

DATED this 1st Day of November 2017

Service Contract

between

**THE FOOD SAFETY AUTHORITY OF IRELAND
(Údarás Sábháilteachta Bia na hÉireann)**

- and -

**THE MARINE INSTITUTE
(Foras na Mara)**

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SERVICE CONTRACT

THIS SERVICE CONTRACT is made the 1st Day November 2017 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 Rinvilla, Oranmore Co. Galway (hereinafter referred to as the "Official Agency").

I. 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 November 2017

"Competent authority" means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;

"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.

- II.** 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 respect of food legislation.

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 the latter's role as a Competent Authority as defined within the terms of this Service Contract.

- III. The Authority may similarly delegate powers, duties and responsibilities to other agencies, and may request the Official Authority to apply the terms of this service contract to those agencies. Such agencies include those listed in Schedule 5 and as may be notified and agreed with the Marine Institute in writing.

- IV. The Authority and the Official Agency agree that the duties and responsibilities for the Official Agency for food safety activities delivered under this service contract derive from food legislation (as defined by Section 2(1) of the Food Safety Authority of Ireland Act 1998), and specifically, food legislation agreed by the Authority and the Official Agency as being relevant to the Official Agency's geographic and functional remits. The functional remit of the Official Agency is defined by Section 4 of the Marine Institute Act, 1991.

Notwithstanding the generality of this clause, the Authority and the Official Agency may agree to a schedule being added to this Service Contract listing specific legislation (referred to as 'Specified Food Legislation') under which food safety activities must be carried out and reported on.

Nothing in this clause allows the Authority or the Official Agency to avoid or repudiate their respective obligations under the Food Safety Authority of Ireland Act 1998.

- V. 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 **30th November 2022**. The Service Contract may be subject to review, modification or amendment by either party, and may be extended by agreement.

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

- VII. 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. The objectives and targets described in this clause will be assessed by means of an agreed set of performance indicators, a sub-set of which will be identified, by agreement, as 'key performance' indicators.

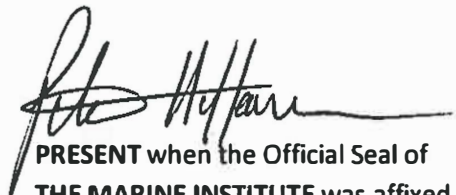
- VIII. The Official Agency has indicated to the Authority that, for the purposes of section 48(4) of the Act, the means by which it proposes to meet the matters specified by the Authority in Schedule 2 of this Service Contract will be submitted to the Authority annually.

- IX. 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.

- X. Without prejudice to the provisions of food legislation, the activities 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. Pamela Byrne, Chief Executive Officer



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

SCHEDULE 1- Specified Food Legislation.

List of the specified legislation, agreed by the Authority and the Official Agency, under Clause IV of this Service Contract, under which food safety activities must be carried out and reported on.

Duties and responsibilities for food safety activities for the Official Agency will derive from food legislation (as defined by Section 2(1) of the Food Safety Authority of Ireland Act 1998) insofar as this food legislation is compatible with the Marine Institute Act, 1991 .

In this context, both the Authority and the Official Agency accept that any actual increase in workload for the Official Agency attributable to the introduction or amendment of food legislation will require the provision of adequate resources.

A reference to an enactment (including any statutory 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.

SPECIFIED FOOD LEGISLATION	Acts and Statutory Instruments
1. General	
Food Safety Authority of Ireland Act 1998, as amended	<u>Act No.29 of 1998</u>

SCHEDULE 2 – Objectives, targets, timeframe and other matters

The objectives, performance indicators (including key performance indicators), targets, timeframe and other matters relating to food safety inspection and analysis which the Authority has agreed with the Official Agency.

2. General requirements

2.1. *Introduction*

The role of the Marine Institute, as defined by the 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 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 scientific information.
- (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. In this context, 'official controls' means any form of control that the competent authority or the Community performs for the verification of compliance with food law.

The Authority acknowledges that the scope of the official controls performed by the Official Agency is limited in scope to those official controls being within the functional remit¹, competence and expertise of the Official Agency.

In the case of the Official Agency, official controls should take account of:

- a. Identified risks associated with food, food businesses, the use of food or any process, material, substance, activity or operation that may influence food safety.
- b. Any information that might indicate non-compliance.

Official controls may be carried out, as appropriate, at any of the stages of production, processing and distribution of food and of animals and animal products.

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. In this instance, the Official Agency agrees to pass the relevant information to the Authority in order that appropriate steps are taken to publicise the matter.

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. This requirement does not prevent the Authority and the Official Agency lawfully sharing data and/or information.

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.

¹ as defined by Section 4 of the Marine Institute Act, 1991

2.2. Legislation.

Duties and responsibilities for food safety activities for the Official Agency will derive from food legislation (as defined by Section 2(1) of the Food Safety Authority of Ireland Act 1998). All staff involved in food control activities shall be provided with access to this legislation or to the Legislation Section of the Authority's Website (www.fsai.ie/legislation.html).

2.3. Ireland's Integrated Marine Plan

The Authority acknowledges the importance of the Integrated Marine Plan for Ireland and further agrees to support and fulfil requests for support and/or advice on matters of food safety associated with the implementation of the Integrated Marine Plan for Ireland, insofar as such requests do not conflict with the Authority's role as the Central Competent Authority for food safety as defined under Clause II to this Service Contract.

2.4. 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) Discuss data standardisation and laboratory information systems.
- (c) Produce Guidance Notes and Codes of Practice.
- (d) Evaluate implications of existing and proposed legislation.
- (e) Evaluate relevant food safety/scientific information.
- (f) Produce other outputs as agreed.

2.5. 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. The content of the plans will be reviewed by the Authority and the Official Agency at liaison meetings. The Official Agency will highlight any issue it regards as an 'emerging risk' to food safety and the Authority will provide a formal response on such issues. This may include developing a co-ordinated response to the issue.

The date of submission of the Service /Annual Control Plan is a key performance indicator as information on planned official controls needs to be gathered and collated as early as possible in each calendar year.

2.6. *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.

2.7. *Information Systems*

Computerisation of sampling, testing and analysis systems must have the functionality to allow data gathered in respect of Clause 2.6 of this Schedule to be transferred electronically to the Authority's database.

2.8. *Out of Hours Emergency Services.*

The Official Agency shall make provision for a set of agreed advisory services to be available outside of normal working hours to deal effectively with emergency situations such as outbreaks and public health food incidents, etc.

2.9. *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 business hours (generally, 0900 to 1700, Monday to Friday) to enable a 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.

2.10. *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.

2.11. *Inter-agency working, Zoonoses Committees.*

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

2.12. *Investigation of Outbreaks.*

Provision shall be made by the Official Agency to provide advice and assist Outbreak Control Teams as required.

2.13. *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.

2.14. *Designated Officers*

The Official Agency may, where necessary, 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.

2.15. *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.

An Annual Training Plan should be developed by the Official Agency to include details of Continuing Professional Development to be provided to all staff with duties under this service contract. Induction training is to be provided for all new staff by the Official Agency.

2.16. *Food Complaints*

Provision shall be made by the Official Agency to provide advice and assist in the investigation of food complaints by other Official Agencies as required.

2.17. *Health and food audits and analysis Missions*

The Official Agency shall participate as required in the preparation and conduct of Health and Food Audits and Analysis missions (formerly known as 'FVO Missions') to Ireland and any follow-up actions associated with a report issued by the European Commission's Directorate-General for Health and Food Safety.

2.18. *Quality Management System*

The Official Agency must maintain an appropriate Quality Management System.

2.19. *Boundaries of the service.*

The Official Agency contracts for provision of services within its administrative and functional areas. 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.

2.20. *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.

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

2.22. *Molluscan Shellfish Safety Committee (MSSC)*

The Official Agency will participate fully in the MSSC, and the associated Management Cell. The Official Agency will also participate in any events run as part of the MSSC, or organised at their behest.

2.23. *Food Fraud*

The Official Agency agrees to advise and assist the Authority investigating possible intentional violations perpetrated through fraudulent deceptive practices in respect of seafood. Where it is agreed the Official Agency will be permitted to participate in the Authority's Food Fraud Task Force.

2.24. *National Reference Laboratories*

2.24.1. *Introduction*

Member States are required to designate one or more National Reference Laboratories for each European Union reference laboratory referred to in Article 32 of Regulation (EC) no 882/2004.

2.24.2. *Authority Support*

The Authority will actively support the Official Agency in its various National Reference Laboratory (NRL) 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.

2.24.3. *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.

2.24.4. 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.

2.24.5. 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 Standard:

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

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.

2.24.6. *Animal health conditions and the marketing of aquaculture animals and products*

The Authority acknowledges that the Official Agency has been designated as the competent authority and NRL “for the purposes of EU Directive 2006/88/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.

2.25. *Shellfish Monitoring Programme*

The Official Agency will provide scientific advice to the Authority on marine biotoxins and related issues.

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

The Official Agency will participate in the Shellfish 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, other relevant agencies, the shellfish industry and associated interested parties, and the Authority will facilitate this communication, when requested. Communication will include e-mail, SMS text message service and web-based services.

The Authority will, in partnership with the Official Agency, and other relevant bodies publish such Guidance Notes, Codes of Practice or other information documents as are necessary to facilitate the operation of the Shellfish Monitoring Programme. The Official Agency will assist the Authority in the provision of training for those involved in the Shellfish Monitoring Programme.

2.26. *Bacterial and Viral Monitoring of Bivalve Molluscs.*

The Official Agency will provide scientific advice to the Authority 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.

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, other relevant agencies, the shellfish industry and associated interested parties, and the Authority will facilitate this communication, when requested.

2.27. *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 the legislation in force at the time.

Extensions to the scope of work in this area will be subject to discussion and agreement with the Authority 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.

2.28. *National Residues Control Plan*

The Official Agency shall undertake monitoring of finfish aquaculture as required under the National Residues Control Plan (NRCP). 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 consult with the Authority, the Department of Agriculture Fisheries and Food and the Sea-Fisheries Protection Authority in the preparation of the 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, and the Sea-Fisheries Protection Authority. The Sea-Fisheries Protection Authority are responsible for carrying out or applying enforcement measures in respect of residue controls and finfish aquaculture.

2.29. Research

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

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

2.30. Fish Health Monitoring

The Official Agency will keep the Authority advised of work done monitoring the health of fish and shellfish, and in particular, 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.

2.31. 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 Marine Strategy Framework Directive (MSFD) and related legislation and specifically the MSFD descriptors that apply, directly and indirectly to seafood:
 - Descriptor 8: Concentrations of contaminants are at levels not giving rise to pollution effects.
 - Descriptor 9: Contaminants in fish and other seafood for human consumption do not exceed levels established by Community legislation or other relevant standards.)
- (c) Certain elements of the Water Framework Directive as it applies to transitional and coastal waters, including shellfish waters.

The Official Agency shall 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.

2.32. Designation of Official Laboratories

The Official Agency agrees to provide advice to the Authority on the suitability of official laboratories for approval as part of the process of designating official laboratories.

2.33. Service Outputs/Activity and Key Performance Indicators

2.33.1. 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.

2.33.2. *Monitoring of Certain Substances and Residues thereof*

The Official Agency will consult with the Authority in the preparation of the National Residues Control Plan (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, Food and the Marine and to the Authority within 3 months of the end of the year to which it applies. The submitted report shall be consistent with the agreed Department of Agriculture, Food and the Marine reporting format for transmission to the EC.

2.33.3. *National Marine Biotoxin Monitoring Programme*

The Official Agency will aim to analyse and report on samples of shellfish submitted to it as part of the National Marine Biotoxin Monitoring Programme within three working days for lipophilic 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. This is an agreed key performance indicator.

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 two 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. This is an agreed key performance indicator.

2.33.4. *Bacterial and Viral Monitoring of Bivalve Molluscs*

The Official Agency will aim to analyse and report on samples of shellfish received by it as part of the Bacterial and Viral Monitoring Programme within 3 working days for *E. coli*. This target will be achieved in respect of a minimum of 90% of samples, with regular improvements to be agreed, where appropriate. This is an agreed key performance indicator.

The Official Agency will also aim to analyse and report on samples received by it as part of the Bacterial and Viral Monitoring Programme for risk management purposes within 5 working days for Norovirus. For routine (survey) samples the Official Agency will aim to analyse and report on samples received by it within 20 working days for Norovirus. These targets

will be achieved in respect of a minimum of 90% of samples, with regular improvements to be agreed, where appropriate

2.33.5. *Chemical Monitoring of Fish & Shellfish*

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

2.33.6. *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 agreed with the Authority.

2.33.7. *Communication with Industry and Associated Interested Parties*

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

2.34. *Monitoring*

2.34.1. *Liaison*

The Official Agency shall nominate person(s) to liaise with the relevant Enforcement Policy Manager of the Authority.

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

The Official Agency agrees to meet with the Authority and the Sea-Fisheries Protection Authority at least bi-annually to discuss areas of common concern.

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

2.34.2. *Access*

The Authority shall have appropriate access as required through the liaison link to the staff with duties under the service contract 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.

2.34.3. Review

The Authority will review the delivery of this Service Contract and provide feedback to the Official Agency. A template for the review of the delivery of the Service Contract is provided in Appendix 1.

The Official Agency will provide the Authority at each Service Contract Liaison Meeting with updates on close-out actions taken in response to findings of:

- (a) Official Agency internal audits,
- (b) The Authority's audits
- (c) Health and Food Audit and Analysis audits

These close-out actions will also be reviewed at liaison meetings with the Authority.

2.34.4. Verification

The Authority will conduct audit activities to satisfy the requirements of Section 48(9) of the Act and in accordance with Schedule 5 of the Service Contract.

The Official Agency will provide, on request, details of any external/ accreditation audits of its service covered by the Service Contract.

2.34.5. 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.

SCHEDULE 3 - Resources

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 Official Agency agrees to provide an update on the resources committed to the delivery of services under this Service Contract at each Service Contract Liaison meeting.

Schedule 4 - Data Sharing

Data Extraction

The Authority and the Official Agency will agree a 'data extract', the scope and extent of which will be subject to variation to meet the collaborative needs of both organisations. The extract will be defined in writing and variations to it may be proposed by either party but will require the assent of both before being accepted. Any variation will require a 'date of implementation' to be agreed which will be applicable to any changes.

The specification for the data extract will be reviewed at each Service Contract Liaison meeting between the Authority and the Official Agency. Reviews and changes may be proposed, agreed and accepted in the interval between Service Contract Liaison meeting between the Authority and the Official Agency with any such changes being noted at the subsequent meeting.

The records contained in the extract will be related to all samples analysed under the supervision of the Official Agency. The only exceptions are quality control tests/proficiency testing.

Data extract criteria & guidelines

Records will be identified for extraction based on the 'Authorised' date in the source LIMS i.e. only authorised records will be extracted and transmitted.

Records amended after initial authorisation should be re-extracted in a subsequent extraction based on the updated authorised date, to ensure ongoing synchronisation of the LIMS and the FSAI's National Food Safety Surveillance (NFSS2) database.

Data Content

Data transmissions will potentially contain a mixture of new records (insertions), changes to existing records and deletions. Validations and quality assurance processes at FSAI will be defined for each.

Transmission Frequency

The agreed dataset will be transmitted on a weekly basis, automated within the reporting tool used by the lab to extract and transmit over a weekend,

Transmission Mechanism

The mechanism for transmission of data will be via the FSAI secure FTP site as defined & implemented. Maintenance of this connection, especially following server upgrade/restart work by local IT should be regularly checked by the lab and their IT support group.

Data Security

Access to the FSAI secure FTP web site is controlled via User ID and Password. Each data source user can access only their directory on the site for data transmission.

Transmission Format

The following:

Three files

Sample Details (contains the LIMS sample reference number)

Test Details (contains the LIMS sample reference number & LIMS test reference number)

Results Details (contains the LIMS sample reference number, LIMS test reference number & LIMS result reference number)

Using æ delimiter

Reconciliation of Sample & Result Numbers

During the course of each year, a reconciliation process and frequency will be agreed between the lab and FSAI.

Report and Service Requests

The Authority agrees to answer requests for reports based on data held by the Authority within 3 working days and to allow access, within the limits allowed by legislation, to data held by the Authority for the purposes of research, information and communication.

SCHEDULE 5 – Audit of the Service Contract

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

1. Legal Basis

Audits by the Authority of Official Agency activities shall be carried out under the provisions of Section 48(9) of the Act.

2. General Requirements

The Authority shall carry out audits to verify conformance by the Official Agency with regard to requirements of the Service Contract and the implementation of NCP. 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.

3. Scheduling

Using risk assessment methodologies, the Authority shall develop audit programmes to determine conformance 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 internal audit or any appropriate third-party registration or accreditation audits.

Audit programmes are circulated on a six monthly basis following approval by the Senior Leadership Team of the FSAI. Audits will be conducted in accordance with the Authority's Audit Charter and documented procedures.

4. Liaison

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

5. Access

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

6. 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 Authority in order to address audit findings where these have arisen. It is also the responsibility of the Authority to monitor closeout of audit outcomes (e.g. by the Authority or European Commission) and to ensure they are adequate and appropriate. The Authority may verify closeout of findings in accordance with Regulation 882/2004 requirements where deemed necessary.

SCHEDULE 6 – Other Authorities

**Other authorities with delegated authority of the FSAI to which the terms of this Service Contract
may apply**

The Sea Fisheries Protection Authority

Service Contract - Appendix 1

Table 1 – Template for Review of the Service Contract

Sch. 2 Clause	Clause Heading	Measureable outcome	Key Deliverable	FSAI Comment & Assessment
2.5	Service plan/Annual Control plan	Prepare the Service Plan/Annual Control Plan or submit the relevant parts of the Official Agency's Divisional Business plans	To be received by the Authority by the end of Q1 of each year	
2.6	Data collection reporting and information	Receipt of Data from the Official Agency in accordance with service contract requirements	Frequency and format of data to be submitted to Authority in accordance with requirements	
2.7	Information Systems	Where the Official Agency has computerised systems for sampling, testing and analysis, data gathered will be transmitted electronically to the Authority.	Transmission of data to the Authority in accordance with requirements	
2.17	Directorate-General for Health and Food Safety, HFAA Missions	The Official Agency will participate in HFAA Missions Mission recommendations to be closed out by the Official Agency	Participation in Missions, respond to HFAA requests, and closeout of recommendations	
2.18	Quality Management System	The Official Agency must maintain an appropriate Quality Management System	?	
2.33.2	National Residue	The Official Agency shall fulfil its obligations regarding the National Residues Control	Agreement on and implementation of the	

Service Contract - Appendix 1

Table 1 – Template for Review of the Service Contract

Sch. 2 Clause	Clause Heading	Measureable outcome	Key Deliverable	FSAI Comment & Assessment
	Control Plan (NRCP)	Plan (NRCP) insofar as it applies to finfish aquaculture	Annual NRCP. Submission of the Annual NRCP Report within 3 months of the end of the year to which it applies.	
2.33.3	National Marine Biotoxin Monitoring Programme, Lipophilics	The Official Agency will aim to analyse and report on samples of shellfish submitted to it as part of the National Marine Biotoxin Monitoring Programme within three working days for lipophilic 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.	
2.33.3 contd	National Marine Biotoxin Monitoring Programme, Phytoplankton	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 two 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	
2.33.4	Bacterial and Viral Monitoring of Bivalve Molluscs, <i>E. coli</i>	The Official Agency will aim to analyse and report on samples of shellfish received by it as part of the Bacterial and Viral Monitoring Programme within 3 working days for <i>E. coli</i> .	This target will be achieved in respect of a minimum of 90% of samples, with regular improvements to be agreed, where appropriate	
2.33.4	Bacterial and	The Official Agency will aim to analyse and	These targets will be	

Service Contract - Appendix 1

Table 1 – Template for Review of the Service Contract

Sch. 2 Clause	Clause Heading	Measureable outcome	Key Deliverable	FSAI Comment & Assessment
contd	Viral Monitoring of Bivalve Molluscs, Norovirus	report on samples received by it as part of the Bacterial and Viral Monitoring Programme for risk management purposes within 5 working days for Norovirus. For routine (survey) samples the Official Agency will aim to analyse and report on samples received by it within 20 working days for Norovirus.	achieved in respect of a minimum of 90% of samples, with regular improvements to be agreed, where appropriate	
2.33.5	Monitoring contaminants in wild fish and shellfish	The Official Agency will carry out sampling and analysis for certain environmental contaminants in fish and shellfish	The Official Agency will report on an annual basis, to the Authority, contaminants in shellfish and wild finfish.	