



Regulated Control Scheme for Limited Processing Fishing Vessels: Operator Guidelines

Prelims

Amendment 0

September 2004

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Preface

This guideline has been produced by the New Zealand Food Safety Authority to provide guidance for operators of limited processing fishing vessels to help them meet the requirements of the Regulated Control Scheme for Limited Processing Fishing Vessels.

Suggestions for Change:

Regulated Control Scheme for Limited Processing Fishing Vessels - Operator Guidelines

Name: Organisation: Address: Email: Phone: Facsimile:	
Section	Suggested Improvements
Signature	Date
Please post to:	Acknowledgement of receipt
Assistant Director (Animal Products Standards) Animal Products Group New Zealand Food Safety Authority P O Box 2835 Wellington	Signature: Date:

Amendment Record

It is important that this publication is kept up-to-date by the prompt incorporation of amendments.

To update this publication when you receive an amendment, remove the appropriate outdated pages, destroy them, and replace them with the pages from the new issue.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 publication and sign off and date this page.

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

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Part 1: Introduction

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1.1 Introduction

The New Zealand Food Safety Authority (NZFSA) administers the Animal Products Act 1999 and its associated legislation.

The Animal Products Act 1999 has the objective of managing and minimising the risks to human and animal health from the production and processing of animal material and products, and of facilitating overseas market access.

The primary method of managing risks is for primary processors to operate under individually tailored risk management programmes registered under the Animal Products Act 1999. The Act also provides for the implementation of regulated control schemes, to enable risks to be managed in a cost-effective and efficient manner when it is not feasible to do so by individual risk management programmes.

The Regulated Control Scheme for Limited Processing Fishing Vessels (hereafter referred to as the RCS in this guideline) has been developed for this purpose. The RCS consists of:

The Animal Products (Regulated Control Scheme for Limited Processing Fishing Vessels) Regulations 2001 (hereafter referred to as RCS regulations); and

The Animal Products (Specifications for Limited Processing Fishing Vessels) Notice 2001 (hereafter referred to as RCS specifications).

Copies of these are available from the Website: www.nzfsa.govt.nz. Other relevant documents are also found on this website.

The key requirements of the RCS are that:

1. Each limited processing fishing vessel is registered by the NZFSA;
2. The operator develops an operator documented system for implementing the requirements of the RCS; and
3. An accredited verifier externally verifies this system.

1.2 Application of Regulated Control Scheme

This RCS covers requirements for the operation of limited processing fishing vessels that export processed fish material and fish products intended for human consumption, without landing the products into an on shore fish packing house. However, processed fish and fish products from limited processing fishing vessels covered by the RCS may also be landed to on-shore processing facilities for further processing, before export or sale on the domestic market.

The requirements included in this RCS cover fish products intended for human consumption and products intended for other purposes (e.g.: fish meal). Compliance with these requirements should ensure that fish products produced on limited processing fishing vessels are fit for their intended purpose.

It is intended that requirements relating to products intended for animal consumption will, in the future, be substantially covered by a separate specification. At that time, the RCS will be reviewed to extend specific requirements to address hazards to animal health.

At present, clauses 5 to 13 and clauses 39 and 40 of the RCS specifications cover requirements applicable to the processing of all products covered by the RCS.

1.3 Scope of the Regulated Control Scheme

Vessels registered under the Fisheries Act 1996 or the Fisheries Act 1983 are eligible to be registered under the RCS. The RCS applies to limited processing fishing vessels operating within the Exclusive Economic Zone (EEZ) of New Zealand.

A foreign-owned (charter) vessel permanently leaving the EEZ to return to its home base or for fishing in the high seas must surrender its registration prior to leaving New Zealand. If the vessel returns to the New Zealand EEZ to fish and intends to land catch in New Zealand, the operator must reapply for registration of the vessel under the RCS (see section 3.7 of these guidelines).

Operators of all vessels who apply or reapply for registration under the RCS, as well as those applying for renewal of registration, must provide an external verification report, made by an accredited verifier not more than 3 months before the date of application (RCS regulations 32(1)(b) and 33). Failure to provide such a report may result in deregistration of the vessel on the grounds that the vessel is no longer operating as a limited processing vessel under the RCS [RCS regulation 37(f)].

Following registration, operators of all vessels registered under the RCS must also ensure that external verification is carried out at the assessment frequency assigned by the accredited verifier. Note that whatever assigned frequency applies, an external verification of processing operations must be carried out at least every six months (clause 61(3) of RCS specifications).

1.4 Fishing Vessels Requiring Registration under the Regulated Control Scheme

All limited processing fishing vessels registered under the Fisheries Act 1996 or Fisheries Act 1983 and processing any quantity of fish material or fish product intended for human consumption for export directly from the vessel (other than landing on shore solely for storage and transport), must be registered under the RCS. Limited processing fishing vessels that, from time to time, land all or part of their catch to on-shore facilities for further processing prior to export or sale on the domestic market may also be registered under the RCS.

Operators of limited processing fishing vessels may choose to operate under a Risk Management Programme (RMP) rather than under the RCS (see 1.6 of these guidelines).

1.5 Vessels Not Requiring Registration Under the Regulated Control Scheme

The following vessels do not require registration under the RCS:

- a. Inshore fishing vessels that supply catch, for further processing, to premises operating a risk management programme (RMP) registered under the Animal Products Act 1999 or to licensed land based premises.
- b. Processing vessels (factory vessels) that carry out skinning, filleting and other operations in addition to limited processing are not covered by the RCS. These vessels require individual RMPs.
- c. Vessels processing fish caught in the New Zealand EEZ that are not landed in New Zealand nor claimed to be a product of New Zealand;
- d. Vessels processing solely fish products that are not intended for human consumption;
- e. Vessels used only for temporary holding, storage or transport of fish or fish product awaiting transport or delivery to the processing premises such as:
 - vessels that keep live fish in containers in the sea, where the fish are taken (eg: rock lobsters); and

- vessels that solely transport the fish to a holding or storage depot or facility or to a primary processor.

1.6 Option of Operating Under a Risk Management Programme

Limited processing fishing vessels may operate under an RMP if the operator prefers. The operator may also elect to change from operating under the RCS, to operating under an RMP, and vice versa (see RCS regulation 6). However, it is not possible to operate under both regimes at the same time, either for the entire operation or a part of it.

Operators who chose to operate under an RMP need not register under the RCS. If limited processing activities are carried out for only short periods, compared with the time allocated to other processing operations on the vessel (e.g.: filleting, canning, mincing), the operator should consider including all processing operations in a registered RMP, rather than switching between the RCS and an RMP.

1.7 Relationship Between the RCS and Other Regulations

The Animal Products Regulations 2000 do not apply to the RCS. Other regulations and specifications, including those of other regulated control schemes made under the Animal Products Act 1999, may apply to this RCS (see RCS regulation 7).

1.8 Payment of Fees

The operator is obliged to pay any fee incurred in association with the development and registration of, and ongoing operation under, the RCS. Specific fees apply to:

- application for registration under the RCS; and
- renewal of registration under the RCS.

The NZFSA will also require the operator to pay an assessment charge (calculated on an hourly basis) for the time involved in assessing any of the above applications.

Further information on fees is provided in the legislation, e.g.: Animal Products (Fees, Charges and Levies) Regulations 2002.

Contractual arrangements regarding payment for any required services, e.g.: verification, are the operator's responsibility. If NZFSA Verification Agency (NZFSA VA) is the nominated verifying agency, fees as set out in the legislation, e.g.: Animal Products (Fees, Charges and Levies) Regulations 2002, will apply.

1.9 Authorities, Responsibilities and Requirements

The RCS identifies two key authorities and their responsibilities. These are:

1. The operator, and
2. The person responsible for the day to day management of the facilities and processes, and who is the Management representative for all aspects of the RCS.

The person/s (described in (2) above) should be able to demonstrate that they have the authority within the business to fulfil this role. This person, who will be expected to deal with MAF and the NZFSA on any RCS issues, may be the operator, the master of the vessel, operational manager, a quality/technical manager or a similar person.

Figure 1 illustrates the tasks that must be carried out to make sure that the requirements of the RCS are fulfilled.

Table 1 expands on each of these tasks and clarifies the obligations and responsibilities (in chronological order) of the various people involved in developing, validating, verifying, registering, operating and ceasing registration under the RCS.

Figure 1: RCS tasks

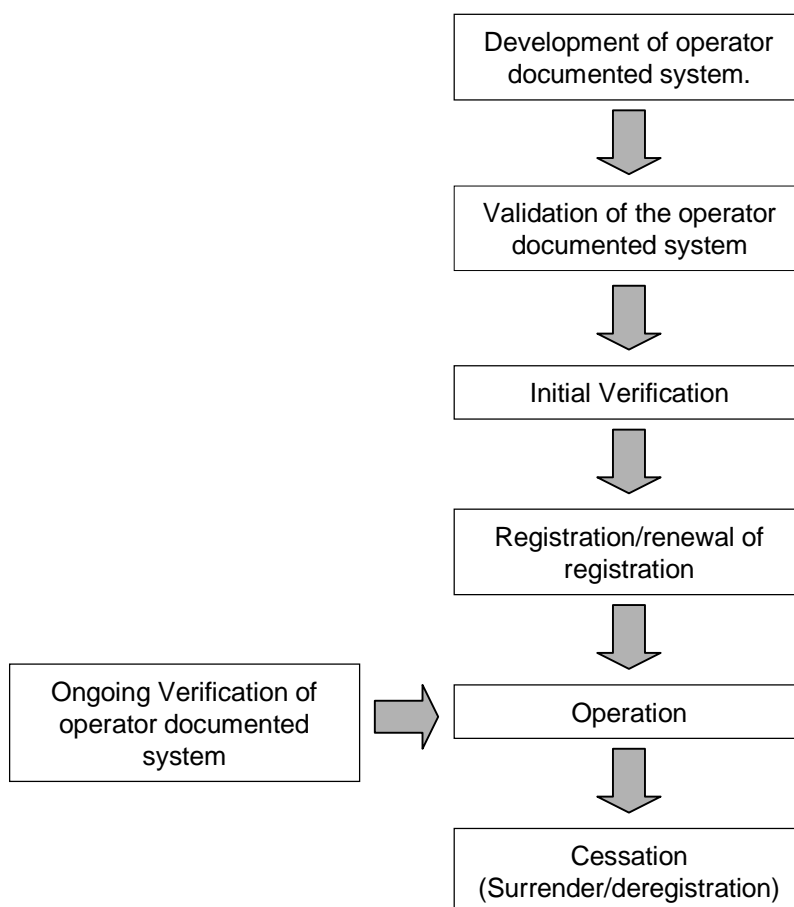


Table 1: Regulated Control Scheme Tasks and Responsibilities

Tasks	Responsibility
Development <ul style="list-style-type: none"> Development of the operator documented system 	Operator
Validation <ul style="list-style-type: none"> Validation of the hazard identification, (and Critical Control Points (CCPs), where identified) 	Operator
Registration <ul style="list-style-type: none"> Naming the recognised verifying agency that has indicated its willingness to carry out verification functions Application for registration under the RCS Initial verification Registration of the limited processing fishing vessel Surrender of registration when the vessel leaves the EEZ on a permanent basis, or to return home Application for renewal of registration 	Operator Operator Accredited Verifier Director, Animal Products Operator Operator
Operation <ul style="list-style-type: none"> Contracting verification services to be used for ongoing verification functions Implementation of the programme Specific operational duties Operator verification External verification Reviewing the Hazard ID system (annually) Documenting minor and significant amendments to the operator documented system and notifying accredited verifier 	Operator Operator Operator Accredited Verifier Operator Operator
Cessation <ul style="list-style-type: none"> Surrender of the registration Deregistration 	Operator Director, Animal Products

1.10 General Requirements for Export (GREX) and Overseas Market Access Requirements (OMARs)

The Animal Products Act provides for NZFSA to issue Official Assurances and to notify general requirements for export (GREX) and overseas market access requirements (OMARs). Exporters of animal products must be registered with NZFSA.

GREX and OMARs are additional to the RCS requirements. Operators must ensure that any OMAR requirements are met, including documenting compliance with these requirements, if necessary.

Part 2: Development of an Operator Documented System

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For each registered vessel, the operator must develop and implement an operator documented system, based on Hazard Analysis and Critical Control Point (HACCP) principles and in accordance with regulation 39 of the RCS Regulations 2001. In most cases where supporting systems are largely used to control and manage identified hazards, a hazard identification process is sufficient. If supporting systems are not able to control and manage all identified hazards, the operator must develop a HACCP plan (see RCS regulation 40).

An operator's documented control system will be legally binding for the vessel registered under the RCS. The fishing vessel must operate according to the programmes described by the operator documented system.

Where necessary, operators should seek external assistance to develop their operator documented system(s).

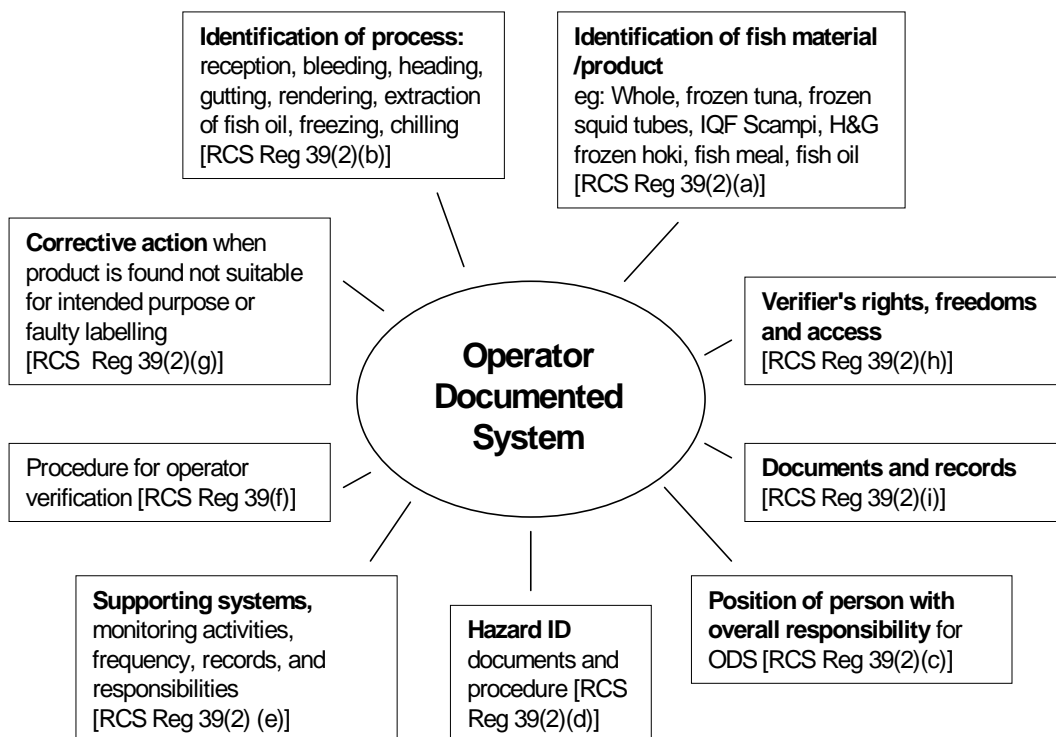
2.1 Contents of the Documented Control System

The operator or the person responsible for day-to day management must sign the operator documented system and must sign the cover sheet of the operator documented system.

Under the Animal Products Act 1999, the fishing vessel operator has the ultimate responsibility for ensuring that the operator documented system is effectively implemented. The operator must also document who is responsible for the day-to-day management of the vessel and the processing operations, and consider documenting how a deputy is assigned to cover for shifts.

The components of the operator documented system are shown in Figure 2A.

Figure 2A: Components of the Operator Documented System



2.2 Identification and Control of Hazards

A key requirement under the RCS is to identify hazards that are reasonably likely to occur during the processing of fish or fish products intended for human consumption [see RCS regulation 40(1)(a)]. The hazard identification may be required for processes applicable to other products, if required by specifications [see regulation 40(1)(b)]. During this procedure, the operator must consider the hazards associated with raw material and other inputs, with process steps, and with other sources.

The main categories of hazards to be addressed are shown in Table 2.1.

Table 2.1: Categories of Hazards and Risk Factors

<p>Hazards RCS Regulation 40(2)</p>	<p>Hazards to human health Hazards to animal health (optional at present) Risks that are reasonably likely to occur from false or misleading labelling; and Risks that are reasonably likely to occur to the wholesomeness of the fish material or product.</p>
<p>New Hazards (Clause 48 of the RCS Specifications)</p>	<p>Operators must notify new hazards (emerging, new or exotic biological, new chemical) that come to their notice to the Director, Animal Products, without delay.</p>

The hazard identification and analysis are based on HACCP principles, which have for some time been used by the seafood industry to control food safety hazards in their processes. The hazard identification and analysis procedure must be incorporated into the operator documented system to demonstrate that hazards to human health are under control. Other risk factors, e.g.: risks to the wholesomeness of the fish material or fish product and risks due to misleading labelling, should be considered and may be included in the operator documented programme if appropriate.

Before identifying hazards, the operator should ensure that the supporting systems are documented and confirmed as effective. For limited processing fishing vessels, the control of hazards is achieved mainly by the proper functioning of the supporting systems unless the operator documented system shows otherwise.

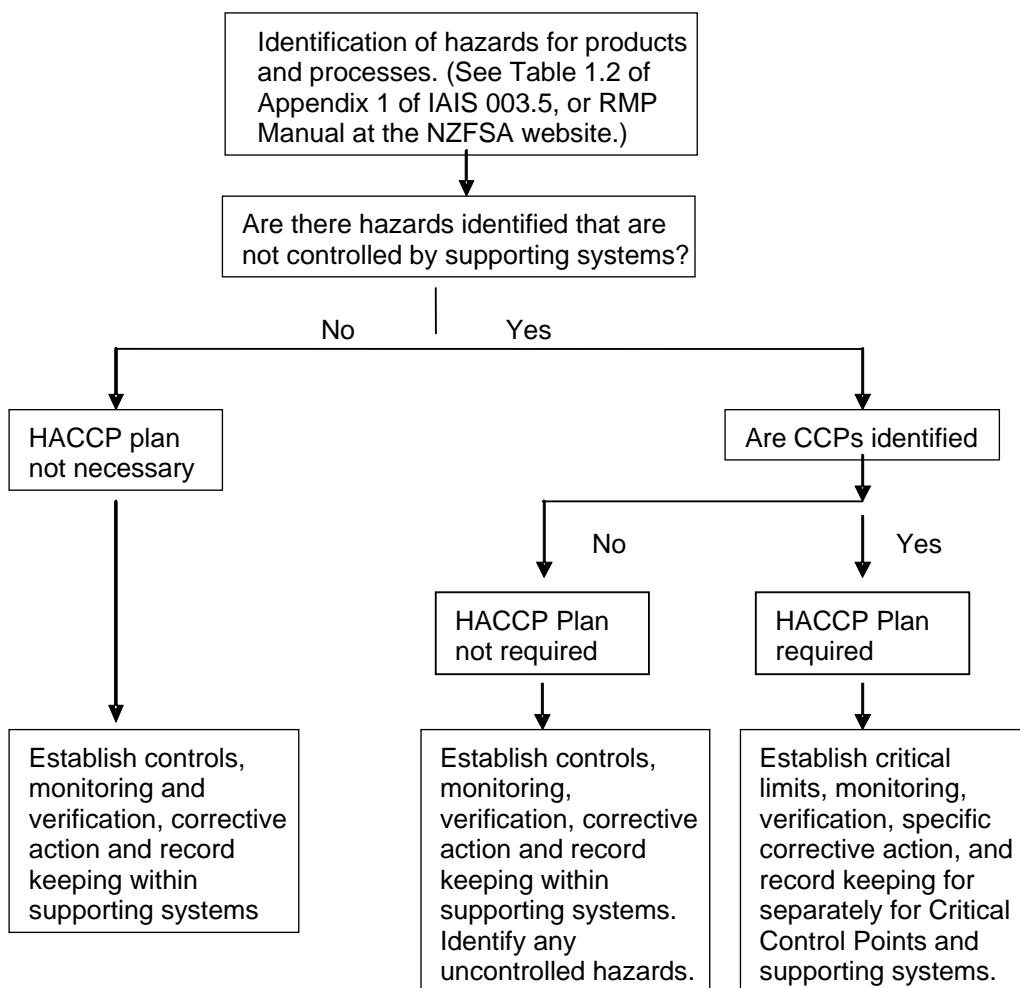
Where a food safety hazard is identified and no adequate control measure exists in the supporting systems, the operator must develop a HACCP plan.

A hazard may remain unaddressed by the process. Such hazards should be identified as uncontrolled hazards (e.g.: parasites in chilled fish, mercury content in certain types of fish meal).

A guideline on the application of HACCP to the seafood industry is available on the NZFSA web site at: www.nzfsa.govt.nz/animalproducts/seafood/guidelines/haccp/

The following Figure summarises the process to be followed in the hazard identification.

Figure 2B: Hazard identification process



2.3 Supporting Systems

It is practical and appropriate to manage some sources of hazards, or the hazards themselves, independent of the process. The systems used for this purpose are referred to as supporting systems (e.g.: prerequisite programmes, good hygienic practice). Supporting systems may interact at a number of process steps both within and across various processes.

A list of supporting systems used in the control of hazards should be included in the operator documented system. These systems should meet the relevant requirements in the RCS specifications.

The operator documented system should also designate the person or persons responsible for the day-to-day management of each supporting system, and state the type and frequency of monitoring activities required.

Examples:

1. The cleaning and sanitation programme should identify:

- the person responsible for the overall programme;
- the specifications or standards adhered to;
- the frequency and locations of visual checks, and any other monitoring procedure performed to confirm the effectiveness of the programme; and
- corrective action procedures in case of failure.

2. The water management plan should identify:

- the person responsible for the overall management of the plan;
- any specifications or standards adhered to;
- procedures, including management of supplier guarantees and frequency of review of those guarantees¹;
- monitoring activities, including visual tests and inspection at specified locations;
- any other testing, including physical examination carried out; and
- corrective action procedure in place in case of failure.

Other examples of supporting systems that are relevant to limited processing fishing vessels are:

- Sanitary design and essential services
 - Design and construction
 - Facilities

¹ The supplier guarantees for potable water should be renewed every year. The Director, Animal Products will authorise further testing of water (for requirements given in Schedule 1 and the definition of potable water in the RCS specifications) if considered necessary by the external verifier.

-
- Water
 - Vermin control
 - Amenities
 - Processing gases
 - Premises hygiene and maintenance:
 - Waste management
 - Management of chemical compounds
 - Personnel hygiene
 - Competency of personnel and training programmes
 - Labelling
 - Traceability and recall procedures
 - Calibration
 - Maintenance of records and documentation

2.4 Operational Authorities and Responsibilities

There are no specific competency requirements in the RCS, but the operator must provide appropriate instruction and supervision of staff.

Operational authorities and responsibilities must be documented at appropriate places within the operator documented system (in any format that suits the operation). In other words, the operator must describe who is responsible for carrying out the tasks required to implement the operator documented system, including:

- monitoring activities;
- corrective action activities;
- operator verification activities;
- recall of non-complying product.

In some vessel operations, the operator may delegate these responsibilities and authorities to different people at different times, depending on availability of personnel e.g.: by roster. In such cases, the operator must document the method for delegating responsibilities and authorities.

Responsibilities can be documented either by name, position or designation. In order to minimise the updates to the operator documented system, it is recommended that the position or designation option is used.

Table 2.2: Activities for which authorities and responsibilities should be identified

Authorities and responsibilities	Clarification
Monitoring activities (used for operator verification, validation)	<p>Including:</p> <ul style="list-style-type: none"> • Observations; • Inspection; • Testing.
Corrective action activities	<p>Including:</p> <ul style="list-style-type: none"> • Restoration of control; • Control and disposition of non conforming product; • Possible re-working of non-conforming product; • Prevention of recurrence; • Recall of non-conforming product.

2.5 Provision for Verification Activities and Verifier's Rights

The description of the arrangements and procedures made to enable accredited verifier activities is an important component of the operator documented system. These requirements are described in clause 53 of the RCS specifications and include:

- providing access to the processing areas of the vessel;
- providing access to records, documentation and information relating to the operator documented system (including electronic records);
- freedom for verifiers to examine and to open any container, packaging and to inspect contents and associated things; and

-
- freedom for verifiers to identify, mark, examine, sample, test and analyse relevant materials.

Accredited verifiers are also authorised to detain any product or associated thing, and to intervene or temporarily interrupt processing if necessary, as described in clause 53 of the RCS specifications.

2.6 Documentation and Record Keeping Requirements

All components of the operator documented system must be documented in writing² and be legible. The operator should ensure that all information in the operator documented system is presented in a format that facilitates process/operational control and operator verification activities, including validation by the operator prior to registration.

The RCS allows operators some flexibility in the way they record the operator documented system. The operator documented system can reference recognised codes of practice, hazard identification or other relevant documented procedures in part or in full, rather than include entire documents. Any such references then become part of the operator documented control system. However, any sections of those documents that are not specifically referenced do not form part of the operator documented system.

All documentation relevant to the operator documented system must be readily accessible to the verifiers and regulators, as necessary. The correct version and dates (year, month and day) of the referenced documents must be included in the operator documented system summary.

2.7 Operator Verification of the Operator Documented System

The operator documented system must specify the procedures for operator verification to determine that requirements of the RCS have been met.

2.7.1 Operator validation of the operator documented system

The following can be used to validate the operator documented system:

- historical data/records

² In writing means printed, typewritten, or otherwise visibly represented, copied, or reproduced, including by fax or email or other electronic means.

- records demonstrating compliance
- adherence to recognised codes of practice and guidelines (e.g.: IAISs).

Validation involves the collection of information and its analysis. This information is commonly obtained using analytical testing, visual observation and inspection equipment.

Visual observation is generally used for inspecting products for visible defects (e.g.: cleanliness of surfaces, spoilage of fish material or fish product) and the presence of visible contaminants (e.g.: foreign objects). It is also appropriate to use visual observation when observing compliance with established procedures, e.g.: for personnel hygiene practices, manual operations.

In some cases visual observation, rather than analytical testing, may be a more practical and economical means for evaluating the adequacy of certain procedures. Records of these visual observations can be used for validation. It is important that observers are adequately trained and procedures are standardised to ensure accurate and consistent results.

Inspection equipment, such as metal detectors, may be used for detecting specific physical contaminants (e.g.: metal, glass) during in-line inspection of raw materials and products.

2.7.2 Ongoing operator verification

Ongoing operator verification activities may include but are not limited to:

- internal audits;
- calibration checks;
- review of monitoring records;
- tests; and
- review of non-conformance and corrective action records.

The frequency of the above activities may be based on performance and will vary according to the part of the operator documented system being verified. The initial frequency used for verification of control of hazards may be reduced if defined parameters are consistently met and results systematically recorded. Flexibility is left with the operator unless otherwise stipulated by a mandatory requirement. As part of the operator verification procedures within the operator-documented system, the operator should document how ongoing operator verification activities will be established, by whom, and where the current frequency is recorded.

2.8 Amendments to the Operator Documented System

The operator should record any changes to the operator documented system where these changes mean that the operator documented system:

- is no longer appropriate, or will no longer be appropriate to the fish material or product, processes, or area covered; or
- will impact on the fitness for intended purpose of the fish material or fish product concerned.

The operator should document these changes, confirm their validity where necessary and bring them to the attention of the accredited verifier during the next scheduled verification.

2.9 Operator Documented Systems in Conflict with Regulations or Specification

Where there is any conflict between documented requirements of an operator documented system and requirements of regulations or specifications made under the RCS, e.g.: by failure to amend or update as required, the requirements of the regulations or specifications will prevail.

Part 3: Registration

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3.1 Application for Registration

The legislation requires the Director-General to provide for the registration of regulated control schemes. For the practical purposes of administering the Animal Products Act, the Director-General has delegated this responsibility to the Director, Animal Products.

The operator must apply to the Director, Animal Products for registration of the fishing vessel on the Application Form (AP17) Registration of a Limited Processing Fishing Vessel, before commencing operations for trade. The form and application guidelines are available from the NZFSA website www.nzfsa.govt.nz/animalproducts/publications/forms/index/htm.

The following is required for registration:

- a copy, or evidence of the current registration of the vessel under the Fisheries Act 1996 or the Fisheries Act 1983;
- a copy of the initial verification report completed by an accredited verifier no more than 3 months before the date of application for registration;
- a list of the documents that form the operator documented system, signed by the accredited verifier;
- the name of the recognised verifying agency that is willing to provide external verification functions for that vessel;
- signed operator declaration as stated on the application form;
- the application fee;
- a completed application form, which specifies:
 - the operator of the fishing vessel;
 - the name, position or designation of a person /persons nominated by the operator as responsible for the day-to-day management of the processing operations on the vessel.

The applicant must also ensure that the list of documents that form the operator documented system accurately represents the system at the time of application for registration.

The Director, Animal Products may require the applicant to supply additional information before determining whether the vessel is fit for registration.

If all the information is not supplied within 3 months from the date of request, or within such time as allowed by the Director, Animal Products, the registration application lapses.

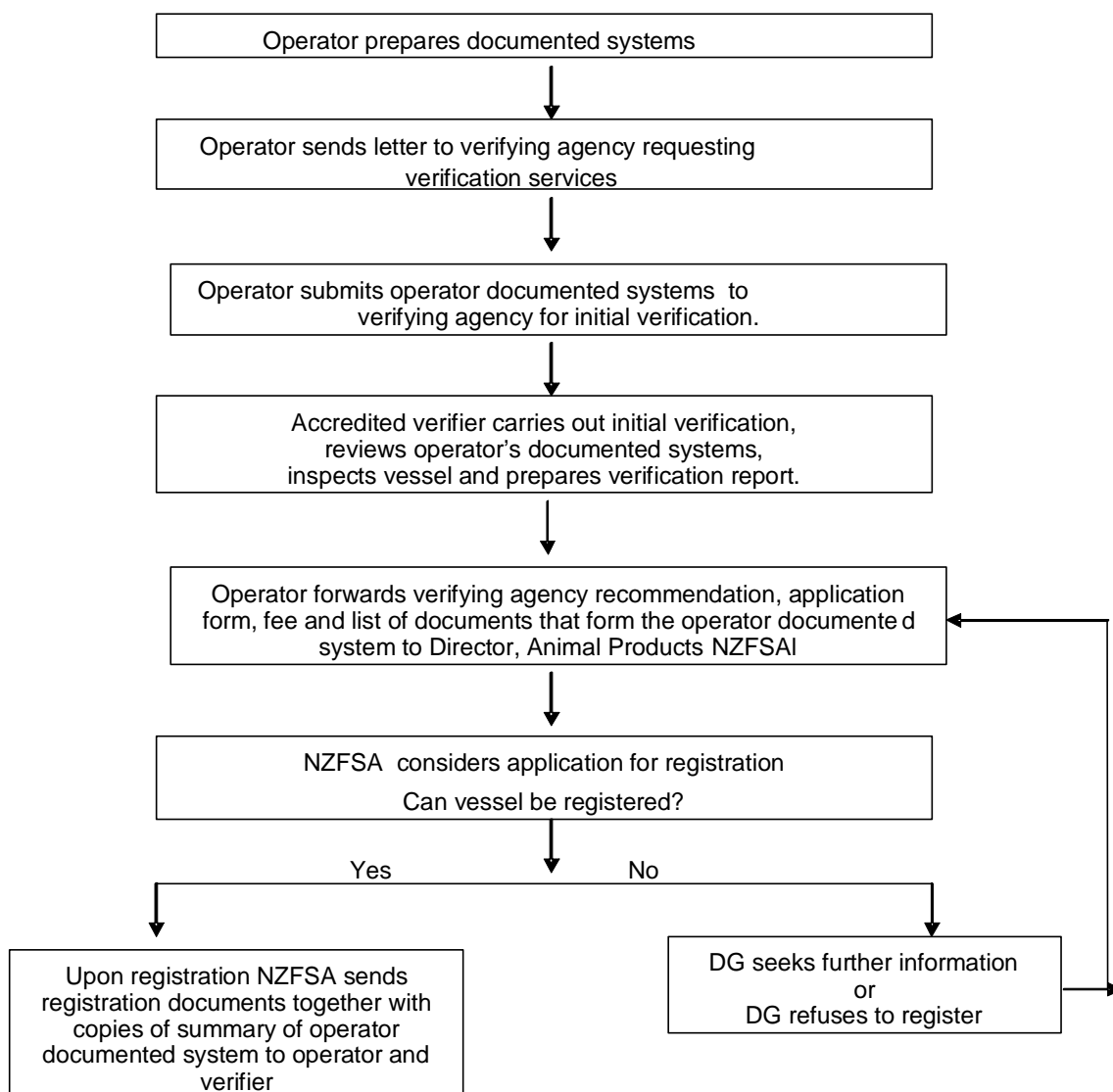
The Director, Animal Products will consider the submitted information and decide whether to register the vessel with or without conditions.

The Director, Animal Products may refuse registration of a vessel, after appropriate consultation with the operator (see section 3.3 of these guidelines).

The prescribed fee must accompany all applications for registration. NZFSA may also require the operator to pay an assessment charge (calculated on an hourly basis) for the time involved in assessing the applications for registration.

The registration procedure is outlined in Figure 3.

Figure 3: Registration Procedure



After registering the vessel, the Director, Animal Products will supply the operator with the notice of registration, as soon as practicable, including:

- registration number of the vessel;
- the period of registration;

- any conditions imposed, some of which may relate to the commencement of operations; and
- a copy of the list of the documents that form the verified operator documented system, submitted for registration.

The Director, Animal Products will also supply the operator's recognised verifying agency with an authorised copy of the submitted documentation as soon as practicable after registration. A further authorised copy of the summary of the operator documented system will be held by NZFSA.

A register of registered vessels is available at www.nzfsa.govt.nz/animalproducts/ under the link registers and lists.

3.2 Renewal of Registration

The operator must apply to the Director, Animal Products for a renewal of registration, prior to expiry of the vessel's current registration.

The provisions in section 3.1 above apply to an application for renewal of registration as if it were an initial application for registration, with any necessary modifications.

Note: The operator must supply an external verification report, made by an accredited verifier not more than 3 months before the date of application (see also section 5.4 of these guidelines).

NZFSA will forward renewal of registration reminder notices one month prior to expiry of registration.

3.3 Change of Registration

The operator documented control system applies only to the operator and the vessel specified in the registration. Registration may not be transferred.

3.3.1 Change in operator only

Where it is proposed to change the "operator" or the "operator's name", the new operator must make a new application for registration and must declare, on the application form (AP17), that no other component of the regulated control scheme has been changed.

At the same time it will be necessary for the existing operator to surrender the existing registration for cancellation (see section 3.6).

The following circumstances will also be treated as involving a change in the operator and will require a new registration:

- a change in the (number of) members of a partnership; or
- the death, bankruptcy, receivership, or liquidation of the operator.

3.3.2 Change in recognised verifying agency

The operator must notify the Director, Animal Products in writing within 7 days of any changes made to the recognised verifying agency. Such changes do not require amendments to the operator documented system.

3.4 Director, Animal Products May Refuse to Register

If, after considering an application, the Director, Animal Products proposes to refuse to register a vessel, the Director, Animal Products will notify the operator in writing, clearly stipulating the reasons for the proposed refusal.

The operator will be given a reasonable opportunity (i.e. within 30 calendar days or as agreed) to make written submissions or be heard in respect of the proposal. This section also applies when the Director, Animal Products proposes deregistration under the regulated control scheme.

3.5 Right to Review Decisions

If a person other than the Director-General refuses to register a vessel under the regulated control scheme, the operator may seek a review of this decision, under section 162 of the Animal Products Act 1999 – *Right of review of certain decision made under delegated authority*. However, no right of review exists when the Director-General makes the decision to refuse registration.

An application for a review must be in writing, must state the reasons why it is believed the original decision was inappropriate, and must be provided to the Director-General within 30 days after the original decision was notified to the operator.

The Director-General or a designated person not involved in the original decision will carry out a review of the refusal to register, usually within 60 days.

The Director-General's decision is final, subject to judicial review.

3.6 Surrender of Registration

Regulation 38 of the RCS Regulations allows the operator of a limited processing fishing vessel, at any time, to surrender the registration of the vessel by notice in writing to the Director, Animal Products. In such cases, the operator must:

- notify the Director, Animal Products in writing and include details as to how any remaining fish material or product, covered by the registered RCS, will be dealt with;
- surrender the notice of registration to the Director, Animal Products; and
- notify the verifying agency.

The Director, Animal Products may agree to the operator's proposal for dealing with remaining fish material or product, subject to conditions, and the operator must comply with these conditions.

When a limited fishing vessel registration under the RCS is surrendered, it is no longer possible to raise an eligibility document (ED) or eligibility declaration (EDec) for fish product from that vessel. This is because the registration is not active in the E-cert database. To overcome this problem, operators need to ensure that before the vessel registration is surrendered, EDs/EDecs are raised for all fish product the operator wishes to export. This can be achieved by either raising EDs/EDecs from the vessel to the receiving land premises or by the receiving land premises raising internal EDs/EDecs to itself.

3.7 Deregistration

The Director, Animal Products may deregister a vessel if satisfied that it is no longer operating as a limited processing fishing vessel under this scheme (see RCS regulation 37(f)), even if the operator has not voluntarily surrendered registration.

Foreign fishing vessels leaving the fisheries waters of New Zealand, e.g.: to return home, must surrender the registration they obtained under Section 38(2) of the RCS regulations. Where the operator fails to surrender the registration, the Director, Animal Products will deregister the vessel according to Regulation 37(f) of the RCS regulations.

If the foreign vessel returns to fish in New Zealand's EEZ, the operator must re-apply for registration (see 3.2 of these guidelines).

Where an operator ceases to manage or control a limited processing fishing vessel, the operator must notify that fact to the Director, Animal Products in writing, within 14 days of so ceasing (RCS Regulation 38(2)).

Part 4: Operating Under the Regulated Control Scheme

Amendment 0

September 2004

4.1 Commencing Operations

The operator may only commence limited processing, including rendering or fish meal processing, from the date of notification of registration of the vessel.

After registration, the operator must comply with the requirements of the RCS and with any conditions imposed by the Director, Animal Products.

4.2 Operator's Duties

The operator of a registered limited processing fishing vessel has the following duties (Regulation 42 of the RCS regulations):

42. Duties of operators of limited processing fishing vessels

- 1. The operator of a limited processing fishing vessel has the following duties:*
 - a. to ensure the facilities and processing operations of the vessel do not contravene the relevant requirements of this scheme and of the operator documented system; including ensuring that—*
 - i. the accredited verifier's requirements relating to verification are complied with:*
 - ii. a designated person (or more than 1 person) responsible for the day-to-day management of the processing operations is on board the vessel while the vessel is operating:*
 - iii. the requirements of this scheme and the operator documented system are implemented by the designated person or persons on board the vessel:*
 - iv. a copy of the operator documented system is kept on board the fishing vessel at all times:*

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- v. a set of instructions is kept on board the fishing vessel at all times in a language readily understood by processing personnel so that they may understand and comply with the operator documented system and this scheme:*
 - b. to ensure that the operator documented system is not inconsistent with the requirements of this scheme:*
 - c. to adequately implement and resource all processing operations under the scheme, including provision for the instruction, training, and supervision of personnel to ensure the production of fish product that is fit for intended purpose:*
 - d. to ensure that all processing operations under the scheme are commensurate with the capability and the capacity of the vessel, facilities, equipment, and personnel to produce fish product that is fit for intended purpose:*
 - e. to ensure relevant accredited persons have such freedom and access as will allow them to carry out their functions and activities under this Act, including verification functions and activities:*
 - f. where fish product is recalled because it is or may not be fit for its intended purpose, to notify the vessel's recognised verifying agency as soon as practicable after the decision or direction to recall the product is made:*
 - g. to maintain procedures and processes to demonstrate that the record-keeping requirements of and under this scheme in relation to the landing, reception, and processing of the fish material or product are being complied with:*
 - h. to provide an interpreter when required by an accredited person or animal product officer or by the Director-General, when records on board a vessel are not kept in English or persons responsible for processing operations do not speak English.*
 - 2. The operator must notify the Director-General, in advance where practicable, and otherwise as soon as possible, of any change in the operator's recognised verifying agency.*
 - 3. The operator must notify the Director-General, in advance where practicable, and otherwise as soon as possible, of any of the matters specified in regulation 37(1)(d) to (g).*

The matters specified in regulation 37 (1) (d) to (g) are as follows:

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- d. *the processing operations on the vessel are no longer managed or controlled by the operator; or*
 - e. *the fishing vessel is no longer suitable for the processing activities carried out on board; or*
 - f. *the fishing vessel is no longer operating as a limited processing fishing vessel under this scheme; or*
 - g. *all the limited processing operations are carried out under a registered risk management programme.*

Part 5: Verification Activities by an Accredited Verifier

Amendment 0

September 2004

5.1 Obtaining an Initial Verification Report

Initial verification is the process of recognising the validity of the operator documented system, with the intent of recommending registration. Initial verification is also required for renewal of registration.

Initial verifiers are available at specific ports only. The onsite pre-registration verification may be done in Auckland, Wellington, Nelson, Lyttleton and Timaru ports. If the operator uses a port other than those listed, the operator must bear any additional costs associated with carrying out such an initial verification. As part of the initial verification, the accredited verifier must conduct an on-site assessment to assess the appropriateness of the facilities and the operations described in the operator documented system. If operator validation is incomplete, the accredited verifier may make a second visit to evaluate the completion of validation.

The contents of the initial verification report will include:

- the name of the accredited verifier carrying out the initial verification and the unique identification number;
- the name and address of the operator of the fishing vessel;
- the name and registration number of the fishing vessel;
- the types of processing carried out on the vessel;
- a list of documents comprising the operator documented system that were reviewed during the initial verification;
- the completion date and location of the initial on board assessment (or reason why this was not included during renewal of registration);
- a statement of whether the operator documented system has been validated and is applicable.

A list of recognised agencies and accredited verifiers is available on the web site at:

www.nzfsa.govt.nz/animalproducts/ under the heading registers and lists.

The operator is responsible for contracting an accredited verifier from a recognised agency, and for contractual arrangements regarding payment for verification services.

5.2 Verification Notification

Part 4 of the RCS specifications describes the provisions relating to external verification.

The operator must provide at least 24 hours notice to the verifier before the ship calls into port (except for emergencies), and products must not be discharged before the external verifier has given their approval.

The accredited verifier should notify the operator, in advance wherever possible, of the timing of routine visits. Unannounced visits may be made where there is a history of poor performance or for other reasons as necessary.

5.3 Verification Frequency

The frequency of verification will depend on the operator's performance. A lower frequency may be applied if the operation complies with the documented system and is consistently meeting required standards under the RCS. A higher frequency may be appropriate if the programme is not implemented correctly (see clause 63 of RCS specifications). Note that whatever assigned frequency applies, the operator must ensure that an external verification of processing operations is carried out at least every six months (clause 61(3) of RCS specifications).

The accredited verifier may carry out additional verification for Overseas Market Access Requirements, in addition to the verification requirements of the RCS.

5.4 Verification at Renewal of Registration

When a vessel applies for a renewal of registration, the application must be accompanied by an accredited verifier's report, under the conditions applied for initial verification procedures. This report must not be more than 3 months old at the time of the application for renewal [see RCS regulations 32 and 33]. Failure to provide such a report may result in deregistration of the vessel on the grounds that the vessel is no longer operating as a limited processing vessel under the RCS [RCS regulation 37(f)].

The application must be made by the operator and received by the Director, Animal Products at least one month before the expiry of the vessel's current registration.

Part 6: Appendix A: Glossary of Terms

Amendment 0

September 2004

Note: Any term or expression that is defined in the Animal Products Act 1999, Animal Products (Ancillary and Transitional Provisions) Act 1999, or regulations made under those Acts and used, but not defined here, has the same meaning as in those Acts or regulations.

Accredited person: in relation to any verification or other specialised function or activity, means a person accredited by the Director-General to perform that function or activity.

Accredited verifier: or accredited risk management programme verifier means a person currently accredited by the Director-General as a risk management programme verifier.

Act: the Animal Products Act 1999 unless otherwise stated.

Animal Products Act Regime: the regime under the Animal Products Act 1999, including the Apiaries Act Regime, the Meat Act Regime and that part of the Food Act Regime that interfaces with the Animal Products Act 1999.

Animal product officer or officer: a person appointed as an animal product officer under the Animal Products Act and includes the Director-General.

Animal product standard or standard: a standard prescribed by regulations and specifications that specifies the criteria that must be met to determine fitness for intended purpose of any class or description of animal product.

Animal product, or product: any animal material that has been processed (other than simply transported or stored in such a way as not to involve any alteration to its nature) for the purpose, or ultimate purpose, of consumption or other use by humans or animals.

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.

Contaminant: any substance or thing which:

- is undesirable, potentially harmful, or unexpected in a particular product or process; and
- is or may be present in, or in contact with, animal material or animal product.

Control (verb): to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan and/or operator documented system.

Control (noun): the state wherein correct procedures are being followed and criteria are being met.

Control measure: any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: any action to be taken when the results of monitoring at the Critical Control Point indicate a loss of control.

Critical control point: a step at which control can be applied that is essential to prevent or eliminate a risk factor or reduce it to an acceptable level, as described in section 17(3)(b) of the Act.

Critical limit: a criterion, which separates acceptability from unacceptability, and includes acceptable parameters as described in section 17(3)(c) of the Act.

Director-General: the chief executive of the Ministry of Agriculture and Forestry.

Exporter: a person who exports any animal material or product from New Zealand that is included in the coverage of the Animal Products Act 1999.

External verification: means the process of verification by an accredited verifier.

Finfish: includes all species of finfish of the classes Agnatha, Chondrichthyes, and Osteichthyes, at any stage of their life history, whether living or dead (Fisheries Act, 1996).

Fish: includes all species of finfish and shellfish, at any stage of their life history, whether living or dead (Fisheries Act, 1996).

Fish material: any live or dead fish, or any tissue or other material taken or derived from a fish.

Fit for intended purpose: the phrase, used in relation to any animal product, that has been processed in accordance with the requirements of a registered risk management programme under the Animal Products Act 1999, means that by reason of animal material or product having had the relevant risk factors managed and meeting any relevant animal product standards and associated specifications, the product is suitable for the purpose for which the product is specifically stated or could reasonably be presumed to be intended having regard to its nature, packaging, and identification.

Good Manufacturing Practice (GMP): assurance that product is consistently produced and controlled to quality standards appropriate to their intended use and as required by the regulatory authority and industry.

HACCP: a system, which identifies, evaluates and controls hazards that are significant for food safety.

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

Hazard: a biological, chemical, or physical agent that:

- is in or has the potential to be in animal material or product, or is or has the potential to be a condition of animal material or product; and
- leads or could lead to an adverse health effect on humans or animals.

Hazard analysis: 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.

Human or animal consumption: used in relation to any animal product, means that the product is intended to be eaten, or taken orally, or administered parenterally, or applied topically.

In writing: printed, typewritten, or otherwise visibly represented, copied, or reproduced, including by fax or email or other electronic means.

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

Operator: the person having the management authority and responsibility for the vessels and the operator documented system.

Operator verification: means the application of methods, procedures, tests and other checks by the operator to:

- validate the controls of the operator documented system; and
- determine the ongoing compliance and applicability of the operator documented system; and

- re-validate the operator documented system when changes occur that may have a significant impact on the outcomes of fish material or fish product.

Overseas Market Access Requirements: access requirements for overseas markets that New Zealand has agreed to meet, as interpreted and notified by the Director-General. These are requirements that must be met by operators of a vessel or exporters when exporting fish material or fish product to those markets covered by the access requirements.

Primary processor: in relation to fish, a person who, for reward (otherwise than as an employee) or for purposes of trade:

- in the case of finfish or shellfish, or animal material derived from finfish or shellfish, processes those animals or that animal material to the extent specified by the Minister by notice in the *Gazette*;

Primary processing is further defined —

- in the case of on shore processing of fish:
 1. the primary processing of fish on shore occurs at the place where –
 - a. the first methodical assessment of the suitability of the fish for processing is made; and
 - b. the fish are processed.
 2. Without limiting the generality of subclause (1), the following operations carried out on-shore also constitute primary processing of the relevant type of fish (whether or not coupled with a methodical assessment of suitability for processing) -
 - a. the deheading, gutting, or filleting of finfish;
 - b. the tubing of squid;
 - c. the wet-storage, depuration, or shucking of shellfish;
 - d. the removing of roe from kina;
 - e. the holding of crustaceans live (otherwise than in a marine farming operation), or their tailing;
 - f. in relation to fish to be sold whole or after processing at sea, any steps (including washing, chilling, freezing, or packing) taken to ensure their delivery to a buyer in good condition.

3. For the purposes of subclause (1)(a), **assessment** may include a visual check to make sure that the fish are in a satisfactory condition for processing to a product fit for human or animal consumption, or any other check provided for under the Act.
 - In the case of processing of fish at sea:
 1. The following operations carried out at sea constitute primary processing of fish -
 - a. The filleting of finfish (but not their mere deheading, gutting or scaling);
 - b. In respect of fish of any species processed at sea for the purposes of export that are not to be delivered to an onshore primary processor, any other process normally applied to fish, including:
 - i. washing, chilling, freezing and preserving;
 - ii. deheading, gutting, scaling, and tubing;
 - iii. packing, transport, and storage.
 2. Subclause (1)(a) does not include the filleting of finfish that are to be consumed by the crew of, or workers on, the vessel concerned.

Readily accessible: means that no matter where documents are stored, they can be mailed, couriered, faxed, emailed or transferred by other means within the time period stated.

Recognised agency: in relation to any function or activity, means a person or body recognised by the Director-General for the purpose of performing that function or activity. This will include the management and supply of accredited persons to perform specialist functions and activities for the purposes of the Animal Products Act, including evaluation and verification functions and activities.

Regulated control scheme: a programme which is imposed by the Director-General to manage risks where risk management programmes would not be feasible or practicable or where it is more efficient for the government to run the programme or it is needed to meet the market access requirements of foreign governments.

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

Risk management programme: a programme designed to identify, control and manage hazards and other risk factors in relation to production of animal material and products, to ensure the resulting animal product is fit for its intended purpose.

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

Supporting system: a documented programme covering GMP-based food hygiene activities that may interact at a number of process steps within and across various processes in a limited processing fishing vessel, and that have the potential to influence the hygiene status of the product.

Trade: sell for human or animal consumption or use; and includes –

- a. selling for resale (including as a constituent part of another article) for human or animal consumption or use; and
- b. offering or attempting to sell, or receiving for sale, or having in possession or exposing for sale, or sending or delivering for sale, or causing or permitting to be sold, offered, or exposed for sale; and
- c. barter; and
- d. supplying an article under a contract, together with other goods or services or both, in consideration of an inclusive charge for the article and the other goods or services; and
- e. supplying an article where there is a statutory responsibility to supply; and
- f. offering as a public prize or reward, or giving away for the purpose of advertisement or in the furtherance of any trade or business; and
- g. every other method of disposition for valuable consideration.

Uncontrolled hazard: a hazard which has been identified in a hazard analysis and for which the operator has no control measures available, and the operator is not required to control that hazard.

Validate: in relation to an operator documented system, means the process by which the operator ensures that the programmes under the system are complete, and meet the requirements, relevant regulations and specifications; and when implemented, will consistently achieve the required outcomes; and re-validate has a corresponding meaning.

Validation of HACCP plan: initial verification by the operator that the HACCP plan is complete and will deliver the expected food safety outcomes.

Verification: includes the ongoing checks carried out by accredited verifiers to determine whether:

- operations that are subject to a risk management programme or a regulated control scheme are in compliance with the requirements of the programme or of the Animal Products Act:
- animal material or products for whose export an official assurance is required have been produced or processed in a way that meets the requirements for the official assurance.

Wholesomeness: in relation to any regulated animal product, means that the product does not contain or have attached to it, enclosed with it, or in contact with it anything that is offensive, or whose presence would be unexpected or unusual in product of that description.

Part 7: Appendix B: Abbreviations

Amendment 0

September 2004

CCP:	Critical Control Point
CL:	Critical Limit
EEZ:	Exclusive Economic Zone
GHP:	Good Hygienic Practice
GMP:	Good Manufacturing Practice
HACCP:	Hazard Analysis and Critical Control Point
MAF:	Ministry of Agriculture and Forestry
NZFSA:	New Zealand Food Safety Authority
NZFSA VA:	New Zealand Food Safety Authority Verification Agency
NZSSC:	New Zealand Seafood Standards Council