CHAPTER 3, SUBJECT 1

QUALITY MANAGEMENT PROGRAM

1. SCOPE

This subject provides an introduction to the Quality Management Program (QMP) and Regulatory Verification. The definitions of terms used in this Chapter are included under "Definitions" at the beginning of this manual. Subjects 2, 3 and 4 of this chapter outline the policies and procedures governing the QMP and Regulatory Verification activities carried out by the Canadian Food Inspection Agency (CFIA).

2. AUTHORITIES

Fish Inspection Act, R.S., c. F-12 Fish Inspection Regulations, C.R.C., c 802

Food and Drugs Act, R.S., c. F-27 Food and Drug Regulations, C.R.C., c. 870

Consumer Packaging and Labelling Act, R.S., c. 38 Consumer Packaging and Labelling Regulations, C.R.C., c. 417

3. THE QUALITY MANAGEMENT PROGRAM

3.1 Introduction

The Quality Management Program is a fish inspection and control system that includes procedures, inspections and records, for the purpose of verifying and documenting the processing of fish and the safety and quality of fish processed in and exported from Canada. All federally registered fish processing establishments in Canada are legally required under the Fish Inspection Regulations to adhere to the QMP.

Note: The term "Quality Management Program" refers both to the overall program operated by the CFIA, and the individual program operated in a fish processing establishment. An individual establishment's documented program is usually referred to as a QMP plan.

A QMP Plan is a document prepared by a registered fish

establishment, in accordance with the <u>Facilities Inspection Manual</u>, that outlines the controls implemented to ensure that fish products are processed under sanitary conditions and that the result is a safe fish product that complies with federal regulations.

3.2 Objective of the Quality Management Program

The CFIA's objective for the QMP is to promote the production of safe and wholesome fish and seafood products, protect consumers of Canadian fish and seafood, meet international trade requirements and maintain open access to international markets.

3.3 History of the QMP

The Quality Management Program, developed as a result of cooperation between the Government of Canada and the fish processing industry, became mandatory for all federally registered fish processing establishments in 1992. At the time, federal fish inspection was under the authority of the Department of Fisheries and Oceans (DFO). QMP was originally based on 5 out of 7 principles of HACCP (Hazard Analysis Critical Control Point), an internationally recognised system for ensuring safe food production.

By 1996, several reviews of the QMP had been conducted, by the processing industry, the federal government and an international panel. A QMP re-engineering project was begun in June, 1996, to assess and implement many of the recommendations of these reviews, including adopting all seven HACCP principles.

The re-engineering process continued when federal fish inspection was transferred to the new Canadian Food Inspection Agency, created on April 1, 1997. The reengineered QMP model (described below in section 3.6) was produced in 1998, after extensive consultation with the fish processing industry. Implementation then began on a voluntary basis, and the program became mandatory in April, 1999.

3.4 Roles and Responsibilities of Government

3.4.1 The CFIA is responsible for developing, in consultation with the fish processing industry, regulations, standards, policies and procedures which set out the requirements for industry compliance with federal legislation. The CFIA is also responsible for verifying that the fish processing

industry operates within regulatory requirements.

- 3.4.2 The CFIA assesses the fish processing industry's compliance through regulatory verification. Regulatory verification focuses on assessing the adequacy of an establishment's QMP plan and verifying that the establishment applies the system as described and that it is effective in maintaining compliance with the regulatory requirements.
- 3.4.3 The CFIA is responsible for taking the appropriate enforcement action, as necessary, to ensure compliance with regulations.

3.5 Roles and Responsibilities of Industry

- 3.5.1 Each federally-registered fish processing establishment is responsible for designing and implementing an appropriate QMP plan to ensure compliance with the applicable legislation and regulations.
- 3.5.2 Fish processing establishments are responsible for ensuring that they have the personnel, on staff or under contract, with the necessary knowledge and skills required to develop, implement and maintain their QMP plans and to ensure that their operation is in compliance with all applicable legislation and regulations.
- 3.5.3 Fish processing establishments are solely responsible and liable for the fish products they produce, sell and/or import.

3.6 The QMP Model

There are three basic control components to a QMP plan: the Prerequisite Plan, the Regulatory Action Point (RAP) Plan, and the HACCP (Hazard Analysis Critical Control Point) Plan.

The Three Control Components of the QMP Model				
Prerequisite Plan		Regulatory Action Point Plan		HACCP Plan
I	Plant Construction & Equipment	I	Minimum Acceptable Fish Product Standards	Critical Control Points (CCP's) - determined through the application of
II	Plant Sanitation & Hygiene	II	Input Materials	HACCP principles
III	Recall	III	Labelling	

3.6.1 Prerequisite Plan: This section of the QMP plan consists of programs that ensure compliance with the Fish Inspection Regulations, and an acceptable environment for food processing, through controls for construction & equipment, sanitation & hygiene and an effective recall system. The Prerequisite Plan is an essential foundation for a HACCP plan, since it includes aspects of plant operations, necessary to the production of safe food, that must be in place before processing begins.

Plant Construction and Equipment Program

Describes how the physical plant facilities are designed, constructed and maintained in a condition to allow for the sanitary production of food.

<u>Plant Sanitation and Employee Hygiene Program</u>

Describes the control of all sources of contamination, and includes written Sanitation, Personnel Hygiene and Pest Control Programs.

Recall Program

Describes the procedures used to allow the processing establishment to rapidly identify the first shipping destination of any food product.

- 3.6.2 Regulatory Action Points (RAP) plan: This section deals with controls established to ensure compliance with the Fish Inspection Regulations and other relevant regulations. These controls are targeted at three elements of fish processing:
 - minimum acceptable fish product quality;
 - input materials; and
 - labelling.

3.6.3 **HACCP Plan:** This section consists of a plan prepared in accordance with the seven principles of the HACCP system to ensure that any significant health and safety hazards identified are controlled during the processing of fish.

3.7 The QMP Reference Standard

The QMP Reference Standard sets out the requirements for the documentation and application of a fish processing establishment's QMP plan. The standard is based on the Fish Inspection Regulations. For a description of the Reference Standard, and Interpretive Guidelines explaining the requirements of the standard, refer to Subject 4 of this Chapter.

4. REGULATORY VERIFICATION

Regulatory Verification encompasses the activities carried out by CFIA Inspectors to verify that a federally registered fish processing establishment's QMP meets the requirements set out in the Fish Inspection Regulations.

Regulatory Verification is intended to answer two fundamental questions about an establishment's QMP:

- 1. Is the QMP plan adequate for the products that are being processed in the registered establishment?
- 2. Is the registered establishment complying with its own QMP plan as written?

4.1 Elements of Regulatory Verification

- 4.1.1 Regulatory Verification includes a combination of audit and inspection activities. Audit activities will be carried out in accordance with recognised audit principles.
- 4.1.2 Regulatory Verification activities include verifying the documented QMP Plan, verifying the application of the QMP plan in the registered establishment, inspecting plant conditions and product, taking samples, investigating corrective actions, and performing tests.
- 4.1.3 Regulatory Verification is divided into the following components:

<u>Systems Verification (SV)</u> Systems Verification is an evaluation of a federally

registered fish processing establishment's documented QMP plan against the QMP Reference Standard to verify that it contains all the necessary components and has the necessary controls to ensure compliance with the Fish Inspection Regulations. The emphasis is on verifying documentation. For a description of CFIA policies and procedures governing Systems Verification, refer to Subject 2 of this Chapter.

<u>Compliance Verification (CV)</u>

Compliance Verification consists of activities carried out by CFIA Inspectors to verify that a federally registered fish processing establishment has implemented its QMP plan as written and that it meets the requirements set out in the Fish Inspection Regulations and the QMP Reference Standard. These activities may include: verifying the operation of the QMP; inspecting plant conditions and product; taking samples; investigating corrective actions; and performing tests. The emphasis is on verifying implementation. For a description of CFIA policies and procedures governing Compliance Verification, refer to Subject 3 of this Chapter.