

DATED this 1st Day of August 2008

Service Contract

between

THE FOOD SAFETY AUTHORITY OF IRELAND

- and -

**THE SEA FISHERIES PROTECTION AUTHORITY,
(AN tÚDARAS UM CHOSAINT IASCAIGH MHARA)**

THIS SERVICE CONTRACT is made the 1st Day of August 2008 **BETWEEN:**

THE FOOD SAFETY AUTHORITY OF IRELAND, established in Ireland pursuant to the Food Safety Authority of Ireland Act, 1998 (hereinafter referred to as the "Authority") having its principal place of business at Abbey Court, Lower Abbey Street, Dublin 1; and **THE SEA FISHERIES PROTECTION AUTHORITY**, having its principal place of business at **Unit C West Cork Technology Park, Clonakilty, Co. Cork** (hereinafter referred to as the "Official Agency").

1. **Interpretation**

In this Service Contract, unless the context otherwise requires -

"Act" means the Food Safety Authority of Ireland Act, 1998 [No. 29 of 1998] as amended;

"Authority" means the Food Safety Authority of Ireland;

"Commencement Date" means the 1st August 2008;

"Food Legislation" means the Food Legislation set out in Schedule 1 of this Service Contract;

"Year" means any 12 month period commencing on 1st January.

"Establishments" means those operations listed in Annex I of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin .

2. The Authority is the Central Competent Authority responsible for the enforcement of all food legislation. An Official Agency carrying out functions under a Service Contract shall be acting on behalf of and as an agent for the Authority and as a Competent Authority.

In order to ensure the safety of food, and to consider all aspects of the food production chain, from and including primary production up to and including sale or supply of food to the consumer, the Authority will delegate the requisite powers, duties and responsibilities to the Official Agency commensurate with its role as a Competent Authority as defined within the terms of this Service Contract.

3. For the purposes of section 48(5) of the Act, this Service Contract shall be in force for a period from the commencement date to the 31st December 2013. The Service Contract may be subject to review, modification or amendment by either party, and may be extended by agreement.

4. For the purposes of Section 11 of the Act, it is agreed that the Official Agency shall carry out in its functional area on behalf of and as an agent for the Authority the following –
 - (a) the determination of compliance with food legislation by means of –
 - (i) the inspection, approval, licensing and/or registration of premises and equipment, including premises or equipment used in connection with the manufacture, processing, disposal, transport and storage of food;
 - (ii) the inspection, sampling and analysis of food, including food ingredients;
 - (b) the provision of food safety and food hygiene information to producers, manufacturers and distributors.

5. For the purposes of Article 10 of Regulation (EC) No 882/2004, it is agreed that the Official Agency shall carry out in its functional area on behalf of and as an agent for the Authority the following: -
 - (iii) the examination of any control systems that food business operators have put in place and the results obtained;
 - (iv) the inspection of:-
 - a. primary producers' installations, food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of food;
 - b. raw materials, ingredients, processing aids and other products used for the preparation and production of food;
 - c. semi finished products;
 - d. materials and articles intended to come into contact with food;

- e. cleaning and maintenance products and processes, and pesticides;
 - f. labelling, presentation and advertising;
- (v) checks on the hygiene conditions in food businesses;
 - (vi) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;
 - (vii) examination of written material and other records which may be relevant to the assessment of compliance with food law;
 - (viii) interviews with food business operators and with their staff;
 - (ix) the reading of values recorded by food business measuring instruments;
 - (x) controls carried out with the Official Agency's own instruments to verify measurements taken by food business operators; and
 - (xi) any other activity required to ensure that the objectives of Regulation (EC) No 882/2004 are met.
5. For the purposes of section 48(3) of the Act, and having had regard to the resources available to the Official Agency, the Authority has specified the following matters to the Official Agency and the Official Agency has agreed to those matters -
- (a) the objectives and targets for food inspection the Authority wishes the Official Agency to meet, and the timeframe for achieving those targets and objectives; and
 - (b) any other matters which the Authority considers necessary.

The matters referred to in (a) and (b) are set out in Schedule 2 of this Service Contract.

6. The Official Agency has indicated to the Authority that, for the purposes of section 48(4) of the Act, the means by which it proposes to meet the matters specified by the Authority in Schedule 2 of this Service Contract are those set out in Schedule 3 of this Service Contract.

7. In accordance with the provisions of *Regulation (EC) No 882/2004* the Official Agency may delegate a task or function to a third party subject to the agreement of the Authority.

8. Without prejudice to the provisions of food legislation, the activities and food inspections to be undertaken on behalf of the Authority shall be directed towards bringing about a general acceptance amongst producers, manufacturers and distributors of the principle that, in respect of any food placed on the market, the primary responsibility for the safety and suitability of the food for human consumption is borne by them individually or, as appropriate, collectively and as a consequence, each of the persons mentioned shall take all reasonable steps to ensure, in so far as that person is concerned, the safety and hygienic standard of that food.

IN WITNESS WHEREOF the Authority and the Official Agency have caused their respective Seals to be affixed hereto on the date first above written.

PRESENT when the Official Seal of
THE FOOD SAFETY AUTHORITY
OF IRELAND was affixed hereto by **Dr. John O'Brien, Chief Executive Officer:-**

PRESENT when the Official Seal of
THE SEA FISHERIES PROTECTION AUTHORITY
was affixed hereto by **Mr. Peter Whelan, Chairperson:-**

SCHEDULE 1

List of the Food Legislation contained in the First Schedule to the Act for which the Official Agency has responsibility

Duties and responsibilities for food safety activities for the Official Agency will derive from the following list of legislation.

When

- (a) the Minister for Health and Children makes an order amending the First Schedule of the Act, or
- (b) any Act passed by the Oireachtas or any statutory instrument made thereunder or regulation made under the European Communities Act, 1972, is deemed to be food legislation for the purposes of the Food Safety Authority of Ireland Act, 1998,

The new legislation may be inserted by the Authority into this Schedule. In this context, both parties to the Service Contract accept that any actual increase in workload for the Official Agency will require the provision of adequate resources.

A reference to an enactment (including any instruments made thereunder) shall be construed as a reference to that enactment as amended, adapted, extended or replaced by or under any subsequent enactment, including the Food Safety Authority of Ireland Act, 1998.

FOOD LEGISLATION	Acts and Statutory Instruments
Food General:	
Food Safety Authority of Ireland Act 1998.	No. 29 of 1998
District Court (Food Safety) Rules 2004	S.I 700 of 2004
Sea-Fisheries and Maritime Jurisdiction Act 2006.	No. 8 of 2006
Fisheries (Amendment) Act, 1997.	No. 23 of 1997
European Communities (Hygiene of Fishery Products and Fish Feed) Regulations, 2006.	S.I. No. 335 of 2006

FOOD LEGISLATION	Acts and Statutory Instruments
Food General (continued):	
Regulation (EC) no 178/2002 of the European Parliament and of the Council of the 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety	S.I. No. 335 of 2006
Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.	S.I. No. 335 of 2006
Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin	S.I. No. 335 of 2006
Microbiological Criteria:	
Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs	S.I. No. 335 of 2006
Official Controls:	
Regulation (EC) No 882/2004 of the of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules	
Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption	
Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council No 2074/2005	
Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 No 2076/2005	

FOOD LEGISLATION	Acts and Statutory Instruments
Food Labelling:	
European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002	S.I. No. 483 of 2002
Council Directive 2000/13/EC () of 20 March on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs	S.I. No. 483 of 2002
European Communities (Labelling of Fishery and Aquaculture Products) Regulations 2003	S.I. No. 320 of 2003
Council Regulation 104/2000, on the common organisation of the markets in fishery and aquaculture products	S.I. No. 320 of 2003
Commission Regulation (EC) No 2065/2001 of 22 October 2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products	S.I. No. 320 of 2003
Food Additives and Flavourings:	
European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000	S.I. No. 437 of 2000 Amendments: S.I. No.342 of 2001, S.I. No.344 of 2002, S.I. No.380 of 2002 S.I. No. 61 of 2005, S.I. No. 192 of 2005, S.I. No. 193 of 2005, S.I. No. 171 of 2007, S.I. No. 34 of 2008, S.I. No. 59 of 2008
European Communities (Food Additives other than Colours and Sweeteners) Regulations 2004	S.I. No 58 of 2004 Amendments: S.I. No.369 of 2005, S.I. No. 40 of 2008

FOOD LEGISLATION	Acts and Statutory Instruments
Food Additives and Flavourings (continued):	
European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations, 1998	S.I. No. 541 of 1998 Amendments: S.I. No.438 of 2000, S.I. No.343 of 2001, S.I. No.260 of 2002, S.I. No. 488 of 2003, S.I. No. 892 of 2004, S.I. No. 174 of 2005, S.I. No. 94 of 2008.
European Communities (Flavourings for use in Foodstuffs for Human Consumption) Regulations, 1992.	S.I. No. 22 of 1992
Materials in contact with foodstuffs:	
European Communities (Plastics and other materials) (Contact with food) Regulations 2007	S.I. No. 587 of 2007
Residues / Contaminants:	
Animal Remedies Act, 1993	No. 23 of 1993
Control of Animal Remedies and their Residues Regulations, 1998	S.I. No. 507 of 1998
Health (Arsenic & Lead in Food) Regulations, 1972 and 1992	S.I. No. 44 of 1972 S.I. No. 72 of 1992
COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs	

FOOD LEGISLATION	Acts and Statutory Instruments
Zoonoses:	
European Communities (Monitoring of Zoonoses) Regulations 2004	S.I. No. 154 of 2004
European Communities (Zoonoses) Regulations, 1996 (other than part III)	S.I. No 2 of 1996
Trade in Fish:	
European Communities (Veterinary Checks on Fish and Fishery Products Imported from Third Countries) Regulations 2003	S.I. No. 548 of 2003
European Communities (Aquaculture Animals and Fish) (Placing on the Market and Control of Certain Diseases) Regulations, 1996	S.I. No. 253 of 1996

SCHEDULE 2

The objectives, targets, timeframe and other matters relating to food inspection and analysis which the Authority has agreed with the Official Agency

1. General requirements

1.1 Introduction

The Official Agency will fulfil all obligations regarding food safety as agreed with the Authority from time to time.

The Official Agency shall work in partnership with the Authority and its other Official Agencies to enhance consumer protection and ensure a seamless inspection service. The Official Agency shall encourage its staff to engage in inter-agency activities such as:

- (a) Sharing of information on food businesses .
- (b) Provision of reasonable assistance as appropriate .
- (c) Participation in cross-agency meetings.
- (d) Inter-agency training.
- (e) Multi-disciplinary working.

Within its area of competence, the Official Agency shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Service Contract and section 11 of the Act. Official controls should take account of:

- (i) Identified risks associated with food, food businesses, the use of food or any process, material, substance, activity or operation that may influence food safety.
- (ii) Food business operators' past record as regards compliance with food law.
- (iii) The reliability of any own checks that have already been carried out.
- (iv) Any information that might indicate non-compliance.

Official controls shall be carried out, as appropriate, at any of the stages of production, processing and distribution of food and of animals and animal products. They shall include controls on food businesses, on the use of food, on the storage of food, on any process, material, substance, activity or operation including transport

applied to food and on live animals, required to achieve the objectives of this Service Contract.

The Official Agency shall have due regard to recognised guidance notes, Codes of Practice, Standard Operating Procedures or accreditation systems as may be agreed between the Official Agency and the Authority from time to time.

The Official Agency must ensure that official control activities are carried out to a high level of transparency. Relevant information held by the Official Agency must be made available as soon as possible. Information must be made available on the control activities of the Official Agency and their effectiveness.

In accordance and as required by Regulation (EC) No 882/2004, where there are reasonable grounds to suspect that a food may present a risk to health the public must be informed to the fullest extent possible.

1.2 Legislation.

Duties and responsibilities for food safety activities for the Official Agency will derive from the legislation listed in Schedule 1. All staff involved in food control activities shall be provided with access to this legislation.

1.3 Participation on Working Groups.

The Official Agency shall participate as agreed in working groups, interagency working groups and expert working groups to:

- (a) Produce and keep under review the multi-annual national control plan for Ireland.
- (b) Produce Guidance Notes, Codes of Practice and Guides to Good Hygiene Practice.
- (c) Evaluate the implications of existing and proposed legislation.
- (d) Evaluate relevant food safety/scientific information .
- (e) Produce other outputs as agreed .

1.4 Service / Annual Control Plan.

From the 1st January 2009 and every year thereafter, the Official Agency shall prepare a Service / Annual Control Plan each year. The content and format of the plan will be agreed between the Authority and the Official Agency, and will include details and a schedule of the proposed internal audits the Official Agency intends to carry out in the year in question.

The plan is to be submitted to the Authority in the first quarter of each calendar year.

1.5 Data collection, reporting and information.

The Official Agency shall collect data and provide reports to the Authority as detailed in Schedule 4 and other information as agreed from time to time and submit it to the Authority on a quarterly basis. Such returns submitted shall be done so within 4 weeks of the end of the quarter to which they apply.

1.6 Information Systems.

Computerisation of inspection, sampling, testing and analysis systems will be developed and will have the functionality to allow data gathered in respect of Clause 1.5 of this Schedule to be transferred electronically to the Authority's database.

1.7 Food Incident Management, Contingency Planning and Out of Hours Emergency/On Call Services.

The Official Agency, in conjunction with the Authority, shall develop incident management and contingency plans at central and regional level for dealing with crisis incidents, large scale food safety incidents and outbreaks of food related disease.

As part of these plans, the Official Agency shall provide the Authority with a single central contact point for emergency and out of hours contact for emergency and crisis situations.

The Official Agency shall facilitate training of personnel in the operation and exercise of the contingency plans. Periodic review of the plans shall take place in conjunction with the Authority.

1.8 Rapid Alert System for Food and Feed.

The Official Agency shall facilitate and participate in the operation of the Rapid Alert System for Food and Feed as required.

1.9 Zoonoses.

Where participation is facilitated, the Official Agency shall provide staff to attend Regional Zoonoses Committee meetings.

The Official Agency shall, in conjunction with the Authority and other Official Agencies, fulfil its obligations arising under the zoonoses legislation listed in Schedule 1.

1.10 Investigation of Outbreaks.

Provisions shall be made by the Official Agency to deal effectively with food borne outbreaks in accordance with agreed protocols. Staff shall assist Outbreak Control Teams as required.

1.11 Complaints Regarding the Implementation of the Service Contract.

Without prejudice to Section 49 of the Sea-Fisheries and Maritime Jurisdiction Act 2006 (No. 8 of 2006), the Official Agency shall provide information to the Authority on complaints regarding the Food Control Services provided under this Service Contract within 7 days of the complaint being made.

Complaints will be managed in accordance with an agreed procedure, and in a manner consistent with "The Ombudsman's Guide to Standards of Best Practice for Public Servants." The Official Agency shall co-operate with the Authority in any investigation regarding these complaints.

1.12 Enforcement Policy.

The Official Agency shall develop an enforcement policy and communicate it to the Authority before the 1st March 2009.

1.13 Authorisation Policy.

The Official Agency shall develop an authorisation policy and communicate it to the Authority before the 1st March 2009.

1.14 Designated Officers.

The Official Agency shall nominate officers for designation by the Board of the Authority to carry out the consultation function outlined in Sections 52, 53 and 54 of the Act.

1.15 Continuing Professional Development .

Appropriate training must be provided for staff performing official controls to ensure competent and consistent implementation in accordance with Annex II, Chapter 1 of Regulation 882/2004. All staff performing official controls must be kept up to date in their area of competence and be provided with additional regular training as necessary.

A training strategy shall be developed by the Official Agency to include details of Continuing Professional Development to be provided to all staff listed in Schedule 3. Induction training is to be provided for all new staff by the Official Agency.

1.16 Missions of the Food and Veterinary Office (FVO).

The Official Agency shall participate as required in the preparation and conduct of FVO missions to Ireland and any follow-up actions associated with a report issued by the FVO.

1.17 Quality Management System.

The Official Agency must carry out official controls in accordance with documented procedures. These procedures must provide information and instructions for staff performing official controls.

A quality management system will be developed and implemented by the Official Agency by 31st December 2010.

The scope of the Quality Management System is to be agreed with the Authority who will provide technical and professional support during the establishment phase of the system.

In the process of establishing a Quality Management System the Official Agency shall establish an Internal Audit function to ensure official control activities achieve the objectives set out in relevant statutory requirements. The Official Agency shall take appropriate measures in light of audit findings and make the all relevant documentation available for external audit by relevant authorities.

The Official Agency shall make available to the Authority when requested reports, corrective action plans and other any other documentation related to its internal audit function.

1.18 Boundaries of the service.

The Official Agency contracts for provision of services within its administrative area. Where requested and agreed, assistance may be provided to another Official Agency. The Official Agency will ensure such arrangements are in accordance with statutory requirements and best practice.

1.19 EU Co-ordinated Control Plans.

The Official Agency shall carry out activities in accordance with the E.U. Co-ordinated Control Plans (under Regulation (EC) No 882/2004) as agreed with the Authority.

1.20 Inspection Reports.

A report of the outcome of each inspection of a food premises shall be issued to the relevant food business operator within 21 days of the inspection being carried out.

1.21 Administrative assistance and co-operation.

The Official Agency shall record any assistance provided to or from other Member States under Articles 36-40 of Regulation 882/2004 and include such activity in its Section 48(8) report to the Authority.

Requests for assistance made or received by the Official Agency under Article 38, where a risk to human health or a serious infringement of food law is identified, shall be notified to the Authority within 24 hours of them being made.

1.22 Food Safety Information.

The Official Agency shall provide information to the seafood sector on food safety law and relevant matters within its remit, through the Consultative Committee established under section 48 of the Sea-Fisheries and Maritime Jurisdiction Act 2006 (No. 8 of 2006) or by any other means it considers appropriate,

1.23 Guides to Good Practice.

In accordance with the Authority's Guidance Note Number 23 (Development and Assessment of Recognised National Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles) the Authority and the Official Agency shall implement an agreed policy to encourage and facilitate the development of Guides to Good Practice on Hygiene and HACCP principles by the seafood industry.

1.24 Molluscan Shellfish Safety Committee (MSSC).

The Official Agency will participate in the MSSC, and the associated Management Cell.

1.25 Border Inspection Posts

The Official Agency will be the competent authority for the import of fishery products and other seafood from third countries.

1.26 Additional Activities.

The Official Agency will participate in activities relating to food safety that may be arranged by the Authority, in collaboration with the Authority or other agencies as appropriate. The Official Agency will undertake tasks as agreed and provide results to an agreed format and timescale.

2. Seafood Control Services

2.1 Introduction.

The Official Agency will maintain specified and dedicated resources for the enforcement of Food Legislation, including providing a central Food Safety Liaison Unit and specialised Food Safety Officers in such numbers and deployed in locations as may be required and agreed with the Authority.

2.2 Official Food Control Services to be Provided .

The Official Agency shall fulfil all obligations regarding food safety as may be agreed from time to time by the Authority and the Official Agency in the context of the legislation outlined in Schedule 1.

This includes fulfilling all obligations regarding food safety in the context of the list of legislation outlined in Schedule 1 for primary producers.

The determination of compliance with food legislation will be by means of:

- (a) The inspection, approval, and registration of establishments and equipment, including premises or equipment used in connection with the manufacture, processing, disposal, transport and storage of food.
- (b) The inspection, sampling and analysis of food, including food ingredients.
- (c) Ensuring veterinary checks are carried out on such imports and consignments as required by the relevant legislation.
- (d) Labelling checks should where possible take place as part of the control activities carried out by the Official Agency.
- (e) The verification of compliance with potable water requirements.
- (f) The provision of food safety and food hygiene information to producers, manufacturers and distributors.
- (g) The management and supervision, in accordance with agreed protocols or Codes of Practice, of:
 - (i) Molluscan production and relaying areas, including compliance with the Codes of Practice on Monitoring of Marine Biotoxins in Bivalve Molluscs , and, Microbiological Monitoring of Bivalve Mollusc Production Areas.
 - (ii) The inspection of finfish aquaculture installations .

- (iii) Purification plants and dispatch centres.
- (iv) Fishing vessels.
- (v) Auction centres and wholesale markets.
- (vi) Processing establishments.
- (vii) Ice Plants.
- (viii) Storage
- (ix) Transport.
- (x) Third Country Imports and Border Inspection Posts.

Notwithstanding the obligations outlined in this section, the Official Agency and the Authority acknowledge the availability of statutory powers under the Food Safety Authority of Ireland Act which permit the Authority to carry out inspections, visits and other official controls in establishments subject to supervision by the Official Agency.

However, it is accepted that such visits will generally be conducted in the company of an officer from the Official Agency.

Where this is not possible because of the exigency of the circumstances, as much notice as is practical will be provided to the Official Agency.

Furthermore, the Authority will provide written details of the reasons for their visit and the findings at the earliest possible opportunity to the Official Agency so as to allow them to fully and effectively discharge their role under this service contract.

3. Service Outputs/Activity.

3.1 Advice.

The Official Agency will provide advice to the Authority on:

- (a) Risk management measures necessary to ensure the safety of food harvested from the sea.
- (b) The marine environment and its actual or potential impact on food safety.

Advice may be given proactively, or following a request from the Authority.

3.2 Premises' Frequency of Inspection.

The frequency of inspection for establishments mentioned in Clause 2.2 of Schedule 2 of this Service Contract will be as agreed in the

relevant operational procedures between the Authority and the Official Agency.

Where operational procedures relating to the abovementioned services have not been developed, both the Official Agency and the Authority will co-operate to develop and publish them in a manner that will allow them to be incorporated in to the Quality Management System to be developed by the Official Agency.

3.3 Molluscan Production Areas .

The Official Agency will ensure that 90% of samples of shellfish and water taken as part of the National Marine Biotoxin Programme arrive at the analysing laboratory within 24 hours of sampling.

The Official Agency will co-operate with the Authority and the Marine Institute in the development of a programme to monitor the microbiological contamination of live bivalve molluscs. This will include the ongoing development and implementation of Codes of Practice on monitoring, sampling and management of shellfish under this programme.

As part of this programme, the Official Agency will ensure that 90% of samples taken for the purposes of microbiological monitoring and classification arrive at the examining laboratory within 24 hours of sampling.

The Official Agency will follow up all instances of missing, rejected or otherwise non-conforming samples taken for either biotoxin or microbiological purposes and implement corrective action. Details of all such samples shall be provided to the Authority and the MSSC.

The Official Agency will classify shellfish production areas according to the Code of Practice on Microbiological Monitoring of Bivalve Mollusc Production Areas

The Official Agency will participate in all MSSC meetings, and the associated Management Cell.

The Official Agency will respond to all Management Cell requests within 24 hours.

3.4 Official Control of Certain Substances and Residues thereof .

The Official Agency will respond within 3 working days to all reports provided by the Marine Institute of non-conformances detected as part of the National Residues Control Plan (NRCP) insofar as it applies to seafood.

Reports on the progress of such investigations will be submitted to the Authority.

3.5 Delegation of tasks.

The Official Agency may delegate specific tasks to a laboratory only if the delegated laboratory is accredited for those tasks to EN ISO/IEC 17025. The Authority shall be informed of such delegations as soon as is reasonable practicable after they are made. Any such delegations must be made in a manner consistent with Article 5 of Regulation (EC) No. 882/2004 of the European Parliament and of the Council of the 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

4. Monitoring

4.1 Liaison.

The Official Agency shall nominate person(s) to liaise with the Contracts Manager in the Authority.

The following liaison meetings shall be held:

- (a) Two Management liaison meetings, in quarters 1 and 3 of each calendar year.
- (b) Two Food Safety liaison meetings, in quarters 2 and 4 of each calendar year.
- (c) One annual food safety meeting for all Sea-Fishery Protection Officers held at a number of agreed venues around the country.
- (d) Additional meetings will be held as required by either party.
- (e) Cross Agency meetings as arranged by the Authority to which the Official Agency will send representatives.

Prior to each scheduled meeting of the MSSC, the Official Agency agrees to meet with the Authority and the Marine Institute on a trilateral basis, with a view to discussing and achieving consensus on key issues.

4.2 Access.

The Authority shall have appropriate access as required through the liaison link to the staff referred to in Schedule 3 and to all records, data and sites relevant to food safety duties. Officers of the Official Agency

shall have access as required through the liaison link to records relevant to the Official Agency held by the Authority.

4.3 Audit Techniques.

The Authority may take such measures, as it considers appropriate to determine compliance by the Official Agency with the requirements of this contract. This will include audit in accordance with Schedule 5 and the Official Agency agrees to cooperate with the Authority's audit activities.

The Authority and the Official Agency will agree corrective action plans following audits carried out by the Authority. The service contract liaison process shall be used to monitor progress on corrective action to ensure closeout of all findings.

The Official Agency will provide details of any external audits of its service covered by the Service Contract.

SCHEDULE 3

The Means by which the Official Agency proposes to meet the matters specified in this Service Contract

The Official Agency, as a competent authority, performing official controls shall meet a number of operational criteria. They shall have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.

The Official Agency will provide staff and all resources required to ensure delivery of service outputs/activity as outlined in Schedule 2.

Staffing Resources

At each Service Contract Liaison Meeting, the Official Agency shall provide an indication of all staff involved for the purposes of this Service Contract.

SCHEDULE 4

Data Collection and Reporting

1. General requirements for data collection and reporting

The Official Agency shall collect and store information generated from food control activities specified in Schedule 2.

A file is to be maintained for each food business under the supervision of the Official Agency.

The data collected is to be maintained and all records are to be kept up to date. Records relevant to this service contract will be kept for a minimum of 5 years.

An agreed dataset is to be electronically transferred to the Authority. The agreed dataset to include information on internal audit activities.

The frequency of electronic transfer is to be agreed with the Authority.

The Official Agency shall notify the Authority of enforcement orders served under the Food Safety Authority of Ireland Act, 1998, without delay.

2. Resources

Schedule 3 shall be updated and submitted to the Authority as changes arise. The Official Agency shall maintain a current electronic list of Authorised, Liaison and Designated Officers. The list shall include names, contact addresses, telephone numbers and email addresses for all officers. This list shall be submitted to the Authority at the liaison meetings.

The Official Agency shall maintain an up-to-date list of laboratories used for testing and analysis under the legislation listed in Schedule This list shall be provided to the Authority annually, and as changes arise.

3. Activities undertaken outside of returns outlined at 2.0

The Official Agency will record and submit to the Authority annually details of:

- (a) Food incidents/outbreaks.
- (b) Internal audit activities as required by Regulation 882/2004
- (c) Participation on Food Safety Authority of Ireland working groups, interagency working groups and expert working groups and any other similar activity.

- (d) Continual Professional Development undertaken by staff.
- (e) Complaints regarding the implementation of the service contract.
- (f) Provision of food safety information to the food industry.
- (g) Additional food safety activities as agreed .

SCHEDULE 5

The Means by which the Authority proposes to audit the Service Contract

1. General Requirements

The Authority shall carry out audits to:

- (a) Meet its legislative requirements with respect to audit as set out in Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- (b) Determine compliance with the legislation listed in Schedule 1.
- (c) Determine conformance with the other administrative and technical requirements as set out in schedules other than Schedule 1.

These audits will verify compliance by Official Agencies with regard to relevant legislation, implementation of MANCP and adherence to the FSAI Service Contract requirements. These audits will also verify the effectiveness and appropriateness of official controls, by testing official agencies against their own system of controls and evaluate whether their documented procedures and planned arrangements are being followed, and whether they are suitable to achieve the objectives of Regulation (EC) No. 882/2004.

2. Definitions

- (a) **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.
- (b) **Audit Team:**
The audit team will vary depending on the scope of the audit, but will consist of a lead auditor and additional team members with any combination of general and technical expertise
- (c) **Technical Expert:**
A person who provides specific knowledge or expertise to the audit team.

3. Scheduling

Using risk assessment methodologies The Authority shall develop audit programmes to determine compliance with the requirements of this contract depending on the scope and the nature and extent of the duties and responsibilities of the Official Agency's food safety activities. In drawing up these audit programmes due consideration shall be given to the extent to which the Official Agency's food control activities have been subjected to any appropriate third-party registration or accreditation audits.

4. Audit Methodology

Audits shall be carried out against documented processes and procedures developed by the Authority. The Authority shall incorporate into this documentation:

- a. The requirements of Commission Decision EU 677/2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules.
- b. established practices as set out in ISO 19011: Guidelines for Quality and/or Environmental Management Systems Auditing .

5. Liaison

Liaison for the purpose of audit shall be through a representative(s) nominated by the Official Agency.

6. Access

The Official Agency shall allow the Authority's audit team access to those premises, personnel, documents and records applicable to the audit.

7. Corrective Action

It is the responsibility of the official agency to closeout all audit findings. A corrective action plan should be developed by the official agency in liaison with the Service Contract Division in order to address audit findings where these have arisen. It is also the responsibility of the Service Contracts Division to monitor closeout of audit outcomes (e.g. FSAI & FVO) and to ensure they are adequate and appropriate. The audit and compliance Division may verify closeout of findings in accordance with Regulation 882 requirements where deemed necessary.