern boarfish	<i>Pseudopentaceros richardsoni</i>						
Spiky oreo dory (SOR)	<i>Neocyttus rhomboidalis</i>						
Spiny dogfish (SPD)	<i>Squalus acanthias</i>		✓			✓	7, 17
Spiny seadragon	<i>Solegnathus spinosissimus</i>						
Splendid perch	<i>Callanthias allporti</i> <i>Callanthias australis</i>						

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Spotted gurnard (JGU)	<i>Pterygotrigla picta</i>						
Spotted stargazer (SPZ)	<i>Genyagnus monopterygius</i>		✓				7
Sprats	<i>Sprattus antipodum</i> <i>Sprattus muelleri</i>						
Striped marlin	<i>Tetrapurus audax</i>		✓				7
Tarakihi (TAR)	<i>Nemadactylus macropterus</i>		✓				7
Trevally (TRE)	<i>Pseudocaranx dentex</i>		✓		✓		7, 16
Trumpeter (TRU)	<i>Latris lineata</i>		✓				7
Turbot (TUR)	<i>Colistium nudipinnis</i>						
White warehou (WWA)	<i>Seriolella caerulea</i>				✓		7
Whitebait	<i>Galaxias</i> spp.						
Witch	<i>Amoglossus scapha</i>		✓				7
Yellowbelly flounder (YBF)	<i>Rhombosolea leporina</i>		✓				7
Yelloweye mullet (YEM)	<i>Aldrichetta forsteri</i>		✓				7
Yellowfin tuna (YFN)	<i>Thunnus albacares</i>						
Yellowtail kingfish (KIN)	<i>Seriola lalandi</i>		✓		✓		7, 13, 14, 15, 16

VI.3 Potential Raw Material Hazards in Crustacean Species

Note that the lack of a tick does not mean that the hazard is not associated with that species, only that there is no documented or published information available to categorically link the hazard with the species. Careful thought must be given to the relevance or applicability of information given in this guide before it is adopted. Raw material hazards should not be restricted to those given in this guide, but all those listed should be considered. When available, other sources of relevant information such as company records and unpublished reports should be used by processors to assist them in hazard identification and analysis.

Common names	Scientific names	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxin	Histamine	Heavy metals	
Cancer crab	<i>Cancer novaezelandiae</i>						
Freshwater crayfish	<i>Paranephrops planifrons</i> <i>Paranephrops zealandicus</i>						
Giant spider crab	<i>Jacquinitia edwardsii</i>						
Golden prawn	<i>Plesionika martia</i>						
Jack-knife prawn	<i>Haliporoides sibogae</i>						
King crabs	<i>Lithodes murrayi</i> <i>Neolithodes brodiei</i>						
Lobster krill	<i>Munida gregaria</i>						
Packhorse rock lobster (PHC)	<i>Jasus verreauxi</i>						
Paddle crab (PAD)	<i>Ovalipes catharus</i>						
Red rock crab	<i>Plagusia chabrus</i>						
Red swimming crabs	<i>Nectocarcinus antarcticus</i> <i>Nectocarcinus bennetti</i>						
Royal red prawn	<i>Aristaeomorpha foliacea</i>						
Sabre prawn	<i>Campylonotus rathbunae</i>						
Scampi (SCI)	<i>Metanephrops challengerii</i>					✓	20
Southern spider crab	<i>Leptomithrax australis</i>						
Spiny rock lobster (CRA)	<i>Jasus edwardsii</i>					✓	19

VI.4 Potential Raw Material Hazards in Molluscan Species

Note that the lack of a tick does not mean that the hazard is not associated with that species, only that there is no documented or published information available to categorically link the hazard with the species. Careful thought must be given to the relevance or applicability of information given in this guide before it is adopted. Raw material hazards should not be restricted to those given in this guide, but all those listed should be considered. When available, other sources of relevant information such as company records and unpublished reports should be used by processors to assist them in hazard identification and analysis.

Note that pathogens and natural toxins are possible hazards for all shellfish, not just those highlighted below.

Common names	Scientific names	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxin	Histamine	Heavy metals	
Arrow squids (SQU)	<i>Nototodarus gouldi</i> <i>Nototodarus sloanii</i>					✓	17
Blue mussel	<i>Mytilus galloprovincialis</i>	✓		✓			2, 8
Broad squid (BSQ)	<i>Sepioteuthis australis</i>						
Cockle (COC)	<i>Austrovenus stutchburyi</i>			✓		✓	8, 22
Dog cockle	<i>Tucetona laticostata</i>						
Dredge oyster (OYS, OYU)	<i>Tiostrea chilensis lutaria</i>			✓		✓	11, 21, 22
Fan shell	<i>Atrina pectinata zelandica</i>						
Limpet	<i>Cellana denticulata</i>						
New Zealand greenshell mussel	<i>Perna canaliculus</i>	✓		✓		✓	2, 3, 9, 11, 12, 22
New Zealand king clam (PZL)	<i>Panopea zelandica</i>						
New Zealand queen scallop (QSC)	<i>Zygochlamys delicatula</i>					✓	18
Octopus (OCT)	<i>Octopus maorum</i>						
Pacific oyster	<i>Crassostrea gigas</i>	✓		✓		✓	1, 4, 5, 6, 12, 24

Common name (Species code)	Scientific name	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxins	Histamine	Heavy metals	
Paua (PAU)	<i>Haliotis iris</i>						
Pipi (PPI)	<i>Paphies australis</i>						
Rock oyster	<i>Saccostrea cucullata</i>					✓	22
Scallop (SCA)	<i>Pecten novaezelandiae</i>			✓		✓	11, 22
Toheroa	<i>Paphies ventricosa</i>						
Tuatua (TUA)	<i>Paphies subtriangulata Paphies donacina</i>			✓			10
Yellowfoot paua (PAU)	<i>Haliotis australis</i>						

VI.5 Potential Raw Hazards in Echinoderm Species

Note that the lack of a tick does not mean that the hazard is not associated with that species, only that there is no documented or published information available to categorically link the hazard with the species. Careful thought must be given to the relevance or applicability of information given in this guide before it is adopted. Raw material hazards should not be restricted to those given in this guide, but all those listed should be considered. When available, other sources of relevant information such as company records and unpublished reports should be used by processors to assist them in hazard identification and analysis.

Common names	Scientific names	Hazards					Ref
		Biological				Chemical	
		Pathogens	Parasites	Natural toxin	Histamine	Heavy metals	
Sea cucumber (SCC)	<i>Stichopus mollis</i>						
Sea urchin (SUR)	<i>Evechinus chloroticus</i>						

VI.6 References

General

Clement and Associates (1998) The Atlas of Area Codes and TACCs 1998/99. Clement and Associates, Tauranga, New Zealand.

USFDA (1998) Fish and Fisheries Products Hazards and Controls Guide: 2nd Edition. United States Federal and Drug Administration, Maryland, USA.

Pathogens

1. Anonymous (1989) *Vibrio parahaemolyticus*. Communicable Disease N.Z. 89(2): 7.

An increase in the number of isolates of *V. parahaemolyticus* was received by the Enteric Reference Laboratory of the National Health Institute in March 1989. The consumption of raw oysters was thought to be a contributing factor. Isolates of *V. parahaemolyticus* from oysters were found to be in low numbers, as would be expected of this naturally occurring marine commensal.

2. Baker, M. & Wilson, N. (1993) Microbial hazards of seafood: a New Zealand perspective. Communicable Disease N.Z. 93(1): 1-12.

The main microbial hazards associated with eating seafood are summarised. A range of sources is identified: naturally present in the aquatic environment; pollution of the aquatic environment; workers, equipment, the environment of food handling, processing or service establishments. The report discusses bacterial, parasitic, and viral diseases, and toxin, scombroid and tetrodotoxin poisonings. Included are reported cases of salmonellosis which have been linked to shellfish collected in sewage-contaminated water.

3. Brett, M., Short, P. & McLauchlin, J. (1995) Listeriosis associated with smoked mussels. Proc. XII International Symposium on Problems of Listeriosis (2-6 October 1995). Perth, Australia. p. 467.

This report outlines the results of an investigation of two perinatal listeriosis cases in Auckland who had consumed smoked mussels. Use of a combination of typing methods enabled the identification of links between these two cases and one other, a food source and the factory environment.

4. Fletcher, G.C. (1985) The potential food poisoning hazard of *Vibrio parahaemolyticus* in New Zealand Pacific oysters. N.Z. J. Marine and Freshwater Res. 19: 495-505.

Samples of Pacific oysters from four New Zealand oyster farms were tested for *Vibrio parahaemolyticus* between November 1992 and May 1993. The level of *V. parahaemolyticus* was found to be generally very low. *Vibrio parahaemolyticus* was detected in 57% of the oyster samples but 95% of these contained less than 10 organisms per gram. Maximum levels appeared to coincide with high water temperatures at the farm sites. Chilling, freezing and depuration

reduced *V. parahaemolyticus* numbers in oysters after harvest. However, holding at ambient temperatures (19-25 °C) resulted in up to a 35-fold increase in organism numbers, with a maximum after one day. The food poisoning hazard from *V. parahaemolyticus* in New Zealand-grown Pacific oysters therefore appears to be minimal.

5. Jarman, J. & Brown, P. (1995) Outbreaks of gastroenteritis associated with consumption of oysters in Northland. N.Z. Public Health Rep. 2(3): 26-27.

The preliminary results of three gastroenteritis outbreak investigations in Northland between November 1994 and January 1995 are summarised. Oysters harvested from the Waikare Inlet of the Bay of Islands during a two-week period in November 1994 were implicated in all of the outbreaks. A viral aetiology was thought likely and this was supported by the detection of Norwalk-like virus in the stools of one patient. Northland Health requested a recall of products.

6. Jones, N. & Graham, J. (1995) Outbreak of gastroenteritis associated with oysters: a Norwalk-like virus most likely cause. N.Z. Public Health Rep. 2(3): 25-26.

Thirty six (38%) of 95 people attending a Christmas party at a yacht club in December 1994 developed a gastrointestinal illness. Epidemiological and microbiological investigation indicated that oysters contaminated with Norwalk-like virus were the most likely cause of infection. The oysters were probably from a Bay of Islands farm.

Parasites

7. Hine, P.M., Jones, J.B. & Diggles, B.K. (1998) A checklist of the parasites of New Zealand fishes, including previously unpublished records. National Institute of Water and Atmospheric Research, Wellington, N.Z. (In Press)

This report summarises the life cycle of fish nematodes and the parasites of importance to commercial fisheries. Of particular concern is *Anisakis*, which may infect humans, and many of the closely related genera in the Anisakidae (Order Ascaridoida), which normally infect marine mammals and may also be zoonotic. This includes the genera *Anisakis*, *Hysterothylacium* (*syn. Contracaecum* and *Thynnascaris*), *Paranisakis*, *Porrocaecum*, *Pseudoterranova* (*syn. Phocanema*), and *Terranova*, which occur in New Zealand fishes. The genera *Raphidascaaris* is also mentioned in the report.

Natural Toxins

8. ESR [Institute of Environmental Science and Research Ltd., Health] (1995) First reported cases of diarrhoeic shellfish poisoning (DSP) in New Zealand. N.Z. Public Health Rep. 2(5): 4.

In March 1995, 11 people were reported to be ill after eating shellfish associated with raised levels of DSP biotoxins. The shellfish were consumed at three separate meals and were recreationally harvested from either Queen Charlotte Sound or Akaroa harbour. At the time the shellfish (mussels and cockles) were collected, both areas were closed to harvesting because of the presence of DSP toxins above the regulatory limit.

9. Mackenzie, L. (1994) More blooming problems. Toxic algae and shellfish biotoxins in the South Island (January - May 1994). *Seafood N.Z.* 2(5): 50-52.

On 31 December 1993, a positive test for paralytic shellfish toxins was obtained from a sample of mussels collected, as part of the routine biotoxin monitoring programme, from a mussel farm in Anakoha Bay in outer Pelorus Sound. This followed an earlier minor incident in Croisilles Harbour in the Sounds in November 1993.

10. Mackenzie, L., White, D., Rhodes, L., Berkett, N., Burke, B., & Haywood, A. (1994) Alexandrium and PSP in New Zealand - another chapter in the marine biotoxin saga. *Seafood N.Z.* 2(6): 72-75.

This report gives a summary of the known species of *Alexandrium* in New Zealand, their life cycle, methods of identification, and follow up testing of tuatua from a PSP incident in the Bay of Plenty in 1993.

11. Mackenzie, L., Rhodes, L., Haywood, A., & Gibbs, W. (1995) Of mice and microscopes; toxic phytoplankton and the biotoxin monitoring programme. *Seafood N.Z.* 1995: 42-46.

There have been no confirmed cases of human illness due to paralytic shellfish poisoning in New Zealand. All documented PSP contamination incidents (tuatua, cultivated mussels, Foveaux Strait oysters) in New Zealand to date have been due to contamination by toxins produced by the dinoflagellate *Alexandrium minutum*. When found, the toxin concentrations have generally been low.

Several confirmed cases of diarrhetic shellfish poisoning were attributed to the consumption of cockles and mussels within a closed area (see Reference 8).

A new "toxin" similar to toxins that cause neurotoxic shellfish poisoning was discovered in Foveaux Strait oysters in 1994, but was eventually disregarded as a hazard to human health. This "toxin" resulted in shellfish returning positive results throughout the south and east coasts of the South Island between February and May 1994.

During 1994, it was discovered that domoic acid (causative agent of amnesic shellfish poisoning) contamination of shellfish is rather common and widespread in New Zealand. Most analyses have revealed only trace amounts though some results have been high and a cause for real concern. Scallops seem to be particularly prone to this type of contamination and retain the toxin for a long time. A few cases of mussel contamination have been documented, all of which have been very brief events. An alarming level of 187 ppm was found in commercial mussels from Kenepuru Sound in December 1994 (the acceptable level is set at 20 ppm).

12. Mackenzie, L., Rhodes, L., Till, D., Chang, F.H., Kaspar, H., Haywood, A., Kapa, J., & Walker, B. (1995) A *Gymnodinium* sp. bloom and the contamination of shellfish with lipid-soluble toxins in New Zealand, Jan-April 1993. In *Harmful Marine Algal Blooms - Proc. Sixth International Conference on Toxic Marine Phytoplankton, October 1993, Nantes, France.* (ed. P. Lassus, G. Arzul, E. Erard-Le Denn, P. Gentien, & C. Marcaillou-Le Baut). Lavoisier, London. p. 795-800.

During the summer of 1992/1993, wild and cultivated shellfish throughout the northern region of New Zealand became contaminated with lipid-soluble toxins resembling “breve toxins”. This toxicity was associated with a multi-species dinoflagellate bloom within which a *Gymnodinium* species was a significant component. The rates of toxin elimination were slow, and in some areas cultivated mussels still showed a residue of toxicity two months after the disappearance of this dinoflagellate from the plankton.

Histamine

13. Fletcher, G.C., Summers, G., Winchester, R.V. & Wong, R.J. (1995) Histamine and histidine in New Zealand marine fish and shellfish species, particularly Kahawai (*Arripis trutta*). J. Aquatic Food Product Tech. 4 (2): 53 - 74.

Forty-seven retail samples of fish (28 species) were tested for levels of free histidine, histamine and aerobic plate counts. Five samples (albacore, two jack mackerel, kingfish, kahawai) had elevated levels (≥ 20 mm/100 g) of histamine and all had < 100 mg/100 g. Three species (albacore, kingfish, kahawai) had free histidine levels of more than 1000 mg/100 g and these have been implicated in scombroid poisoning in New Zealand. One species with high histidine levels, kahawai (*Arripis trutta*), was chosen to determine the conditions under which potentially hazardous levels of histamine might develop. Two trials were carried out in which kahawai were stored under 17 regimes at temperatures between 0 °C and 35 °C. Histamine levels varied greatly in fish held under identical conditions. Fish held at ambient temperatures developed the highest levels of histamine. Of the 59 samples with elevated histamine levels, nine had acceptable sensory characteristics, while all had aerobic plate counts exceeding 10^6 colony-forming units/g. Aerobic plate counts at 20 °C are recommended over those at 35 °C. It is concluded that fresh kahawai will only present a hazard from scombroid poisoning under conditions of extreme temperature abuse and that the presence of high numbers of bacteria is a good indicator of the hazard, while sensory quality is not.

14. Foo, L.Y. (1975) The content of histamine and fish food poisoning. N.Z. Med. J. 82: 381-383.

This paper outlines the role of histamine in fish spoilage, reports the level of histamine in various fish samples that were involved in food poisoning incidents in New Zealand (kingfish fillet, smoked kahawai) and the British Solomon Islands, and suggests the use of histamine levels as an indicator of fish quality.

15. Mitchell, J.W. (1984) Scombroid food poisoning from fish. N.Z. Med. J. 2: 127.

This report gives a brief outline of symptoms, and a summary of two cases of scombroid food poisoning in Rotorua; one from eating kingfish fillets from a fish and chip shop; the other from eating smoked kahawai.

16. Mitchell, J.W. (1993) Scombrototoxic fish poisoning: a report for the Ministry of Health, Wellington, N.Z.

Overseas and New Zealand literature on scombrototoxic fish poisoning are reviewed. Previously unpublished data from analysis of New Zealand retail fish for histidine and histamine are

presented, together with a summary of analyses from recent food poisoning incidents. Results of the 1992-3 survey of histamine levels in high-risk samples (mostly smoked fish) are presented. Histamine was detected in only four of 91 samples (trevally, kahawai, mackerel, warehou, all smoked), but two of those samples contained histamine levels of 100 mg/100 g or greater (trevally, kahawai). It is not clear whether high levels of histamine are a result of mistreatment before or after smoking. Of the samples, 19% had unacceptably high total viable bacteria counts based ICMSF criteria.

Heavy Metals

17. Fenaughty, C.M., Tracey, D.M., & Lock, J.W. (1988) Heavy metal and organochlorine concentrations in New Zealand aquatic fish, crustaceans, and molluscs. N.Z. Fisheries Data Rep. No. 34. Ministry of Agriculture and Fisheries, Fisheries Research Division, Wellington.

This report summarises the data on heavy metal concentrations in various New Zealand seafoods. The molluscan, crustacean, and most finfish samples had total mercury levels below the maximum permissible level of 0.5 mg/kg. Those fish species that had concentrations equal to or above 0.5 mg/kg were predatory or long-lived species. Some of these species consisted of small sample sizes, particularly some sharks and dogfish where only one sample was analysed. All of the finfish and crustacean species had concentrations of cadmium, copper, lead, and zinc below the maximum permissible levels. There is no maximum permissible level set for cadmium and zinc concentrations for shellfish. Cadmium, copper and zinc levels in arrow squid digestive gland and gonad tissue exceeded the maximum permissible levels. The most commonly consumed part of the squid, the mantle, had lower than permissible levels of cadmium, copper and zinc, except for arrow squid sampled from the west coast of the South Island where cadmium levels were exceeded.

18. McCoubrey, D.J. (1995) Cadmium levels in queen scallops (*Chlamys deliculata*). Ministry of Agriculture, Regulatory Authority, Wellington.

This report summarises the issues raised from current world debate on whether cadmium levels in the diet have an adverse health effect on humans, and what levels or guidelines have been set for cadmium. The cadmium intake of New Zealanders appears to be rising and shellfish is one component that could increase this load. Queen scallops have particularly high levels when ungutted (17 µg/g), and once gutted have cadmium levels similar to Bluff oysters (3.2 µg/g). It is recommended that queen scallops should be gutted if eaten within New Zealand, but queen scallops may be exported gutted or ungutted unless there are particular market access requirements for cadmium levels.

19. MAF RA (1992) Unpublished data — Results of Fiordland, Cook Strait and Auckland/Coromandel crayfish heavy metal testing programme. Ministry of Agriculture and Fisheries, Regulatory Authority, Wellington.

Results of a heavy metal testing programme on New Zealand crayfish indicated that regardless of where crayfish were caught, heavy metal concentrations (lead, mercury, selenium, cadmium, copper and zinc) in the muscle tissue of tail complied with New Zealand and Australian maximum residue limits. The visceral content of the body of the crayfish did not comply with regulatory requirements for selenium, cadmium, copper and zinc.

20. MAF RA (1997) Unpublished data provided by the Institute of Environmental Science and Research Limited (ESR). Ministry of Agriculture, Regulatory Authority, Wellington.

Certain parts of scampi samples, such as viscera, were found to contain unacceptably high amounts of cadmium. The tail meat, when separated from the body while fresh, or broken while frozen solid, was found to have levels of cadmium below the Australian MPC of 0.2 mg/kg.

21. Nielsen, S.A. (1975) Cadmium in New Zealand dredge oysters: geographic distribution. Intern. J. Environ. Anal. Chem. 4: 1-7

High cadmium levels of up to 9 ppm wet weight have been found in the dredge oyster, *Ostrea lutaria* (Hutton), from Foveaux Strait, New Zealand. Average cadmium levels in the oysters were determined at 24 stations in order to obtain a pattern of the geographic distribution of cadmium. These data, in combination with a consideration of the prevailing currents, indicate that the source of the cadmium must lie to the west of Foveaux Strait, possibly in Fiordland. These high cadmium levels are naturally occurring as there is no industrial pollution in the area. Compared with other oyster species, *O. lutaria* may have a predilection for accumulating cadmium. High cadmium levels (about 6 ppm wet weight) have also been found in dredge oysters (*Ostrea lutaria* Hutton) from Tasman Bay. Such high levels are not normally found in oyster species from other parts of the world, nor are they representative for *O. lutaria* from other parts of New Zealand.

22. Nielsen, S.A., & Nathan, A. (1975) Heavy metal level in New Zealand molluscs. N.Z. J. Marine and Freshwater Res. 9: 467-481

Cadmium, lead, copper, mercury, zinc and iron were analysed by atomic absorption spectrophotometry in 13 species of edible molluscs from 199 sites around New Zealand. The purpose of this study was to establish average or normal metal levels for the molluscs examined. In fact, the variations in metal levels from one location to another may be so great that it is often difficult to determine what a "normal" metal level is. (All data shown as µg/g, wet weight.)

Cadmium: *Ostrea lutaria* (mean 3.9, range 0.12-7.9) and *Pecten novaezelandiae* (stomach: mean 137, range 15-239; gonad: mean 1.5, range 0.59-2.4; adductor: mean 0.51, range 0.20-0.82) appeared to accumulate cadmium to an unusually high degree, and this may be true to a lesser extent for *Anomia walteri* and *Crassostrea glomerata*. High cadmium levels were found in the stomach of *Pecten novaezelandiae*, but the stomachs are not often eaten, and cadmium does not appear to accumulate significantly in the adductor muscle and gonad which are normally eaten.

Lead: The average lead levels found in the species examined were not generally high, but some samples had quite high lead values. Lead levels in *Perna canaliculus* (mean 1.8, range 0.1-7.8) are about twice as high as other species (except *Chione stutchburyi* which is less commonly eaten). *Perna canaliculus*, which seems to have a predilection for accumulating lead, generally has higher lead levels in the vicinity of large cities.

Mercury: Average mercury levels were generally quite low (much less than 0.50 µg/g) in all six species examined.

Zinc: The outstanding feature was the high mean for *Crassostrea glomerata* (mean 337, range 97-900). It was five times the average for *Ostrea lutaria* and more than ten times the average of all other species. The ability of oysters to accumulate zinc is well known and the average lies well within the range of oysters from other parts of the world.

Copper: With the exception of *Crassostrea glomerata* (mean 40.0, range 4.4-380.0), copper levels were relatively low in the species examined. *Crassostrea glomerata* appears to have a definite tendency of accumulating copper compared with the other species. Some individual oysters from an area surrounding a defunct copper mine had slightly greenish tissue, and green deposits inside the shell. (*Crassostrea glomerata* is a rock oyster, now known as *Saccostrea cucullata*.)

Iron: Iron was relatively high in most species, values of up to 280 µg/g being found in *Perna canaliculus*, but as iron is not a toxic heavy metal, averages are not presented here.

23. Tracey, D.M. (1993) Mercury levels in black cardinalfish (*Epigonus telescopus*). N.Z. J. Marine and Freshwater Res. 27: 177-181.

In 1990, forty-eight cardinalfish (*Epigonus telescopus*) were sampled from a major commercial fishery off the East Coast of the North Island to determine their flesh mercury levels. The mean mercury level was 1.47 mg/kg with a range of 0.59 to 2.15 mg/kg (at the time of publication the Department of Health maximum level for fish sold on the local market was 0.5 mg/kg).

24. Winchester, R.V. & Keating, D.L. (1980) Trace metal and organochlorine pesticide residues in New Zealand farmed oysters: A preliminary survey. N.Z. J. Sci. 23: 161-169

Concentrations of zinc, copper, iron, manganese, chromium, mercury, cadmium, lead, arsenic, selenium, antimony, and the common organochlorine pesticides have been determined in samples of oysters (*Crassostrea gigas*) from several farms in the north of New Zealand. Although site to site variations were found, concentrations of most elements are within the ranges that would be expected for shellfish grown in relatively unpolluted waters. The possible effect of preservatives used in the manufacture of the wooden platforms that the oysters are commonly grown on was also investigated. The limited scale of the survey introduces a measure of uncertainty into the findings.

Zinc: Concentrations exceed the NZ Food and Drug Regulations (1973, obsolete) limit by a wide margin but are similar to those found in seafood from unpolluted areas elsewhere in the world.

Copper, Chromium: Levels are normal in comparison with elsewhere and do not appear to be related to the presence of wood preservatives.

Cadmium: Occasional high results exceed the permissible level (NZ Food and Drug Regulations 1973, obsolete) and require further investigation to identify possible sources.

Arsenic: Concentrations exceed the NZ permissible level (NZ Food and Drug Regulations 1973, obsolete) but are within levels set as acceptable in some other countries. There is a possible contribution from the wood preservative which requires further investigation.

Iron, Manganese, Mercury, Lead, Selenium, Antimony: Concentrations are similar to those found elsewhere in the world and indicate no degree of hazard.

Pesticides: There is no significant pollution of oyster-growing areas by these materials.

Appendix VII. Validation – What Has to be Done

1. Requirements for Validating a HACCP Plan

1.1 Expected outcomes

Validation of the HACCP plan involves the initial confirmation that the HACCP plan is complete and can deliver the expected food safety outcomes (achieve the food safety objectives).

1.2 Confirmation that the HACCP plan is complete

All eleven elements as required by IAIS 003.5 Section 2 should be documented and must reflect the expectations of the standard. These elements are:

- scope,
- product description,
- food safety objectives,
- process flow,
- hazard identification and analysis,
- CCP determination,
- critical limit setting,
- monitoring procedures,
- corrective action procedures,
- verification procedures,
- documentation and recordkeeping requirements.

The contents of the plan should accurately reflect what is actually occurring in an existing process or clearly describe what is expected to occur (new process). If it is a new process, initial confirmation should occur soon after production starts, e.g. after the first two production runs.

The rationale for hazard identification, hazard analysis, critical control point determination, and critical limit setting should be scientifically sound, clearly documented and readily available for audits.

Monitoring, corrective action and verification procedures should be meaningful in relation to the product and process.

1.3 Achievement of the food safety objectives (FSOs)

An FSO is a description of the expectations of hygiene measures that are applied during a particular segment of a food production process. The FSO should include a measurable outcome expected for the final product.

Achievement of an FSO needs to be demonstrated on an ongoing basis before validation is complete.

Premises should be able to demonstrate that FSO(s) are being achieved by implementation of the HACCP plan (and thus ongoing control at relevant CCPs), supported by the relevant effective prerequisite programmes.

2. Validation Procedures/Methods

Evidence necessary to demonstrate that FSOs are being achieved may be obtained from a variety of sources. These include:

- microbiological validation trials,
- (historical) microbiological databases,
- validation trials for other hazards,
- calibration of operators by on-line visual observations,
- calibration tests for technical equipment,
- (historical) prerequisite programme compliance records.

Where published data are available and relevant, this should be used.

Sampling programmes for validation should be based on application of statistical techniques which take into consideration, the **prevalence of the hazard**, the **level of confidence expected** and the **accuracy** the processor wants to achieve.

2.1 Microbiological validation trials/(historical) microbiological databases

The amount of microbiological data required for validation will be influenced by whether the process has changed due to the application and implementation of HACCP. Where the implementation of the HACCP plan does not result in any changes to the process or product, then historical validation results, including product testing where relevant, can be used to already demonstrate that the existing process is in fact achieving the FSO. For example, consider the following FSO:

FSO: To achieve a *Listeria monocytogenes*-free product by application of a validated process and the product testing requirements of IAIS 003.9.

This is an example of an FSO that is extensively dependent on prerequisite programmes. Achievement of this FSO would be validated by an investigation into the effectiveness of supporting prerequisite programmes (e.g. personal hygiene, *Listeria* management, equipment maintenance, raw/cook separation policy) as well as evidence supporting the desired microbiological outcomes from a listeriocidal process step and the entire process, i.e. final product tests.

Microbiological data should include, at a minimum, 25 historical test results supporting the achievement of the FSO. There should already be validation data available for any listeriocidal step existing prior to HACCP. This historical baseline is then verified on an ongoing basis by product testing as per IAIS 003.9 requirements.

When historical data is not available (i.e. for a new process), or inadequate or inappropriate due to changes made to product or process, validation will then involve the collection of new data from the time that the HACCP plan is first implemented. Inclusion

of a new listeriocidal process step will mean that this step should be individually validated (e.g. relevant published data, collected data on-site) and this would be separate to any **final product testing** designed to validate **process outcomes**.

A specific sampling scheme should be identified wherever possible. Where this isn't possible, twenty-five samples would provide a reasonable starting point for validating any process step or the entire process outcome. When evaluating the process, these samples should be taken over a period of time to enable process variability to be incorporated. A **suggested** sampling regime would involve the random selection of five sampling days, then random selection of five samples of final product per day over a two week period of processing to capture process variability.

Statistical advice should be sought when interpreting the sample results. IAIS requirements, where applicable, should be met for noncomplying product.

Where an FSO relates to the achievement of a microbiological target for a particular food pathogen not covered by a current IAIS standard, then validation procedures should reflect the biological significance of that target. Professional advice (e.g. Crop and Food Research, Cawthron Institute, MIRINZ Food Safety group) should be sought to assist in setting up the correct validation procedure for each food pathogen.

Note 1. It is inappropriate to use the sampling schemes of country legal limits or guidelines (e.g. Ministry of Health Microbiological Guidelines) for validation — these guidelines are established for monitoring and verification, and while the limit may be appropriate, the sample size is not.

Note 2. **Validation trials for other hazards.** The same principles apply to non-microbiological food safety objectives. For example, if there is a food safety objective of histamine less than 20 ppm and this is controlled through time-temperature protocols, the number of samples that are required to validate that the time-temperature protocol will in all instances deliver the histamine objective must be determined.

2.2 Calibration of operators/equipment

Visual observation of operator technique, equipment performance or inspection of products for visible contaminants and defects may be used to evaluate the adequacy of procedures at certain process steps to control identified hazards to specified targets. Two examples of an FSO where the use of visual observation is appropriate are as follows:

FSO: To remove metal from the product by the use of a metal detection system that achieves specified targets for metal objects.

The FSO is expected to be achieved by the individual CCP for metal detection. The performance of the metal detector to consistently detect and reject specified metal objects should be evaluated against the target set for the FSO. It is important to take into consideration the **types of metal** likely to occur in the product, the **capability of the machine** (i.e. what size and type of metal detected) and the **characteristics of the product**. The processor will need to adopt a detailed test methodology for checking the performance of the detector. This should include specifying how the test piece is mounted

and passed through the search head with or without product being present, examination procedure for reject material, frequency and interval for testing. The manufacturer's recommendations for calibrating and validating the system are important considerations when establishing test methods and performance targets.

FSO: To minimise the presence of bone in the final product to a specified target

The FSO is expected to be achieved at one or more process steps where normal removal of the hazard occurs. Therefore observations should be targeted at these process steps. An appreciation of the likely level of occurrence of bone in the product is essential before selecting an appropriate target level and then a sampling plan needs to be selected to demonstrate that the target has been met and the FSO achieved. Guidance on selection of an appropriate sampling plan for this type of validation is available from statistical publications.

2.3 Records demonstrating compliance to prerequisite programmes

The use of records demonstrating compliance to prerequisite programmes is particularly applicable when those prerequisite programmes support the achievement of a food safety objective. In most cases, premises would be expected to already have adequate records available for demonstrating an effective prerequisite programme. An example where the use of such records can demonstrate achievement of an FSO is as follows:

FSO: To ensure that all shellstock meets the current requirements of IAIS 005 for microbes, marine biotoxins and toxic substances by only sourcing shellstock from approved growing areas which are open at the time of harvest.

A review of records supporting “approved growing areas open at the time of harvest” for all shellstock received into the premises will provide evidence for validating the achievement of this FSO. Historical information may be used if the application and implementation of the HACCP plan has not resulted in any changes to the process. A minimum of 25 records should be provided as a starting point to validate the achievement of this FSO.

2.4 Mandatory CCPs for ICSS-listed premises

Validation of mandatory CCPs for ICSS-listed premises is also required. It is likely that most premises will have had these CCPs in place for some time as part of their normal activities to meet IAIS 005 requirements and can therefore prove (by historical records as described in Section 2.3) that they have effectively controlled the CCPs over a period of time. Evidence should include documentation to support container closing/covering requirements being met for shucked shellfish. Note that some of these mandatory CCPs would have required a specific and detailed validation, e.g. heat processing requirements in IAIS 005.1, and this should be documented and available for audit.

Where a new process has been established, then appropriate validation will be required as described above.

2.5 Small scale/itinerant manufacturing/new premises/new processes

Validation activities are also required for these premises. Provisional validation of documentation, as per TD 98/200, is essential prior to startup for these premises. Confirmation of the validation process should then follow according to Section 1.5 of this appendix.