

DATED this 1st Day of January 2006

Service Contract

between

THE FOOD SAFETY AUTHORITY OF IRELAND

- and -

THE MARINE INSTITUTE

THIS SERVICE CONTRACT is made the 1st Day of January 2006 **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 MARINE INSTITUTE** having its principal place of business at **Rinville, Oranmore Co. Galway** (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 January 2006;

"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.

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

2010. 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(2) 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 the inspection, sampling and analysis of food, including food ingredients; and,
 - (b) the provision of food safety and food hygiene education to producers, manufacturers and distributors.

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 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*, 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:-

PRESENT when the Official Seal of **THE MARINE INSTITUTE** was affixed hereto by **Dr Peter Heffernan, Chief Executive Officer.**

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
General Food Hygiene:	
Food Safety Authority of Ireland Act 1998	No.29 of 1998
European Communities (Official Control of Foodstuffs) Regulations, 1998	SI No. 85 of 1998
Shellfish Safety:	
European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 1996	SI No. 170 of 1996).
European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996	SI No. 147 of 1996

Residues / Contaminants:	
European Communities (Certain Contaminants In Foodstuffs) Regulations, 2001	SI No. 400 of 2001
European Communities (Sampling Methods and the Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations, 2005	SI No. 68 of 2005
Control of Animal Remedies and their Residues Regulations, 1998	SI No. 507 of 1998
Animal Health	
European Communities (Aquaculture Animals and Fish) (Placing on the Market and Control of Certain Diseases) Regulations, 1996	SI No. 253 of 1996

SCHEDULE 2

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

1. General requirements

1.1 Introduction

The role of the Marine Institute, as defined by Marine Institute Act, 1991, is to undertake, to co-ordinate, to promote and to assist in marine research and development and to provide such services related to marine research and development, that in the opinion of the Institute will promote economic development and create employment and protect the environment.

Within this context the Institute as an Official Agency of the Authority agrees to fulfil all obligations regarding food safety as may be determined by 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.

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.

The Official Agency must ensure that information acquired when undertaking official controls which is covered by 'professional secrecy in duly justified cases' is not disclosed.

For consistency, the Authority, in conjunction with the Official Agency, will, where appropriate develop a series of guidance notes or codes of practice in respect of legislation listed in Schedule 1.

The Authority and the Official Agency also agree to develop a reference resource containing also documents, protocols, and procedures relevant to the operation of this Service Contract.

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 FSAI working groups, interagency working groups and expert working groups to:

- (a) Produce the multi-annual national control plan for Ireland.
- (b) Produce Guidance Notes and Codes of Practice.
- (c) Evaluate 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.

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.

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.

1.6 Information Systems

Computerisation of inspection, sampling, testing and analysis systems must be developed and must 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 Out of Hours Emergency/On Call Services.

The Official Agency shall make provision for food control services to be delivered outside of normal working hours to deal effectively with outbreaks and food incidents, etc.

1.8 Contingency Planning.

The Official Agency, in conjunction with the Authority, shall ensure that there are contingency plans in place 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/out of hours contact for emergency and crisis situations.

The Official Agency shall establish a dedicated contact point for receipt of food alerts and exchange of information relating to food incidents during normal office hours.

The contact point shall be operational during all normal working hours and enable quick response at all times (including cover during leave periods). Details of the contact point or points (telephone and e-mail) shall be notified to the Authority and updated as necessary.

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.

1.9 Rapid Alert System for Food and Feed.

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

1.10 Inter-agency working, Zoonoses Committees.

The Official Agency may contribute as appropriate to Regional Zoonoses Committees.

1.11 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.

1.12 Complaints Regarding the Implementation of the Service Contract.

The Official Agency shall provide information to the Authority on complaints regarding the Food Control Services provided under this Service Contract. 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.

1.13 Enforcement Policy.

The Official Agency shall adopt the Enforcement Policy set out in Schedule 6.

1.14 Authorisation Policy.

The Official Agency shall adopt the Authorisation Policy set out in Schedule 7.

1.15 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.

1.16 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.

An Annual Training Strategy should 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.

1.17 Food Complaints

Food complaints must be managed in accordance with agreed documented procedures.

1.18 Missions of the Food and Veterinary Office.

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.

1.19 Quality Management System

The Official Agency must maintain an appropriate Quality Management System.

1.20 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.

The Authority agrees to provide risk analysis, risk management and risk communication advice and support, within its area of expertise, to the Official Agency.

1.21 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.

1.22 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 or animal health or a serious infringement of food law is identified, shall be notified to the Authority without delay.

1.24 Molluscan Shellfish Safety Committee (MSSC)

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

1.25 Case Management Group

The Official Agency will participate fully in the Case Management Group for Monitoring of Certain Substances and Residues thereof in aquaculture.

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. National Reference Laboratories

2.1 Introduction

Member States are required to designate one or more national reference laboratories for each Community reference laboratory referred to in Article 32 of Regulation (EC) no 882/2004.

2.2 Authority Support

The Authority will actively support the Official Agency in its various National Reference Laboratory roles, including the support for the provision of adequate resources.

Where new NRL functions or roles are assigned to the Official Agency or where deficiencies are identified, the Authority and the Official Agency will prepare an Action Programme to address these issues.

2.3 Role and Scope of the Official Agency as a National Reference Laboratory

The Official Agency will act as a National Reference Laboratory for:

- (a) Monitoring for Marine Biotoxins in Live Bivalve Molluscs.

- (b) Monitoring for Bacteriological and Viral Contamination in Live Bivalve Molluscs.
- (c) Monitoring of Certain Substances and Residues thereof insofar as they apply to finfish aquaculture.

2.4 Functions of the Official Agency as a National Reference Laboratory

In accordance with Article 33(2) of Regulation (EC) no 882/2004 the Official Agency as a National Reference Laboratory, shall:

- (a) Collaborate with the Community Reference Laboratories in the areas of competence outlined in Section 2.3 to Schedule 2 of this Service Contract.
- (b) Coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11 of Regulation (EC) no 882/2004.
- (c) Where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing.
- (d) Ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies.
- (e) Provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53 Regulation (EC) no 882/2004.
- (f) Be responsible for carrying out other specific duties introduced by the European Commission via the committee procedure referred to in Article 62 of Regulation (EC) no 882/2004, without prejudice to existing additional national duties.

2.5 Accreditation

As a National Reference Laboratory, the Official Agency shall comply with Articles 12(2) and 12(3) of Regulation (EC) no 882/2004 and shall operate, be assessed and accredited in accordance with the following European Standards:

- (a) EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories."
- (b) EN 45002 on "General criteria for the assessment of testing laboratories."

- (c) EN 45003 on "Calibration and testing laboratory accreditation system-General requirements for operation and recognition."

Furthermore, the accreditation and assessment referred to in Section 2.5 of Schedule 2 of this Service Contract may be applicable only to individual tests or groups of tests.

Relevant tests will be added to the scope of accreditation as part of an ongoing programme of accreditation. The Authority, as the nominal client, will support the Official Agency in achieving accreditation for these tests.

2.6 Animal health conditions governing the placing on the market of aquaculture animals and products

The Authority acknowledges that the Official Agency has been designated an "approved laboratory" for the purposes of Council Directive 91/67/EC, and the Official Agency will report to the Authority information or observations generated in the course of this work which may be relevant to food safety.

3. National Biotoxin Monitoring Programme.

The Official Agency will provide scientific advice to the Authority, and the Department of Communications, Marine and Natural Resources on marine biotoxins and related issues.

The Authority will provide risk analysis, risk management and risk communication advice to the Official Agency, as requested.

In respect of the European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996 (as amended) the Official Agency will participate in the National Biotoxin Monitoring Programme, in accordance with the Molluscan Shellfish Safety Committee's Code of Practice.

The Official Agency will provide representatives for and advice to the Molluscan Shellfish Safety Committee (MSSC), the Management Cell of the MSSC, and any other relevant working group or sub-committee.

The Official Agency will communicate regularly, by appropriate means, with the Authority, the Department of Communications, Marine and Natural Resources, the shellfish industry and associated interested parties, and the Authority will facilitate this communication, when requested. Communication will include e-mail, fax (by subscription), SMS text message service and web-based services,

The Authority, in partnership with the Official Agency, and other relevant bodies, will provide training and publish such Guidance Notes, Codes of Practice or other information documents as are necessary to facilitate the operation of the National Marine Biotxin Monitoring Programme.

4. Bacterial and Viral Monitoring of Bivalve Molluscs.

The Official Agency will provide scientific advice to the Authority, and the Department of Communications, Marine and Natural Resources on the microbiological and virological safety and quality of shellfish and shellfish growing waters, and on related matters.

The Authority will provide risk analysis, risk management and risk communication advice to the Official Agency, as requested.

In respect of the European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996 (as amended) the Official Agency will co-operate with the Department of Communications, Marine and Natural Resources and the Authority in the development of a programme to monitor the microbiological and virological quality of live bivalve molluscs. This will include the development of a Code of Practice on monitoring, sampling and management of shellfish under this programme.

Furthermore, the Authority, in partnership with the Official Agency, and other relevant bodies, will provide training and publish such Guidance Notes, Codes of Practice or other information documents as are necessary to facilitate the operation of this monitoring programme.

The Official Agency will provide representatives for and advice to the MSSC, and any other relevant working group or sub-committee of the MSSC.

The Official Agency will communicate regularly, by appropriate means, with the Authority, the Department of Communications, Marine and Natural Resources, the shellfish industry and associated interested parties, and the Authority will facilitate this communication, when requested.

The Official Agency will contribute as appropriate in Regional Zoonoses Committees.

5. Chemical Monitoring of Fish & Shellfish.

The Official Agency will continue to carry out sampling and analysis for certain environmental contaminants of fish and shellfish in accordance with

- (a) The European Communities (Certain Contaminants In Foodstuffs) Regulations, 2001.
- (b) European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 1996.
- (c) European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996.
- (d) The Quality of Shellfish Waters Regulations 1994 (SI 200 of 1994).

Extensions to the scope of work in this area will be subject to discussion and agreement with the Authority and the Department of Communications, Marine and Natural Resources and subject to the provision of additional resources.

The Official Agency will report results of such monitoring to the Authority on an annual basis. The Official Agency will inform the Authority of any results which give cause to question the safety for human consumption of the species sampled, or any species harvested in the area from which the sample was obtained.

6. National Residues Control Plan

In accordance with The Control of Animal Remedies and their Residues Regulations, 1998 (SI 507 of 1998) the Official Agency shall fulfil their obligations regarding the National Residues Control Plan (NRCP) insofar as it applies to finfish aquaculture. This includes sampling and analysis of samples of farmed fish for a range of veterinary substances and possible contaminants and reporting of results.

The Official Agency will participate in the process of drafting the annual NRCP.

Where the Official Agency obtains results and / or information that which give cause to question the safety for human consumption of the species sampled, they will advise the Authority.

In consideration of the manner in which the Residues Programme is organised and delivered, the Official Agency will advise the Authority

of alternative arrangements for delivering it to the same level, in the event of the contractor withdrawing from the cooperative agreement. The Authority will assist the Official Agency in preparing contingency plans to ensure the continuity of this programme.

Enforcement or formal follow up action arising from the results of analysis of samples taken as part of the NRCP will be consistent with a protocol agreed between the Official Agency, the Authority, the Department of Communications, Marine and Natural Resources.

Where a Case Management Group (CMG) is convened to address an analysis result or results which give cause for concern, the Official Agency will provide appropriate staff to be involved in and advise the CMG.

7. Research

The Authority agrees to collaborate and assist the Official Agency in the formulation, commissioning, and provision of agreed research projects and studies in relevant areas of food and seafood safety.

This includes the Authority providing expertise and, where available, resources, both financial and personnel. The Authority also agrees to assist the Official Agency in disseminating the results of such research.

8. Fish Health Monitoring

The Official Agency will keep the Authority advised of work done monitoring the health of fish and shellfish, and particularly, the Official Agency will inform the Authority of any results which give cause to question the safety for human consumption of the species sampled, or any species harvested in the area from which the sample was obtained.

9. Marine Environment Monitoring

The Authority acknowledges the environmental monitoring and assessment undertaken by the Official Agency, including that done in fulfilment of:

- (a) Annex IV of the 1992 Oslo Paris Convention for the Protection of the Marine Environment of the North-East Atlantic.
- (b) The Quality of Shellfish Waters Regulations 1994 (SI 200 of 1994).

The Authority also acknowledges that the Official Agency may bring to the attention of the Authority information generated as a result of this work which has a bearing on the safety of food harvested from the sea.

10. Approval of Laboratories

In accordance with Commission Decision 94/356/EC of 20 May 1994, “own-check” laboratories will be required to participate in existing Quality Assurance Schemes.

To secure their involvement, by the 31st of December 2006, the Authority, the Official Agency and the Department of Communications, Marine and Natural Resources will prepare an inventory of official, own-check and approved laboratories, which shall be kept up to date. This will be followed up by the preparation and implementation of an Action Plan, taking account of the scientific, regulatory and financial aspects of setting up and running such a scheme.

Following the preparation of this Action Plan, the Official Agency will develop a system for the approval of laboratories within the Official Agency’s area of competence (including a Performance Assessment Scheme) in accordance with:

- (a) European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996 (SI No. 147 of 1996).
- (b) European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 1996 (SI No. 170 of 1996).
- (c) Commission Decision 94/356/EC of 20 May 1994 laying down detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products.
- (d) Other relevant legislation.

The Authority agrees to assist in the development of this approval system.

11. Service Outputs/Activity and Key Performance Indicators

11.1 General

The Official Agency will provide scientific advice to the Authority on:

- (a) 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.

11.2 Monitoring of Certain Substances and Residues thereof

The Official Agency will consult with the Authority in the preparation of the NRCP.

When the NRCP is finalised for the year in question, the Official Agency will prepare a report based on the results gathered from the delivery of this plan and submit it to the Department of Agriculture and Food and to the Authority within 3 months of the end of the year to which it applies.

11.3 National Marine Biotoxin Monitoring Programme

The Official Agency will aim to analyse and report on samples shellfish submitted to it as part of the National Marine Biotoxin Monitoring Programme within 3 working days for lipophyllic toxins (DSP & AZP), PSP and ASP. This target will be achieved in respect of a minimum of 90% of samples, with regular improvements to be agreed, where appropriate.

The Official Agency will also aim to analyse and report on water samples submitted to it as part of the National Marine Biotoxin Monitoring Programme within 2 working days for toxic phytoplankton species associated with the production of DSP, AZP, PSP and ASP toxins. This target will be achieved in respect of a minimum of 90% of samples, with regular improvements to be agreed, where appropriate

11.4 Chemical Monitoring of Fish & Shellfish

The Official Agency will report on an annual basis, to the Authority, contaminants in shellfish and wild fin fish.

11.5 Molluscan Shellfish Safety Committee (MSSC)

The Official Agency will participate in all MSSC meetings, and the associated Management Cell. It will provide reports on analytical performance, Management Cell activity and toxicity profiles/patterns to the scheduled meetings of the MSSC in a format to be agreed with the Authority.

11.6 Communication with Industry and Associated Interested Parties

The Official Agency will organise and run an annual workshop on shellfish safety and other topics as agreed. The Authority will support and participate in the organising and running of these events.

11.7 Approval of Laboratories

The Official Agency will submit a list of laboratories approved under the scheme mentioned at paragraph 9 of this Schedule, to the Authority, on an annual basis.

12. Monitoring

12.1 Liaison

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

Liaison meetings shall be held at least twice a year and more frequently as required by either party.

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

Cross Agency meetings may also be arranged by the Authority to which the Official Agency will send representatives.

12.2 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.

12.3 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 Audit Inspections.

The Authority and the Official Agency will agree corrective action plans following audits carried out by the Authority. Corrective action plans will be closed out as part of the service contract liaison process.

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

The annual allocation and use of all revenue (pay and non-pay) and capital resources will be submitted annually to a format specified by the Authority.

Staffing Resources

List of all staff involved for the purposes of this contract.

Grade /Title		All Duties		Official Control of Food		
		Total no. of posts (WTE ¹)	Total no. of posts filled (WTE ¹)	Total (no of staff)	Total no. of posts filled (WTE ¹)	² Total no. of posts (WTE ¹) *
Admin	Director	1	1	1	0.5	0.5
	Team Leader	1	1	1	1	1
	Assistant	1	1	1	1	1
Shellfish Safety Section.						
	Section Manager	1	1	1	0.5	0.5
	Section Manager (Acting)	1	1	1	0.8	0.8
	Administrator	1	1	1	0.75	0.75
Biotoxin Unit Incl. Bioassay, Phytoplankton.	Scientific & Technical Officer	1	1	1	1	1
	Senior Technician	1	1	1	1	1
	Technicians	3	3	3	2.5	2.5
	Lab Attendant	1	1	1	1	1
Bacteria & Virus	Team Leader	1	1	1	1	1
	Scientific & Technical Officer	2	2	1	1	1
	MI Fellowship	1	1	1	0.5	0.5
Biotoxin Chemistry Unit	Team Leader	1	1	0.33	0.33	0.33
	Scientific & Technical Officer	1	1	0	0	0
	Technician	6	6	5.5	5.5	5.5
	Lab Attendant	2	1	1	0	0
	MI Fellowship	1	1	0.4	0.4	0.4
	Post grad students	4	3	0	0	0

Grade /Title		All Duties		Official Control of Food		
		Total no. of posts (WTE ¹)	Total no. of posts filled (WTE ¹)	Total (no of staff)	Total no. of posts filled (WTE ¹)	² Total no. of posts (WTE ¹) *
Chemistry Section						
Chemical Monitoring Port/Shellfish	Senior Chemist	1	1	1	0.35	0.35
	Team Leader	1	1	0	0	0
	Scientific & Technical Officer	1	1	1	0.5	0.5
	Senior Technician	1	1	1	0.5	0.5
	Technician	3	3	3	2.1	2.1
	Lab Attendant	1	1	1	0.5	0.5
Residue Programme	Manager	1	0.6	1	0.1	0.1
	Team Leader (FHU)	1	1	1	0.25	0.25
	Senior Chemist	1	1	1	0.25	0.25
	Scientific & Technical Officer	1	1	1	1.0	1.0
	Technician	3	3	3	3	3
	Technician (FHU)	1	1	1	0.5	0.5
	MI Fellowship	1	1	1	0.8	0.8
	Lab Attendant	1	1	1	0.75	0.75
Admin	1	1	1	1	1	

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.

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

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 1. 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) Participation on Food Safety Authority of Ireland working groups, interagency working groups and expert working groups and any other similar activity.
- (c) Continual Professional Development undertaken by staff.
- (d) Complaints Regarding the Implementation of the Service Contract.
- (e) Hygiene education activities undertaken.
- (f) 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 of this service contract 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. The Authority shall also incorporate into its audit processes any additional requirements documented in Commission guidelines published regarding national audit systems.
- (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.

2. Definitions

- (a) **Audit:**
A systematic and independent evaluation 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:**
One or more auditors conducting an audit supported, if needed, by technical expert.
- (c) **Technical Expert:**
A person who provides specific knowledge or expertise to the audit team.

3. Scheduling

The Authority shall schedule audits 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 this schedule 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 the current revision of the Authority's documented protocol "The FSAI Audit Scheme".

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. Techniques

The audit scheme shall be in accordance with established practices as set out in ISO 19011: Guidelines for Quality and/or Environmental Management Systems Auditing.

SCHEDULE 6

National Enforcement Policy

Introduction

The Mission of the Food Safety Authority of Ireland is to protect consumers' health and consumers' interests by ensuring that food consumed, distributed, marketed or produced in the state meets the highest standards of food safety and hygiene.

To this end, the Authority has agreed Service Contracts with "Official Agencies" to have these functions carried out on its behalf. In the execution of these functions, officers within the Official Agencies and officers of the Authority will come across contraventions of food legislation.

The purpose of this policy is to provide guidance on the type and nature of enforcement appropriate for dealing with such contraventions, and to assist officers in compliance building among food business operators.

Enforcement options available to officers include informal means, for example verbal or written advice, and formal means, for example service of statutory notices (see FSAI Guidance Note No. 13 – "Use of Enforcement Powers under the Food Safety Authority of Ireland Act, 1998.") or prosecution. Enforcement may also require the use of both formal and informal options in combination.

Enforcement action, where it is contemplated should be discharged in such a way that it complies with the Standards of Best Practice for Public Servants (published by the Office of the Ombudsman), and the Principles of Good Enforcement referred to in this document.

Overall, the primary objective of any enforcement action should be to protect consumers' health or interests.

A secondary objective is to bring about a general acceptance amongst producers, manufacturers, distributors, retailers and caterers 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.

Standards of Best Practice for Public Servants

The Irish Ombudsman's Office, whose remit includes the civil service, local authorities and the health boards, has published Standards of Best Practice for Public Servants. The publication aims to promote the highest standards of administration when public bodies deal with people. In summary this means that people should be dealt with properly, fairly, openly and impartially. Regard should be had for this publication when decisions are made in respect of enforcement.

However, it should be noted that the Ombudsman is precluded from investigating matters where a right of appeal exists to the courts, for example where a closure order is served.

Principles of Good Enforcement

In determining the Principles of Good Enforcement that should apply in the application of food law, the Authority has taken into account the requirements contained in the “Regulating Better” white paper published by the Department of the Taoiseach.

The principles of Regulating Better are necessity; effectiveness; proportionality; transparency; accountability and consistency. Within the context of food safety legislation the Principles of Good Enforcement that should apply are:

- **Proportionality** – The enforcement response to contraventions of food legislation should be proportionate to the risk created to consumer health and interests. The enforcement option chosen should be proportional in both degree and kind, with the immediate objective being to protect consumer health and interests, remedy the contravention and dissuade future offending.
- **Targeting** – Enforcement should be targeted at those whose activities give rise to the most serious risks to consumer health and interests. Where contraventions are encountered, enforcement action should be focused on the person or persons responsible for actually contravening the legislation and also responsible for creating the risk. The objective should be to hold those responsible for putting the consumer at risk accountable for their actions.
- **Transparency** – Enforcement should be transparent. Where a person is considered to be responsible for contravening food law they should be provided with information on the nature of the contravention, why they are considered to be responsible and what they need to do to remedy it. The objective should be to help them understand why enforcement was necessary and how in future they can comply with their legal obligations.
- **Consistency** – Enforcement should be carried out in a consistent manner, which means that generally similar contraventions should attract comparable enforcement action. The objective should be to ensure that all responsible persons are treated equitably. Agencies should have in place systems to ensure the quality and reliability of enforcement activities. Further information on promoting consistency can also be found in FSAI Guidance Note No. 1 – “Guidance Note for Health Boards on the Inspection of a Food Business.”

When deciding which on enforcement action, officers should have regard to the nature, seriousness and extent of the risk to the consumer. The enforcing body, whether it is the FSAI or an Official Agency, must also ensure the enforcement activity has a sound legal basis. The following should also be considered:

- **History** – Generally, a business or premises with a history of non-compliance should be subject to more formal means of enforcement, for example statutory notices. Informal enforcement may be justified where the contravention is a first time offence and considered unlikely to be repeated.
- **Attitude** – If the attitude of the responsible person is one of cooperation and there is a demonstrable willingness and ability to remedy any contraventions, then an informal approach to enforcement may be appropriate.
- **Intent** – If possible the intent behind the offence should be considered. Where a contravention has come about because of a wilful, deliberate decision or where commercial considerations have been placed deliberately ahead of consumer protection, then formal enforcement would be justified. Informal enforcement may be justified for contraventions caused by an error of judgment, rather than by deliberate intent.

Prosecution

Prosecution will not be appropriate in the vast majority of cases where contraventions are detected. Each case should be considered on its own merits.

In deciding to pursue a prosecution, officers making decisions on behalf of the Authority or the Official Agencies may wish to have regard to Chapter 4 (The Decision Whether to Prosecute) of the “Statement of General Guidelines for Prosecutors” published by the Director of Public Prosecutions. One of the guiding principles of Chapter 4 states that officers must *“be satisfied that it is in the public interest to prosecute; and that there is sufficient admissible, substantial and reliable evidence to support a reasonable prospect of success”*.

The Authority or Official Agency initiating the prosecution should be satisfied that the right person is being prosecuted for the right offence and that the legislation permits the prosecution by the organisation concerned.

Prosecution for offences committed in respect of food legislation may be considered appropriate when:-

- There has been a disregard for consumers’ health and interests and a serious risk has arisen as a direct result.
- Consumers’ health and interests have been intentionally neglected and a risk has arisen as a direct result of the application of this intent.
- A Closure Order or Prohibition Order has been served.
- An unauthorised, prohibited or banned substance has been administered to a food animal, whether or not the residue of the substance is present.
- A business or premises has a history of failing to comply with other enforcement measures, or persistently contravenes food legislation or legal standards for food.
- A statutory notice has not been complied with.

- An authorised officer has been obstructed in the course of their duties.
- Misleading or false information has been deliberately or recklessly supplied to an authorised officer.
- Premises that are required to be approved or licensed are in fact unapproved or unlicensed for the production, handling or storage of food.
- Any other matter arises that gives rise to significant public concern and / or it is considered in the consumer or wider public interest to prosecute.

Prosecution **may not** be appropriate where the purported offence did not or could not generate a risk to consumer health or interests, or the risk or potential risk was relatively trivial. Similarly, prosecution may not be appropriate where it is considered that the court is likely to impose a very small or nominal penalty.

Monitoring

Agencies should put in place systems to monitor their own compliance with this policy. In addition, compliance with this policy will be monitored as part of the FSAI's ongoing audit programme of Official Agencies.

Documents Referred to in this Policy

- The Ombudsman's Guide to Standards of Best Practice for Public Servants (www.ombudsman.gov.ie/2352/GUIDEBP.pdf)
- FSAI Guidance Note No. 13 – Use of Enforcement Powers Under the Food Safety Authority of Ireland Act, 1998 (www.fsai.ie/publications/guidance_notes/gn13.pdf)
- Regulating Better: A Government White Paper setting out six principles of Better Regulation (www.betterregulation.ie)
- Statement of General Guidelines for Prosecutors (www.dpp.ie/filestore/documents/E_Guidelines.pdf)
- FSAI [No. 1 'Guidance Note for Health Boards on the Inspection of a Food Business' \(Revision 1\)](#)

SCHEDULE 7

National Authorisation Policy.

Introduction

The Mission of the Food Safety Authority of Ireland is to protect consumers' health and consumers' interests by ensuring that food consumed, distributed, marketed or produced in the state meets the highest standards of food safety and hygiene.

To this end, the Authority has agreed Service Contracts with "Official Agencies" to have these functions carried out on its behalf. In the execution of these functions, the Authority and the Official Agencies appoint people as Authorised Officers under the Food Safety Authority of Ireland Act 1998 ("the Act") to do the necessary enforcement work.

The purpose of this policy is to provide guidance on the authorisation of officers charged carrying out enforcement work under the Food Safety Authority of Ireland Act 1998.

Powers of Authorised Officers

An officer authorised under Section 49 of the Act is conferred with extensive statutory powers, including the power to:

- Require employees or former employees of the Authority or of an official agency to provide information and assistance.
- Require a food business operator or employee of a food business to provide them with assistance.
- At all reasonable times enter, search and inspect any food premises.
- Secure a premises for later inspection .
- Inspect and take copies of or extracts of records.
- Remove and retain records for further examination.
- Rquire the assistance of a member of an Garda Síochána.
- Take samples
- Issue improvement notices, closure orders or prohibition orders under the Act.

These statutory powers are extensive, considerable and subject to large measures of individual discretion as to how, when, where and to whom they are applied. Their correct application is essential to protecting consumer health, while their incorrect application can have substantial consequences for consumers' health, businesses, the Official Agencies and the Authority.

Authorisation of Officers

Official Agencies and the Authority, as competent authorities are required to ensure that authorised officers have the legal powers to carry out official controls

and to take the measures provided for in food legislation. Authorised Officers are also required to be free of any conflict of interest.

Generally, the degree to which an officer is authorised should reflect their competence as determined by reference to their professional, vocational and academic training, their qualifications and their experience. This should apply regardless of whether the officer in question is directly employed by the Authority or Official Agency or retained on a contractual basis.

On appointment, an assessment should be made of an officer's competence before a decision is made on the extent to which they are to be authorised. Newly qualified officers or officers returning to official food control duties after an extended absence may need to be provided with additional training and / or a period of professional guidance prior to being fully authorised under the Act.

Appointment of Authorised Officers should also be carried out in accordance with a written procedure prepared by the Official Agency or the Authority having regard to the requirements of Section 49 of the Act and FSAI Guidance Note No. 13 – "Use of enforcement Powers Under the Food Safety Authority of Ireland Act, 1998 (2003)."

Authorised Officers should also be issued with a warrant of appointment and the Authority must be informed as soon as possible of the appointment.