

**DATED this 1<sup>st</sup> day of JULY 2023**

**Service Contract between**

**THE FOOD SAFETY AUTHORITY OF IRELAND**

**(Údarás Sábháilteachta Bia na hÉireann)**

**and**

**The Marine Institute**

**(Foras na Mara)**

**THIS SERVICE CONTRACT** is made this 1<sup>st</sup> day of July 2023

**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 The Exchange, George's Dock, IFSC, D01 P2V6, Dublin 1; and The Marine Institute having its principal place of business at Rinville Oranmore Co. Galway. (herein after 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 1<sup>st</sup> Day of July 2023;

**“Food Legislation”** means the Food Legislation set out in Schedule 1 of this Service Contract;

**“Official Agency”** means The Marine Institute

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 and the production of animal feed 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 31<sup>st</sup> Day of December 2028.

The Service Contract may be subject to review, modification or amendment, and may be extended by agreement between the Authority and the Official Agency.

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 sampling and analysis of food, including food ingredients, and
  - (b) the provision of food safety and food hygiene education to agreed food business operators.
  
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 in Schedule 2 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
  
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.

The Official Agency agrees to collect data and report to the Authority as detailed in Schedule 4.
  
7. In accordance with the provisions of *Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products*, 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 to be undertaken on behalf of the Authority shall be directed towards bringing about a general acceptance, amongst food business operators, 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.

**Signed on behalf of the Food Safety Authority of Ireland**

\_\_\_\_\_  
**Dr Pamela Byrne**  
**Chief Executive**

\_\_\_\_\_  
**DATE**

**Signed on behalf of the Marine Institute**

\_\_\_\_\_  
**Dr Paul Connolly**  
**Chief Executive**

\_\_\_\_\_  
**DATE**

## 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 food 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 food legislation may be inserted by the Authority into this Schedule.

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 'food legislation,' identified as such by legal instrument, is compatible with the requirements of the Marine Institute Act 1991.

Nothing in this definition will preclude the Official Agency from requiring the Authority to specify particular legislation in Schedule 1 when it is considered operationally or legally prudent to do so.

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 additional resources.

A reference to an enactment (including any instruments made hereunder) 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.

<b>2. Official Controls and General Food Hygiene</b>	
<b>2.1 Official Controls and Other Official Activities and The Hygiene Package</b>	
European Union (Official Controls in Relation to Food Legislation) Regulations 2020, S.I. No. 79 of 2020	<a href="#"><u>S.I. No. 79 of 2020</u></a>
European Union (Food and Feed Hygiene) Regulations 2020, S.I. No 22 of 2020	<a href="#"><u>S.I. No 22 of 2020</u></a>

## **Schedule 2 - Section 1**

The objectives, targets, timeframe and other matters relating to official controls and other official activities which the Authority has specified to the Official Agency

### **1.0 General Requirements – Section 1 applies to official controls and other official activities related to food safety of the Marine Institute**

#### **1.1 Introduction**

The Official Agency and the Authority agree that the operation of this Service Contract shall be informed and animated by the principles of commitment, integrity, transparency, excellence, innovation, collaboration and respect.

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 will fulfil all obligations regarding food safety and integrity as agreed with the Authority under the terms of this Service Contract. The Official Agency shall work in partnership with the Authority and its other Official Agencies to ensure effective official controls and other official activities, to enhance consumer protection and consumers' interests in so far as it relates to food legislation.

#### **1.2 Official Controls and Other Official Activities**

The Official Agency shall monitor and verify compliance with the relevant requirements of food law by food business operators within in the Official Agency's remit at any stage of production, processing, distribution and sale as agreed under this Service Contract.

Official controls and other official activities shall be carried out as appropriate and agreed by the Authority and the Official Agency, at any of the stages of production, processing, distribution and sale of food and of animals and animal products.

As necessary, this may include official controls on food businesses, on the use of food, on the storage, transport and sale of food, on any process, material, article, substance, activity or operation applied to food and any information that might indicate non-compliance.

Within its competence, the Official Agency shall ensure that, where it is agreed to be appropriate and relevant, official controls and other official activities 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(2) of the Act.

The Official Agency shall comply with the relevant requirements of Regulation (EU) 2017/625 and associated subordinate legislation.

Frequency of official controls shall be determined in line with the requirements in Article 9

of Regulation (EU) 2017/625 and these official controls shall be conducted in line with the methods and techniques for official controls in Article 14 of Regulation (EU) 2017/625.

The Official Agency shall have due regard to recognised guidance notes, best practice or accreditation systems as may be agreed between the Official Agency and the Authority from time to time in addition to any advice which may be issued by the Authority.

The Official Agency will engage in inter-agency official controls and other official activities, insofar as such activities are allowed for in law and are compatible with the strategic objectives and operational plans of the Official Agency. These inter-agency activities include, but are not limited to:

- (i) Sharing of information on food businesses
- (ii) Provision of reasonable assistance as appropriate
- (iii) Participation in cross-agency meetings
- (iv) Inter-agency training
- (v) Multi-disciplinary working

### ***1.3 Effectiveness and Appropriateness of Official Controls and Other Official Activities***

The Official Agency will ensure that official controls and other official activities are planned and coordinated in order to meet the objectives of the Official Controls legislation.

In line with the requirements of Article 5 of Regulation (EU) 2017/625 the Official Agency will ensure that the structures and arrangements in place facilitate the implementation of official controls and other official activities that are effective and appropriate. Control verification procedures shall be in place to verify the effectiveness of official controls and other official activities performed by the Official Agency, where these procedures identify shortcomings the Official Agency shall take corrective action and ensure documented control procedures are updated accordingly in line with Article 12(2) and 12(3) of Regulation (EU) 2017/625.

The Official Agency and the Authority agree to work co-operatively and collaborate to ensure there is efficient and effective coordination between all competent authorities involved in carrying out official controls and other official activities in Ireland, and to ensure that, as far as is practicable, there is consistency and effectiveness of official controls and other official activities.

### ***1.4 Transparency***

The Official Agency and the Authority shall ensure that official controls are performed with a high level of transparency in accordance with Article 11 of Regulation (EU) 2017/625. The Official Agency shall, at least once a year, make available to the public and the Authority relevant information concerning the organisation and the performance of those official controls.



The Official Agency shall put procedures in place to ensure any inaccuracies in information made available to the public can be rectified, this will also include informing the Authority immediately of any such inaccuracies previously communicated and the information required to enable appropriate rectification.

Where there are reasonable grounds to suspect that a food may present a risk to health the Official Agency and the Authority will ensure the public is informed to the fullest extent possible.

The Official Agency and the Authority must ensure that information acquired when undertaking official controls which by its nature is covered by 'professional secrecy in duly justified cases' is not disclosed to a third party.

### ***1.5 Quality Management System (QMS)***

The Official Agency shall carry out official controls in accordance with documented control procedures established as part of a Quality Management System. These procedures shall provide information and instructions for staff performing official controls in line with Article 12 of Regulation (EU) 2017/625. Documented procedures will be kept under review and updated as required.

The Official Agency agrees to provide the Authority relevant information from its Quality Management System as requested to allow the fulfilment of the Authority's audit role and obligations.

### ***1.6 Written Records of Official Controls***

Where Official Controls are carried out by the Official Agency under section 1.2 of this Service Contract, then, in line with Article 13 of Regulation (EU) 2017/625, the Official Agency shall draw up written reports on each such official control that it has carried out.

These reports shall include a description of the purpose of the official controls, the control methods applied, the outcome of the official control and, where appropriate, action that the business operator concerned is to take. In accordance with Article 13(2) of the Regulation the Official Agency shall provide a report on the outcome of each official control of a food business to the relevant food business operator on request or promptly where non-compliance has been identified through the official controls.

### ***1.7 Data and Information Collection and Reporting***

The Official Agency shall collect data and information regarding official controls and other official activities performed under this contract in respect of:

- Sampling and analysis.

The data and information will be such as to enable the Authority and the Official Agency to:

- Demonstrate that official controls and other official activities have been carried out as planned as part of service delivery
- Verify compliance with the requirements of Regulation (EU) 2017/625, associated tertiary legislation and relevant national legislation
- identify any gaps in the official controls and other official activities performed
- Support addressing newly identified risks which may arise through food or any such risks emerging from new patterns of production, or consumption of food and
- produce reports including the annual report on multi-annual national control plan on the outcomes and effectiveness of food related official controls and other official activities performed by the Official Agency.

The Official Agency and the Authority agree that such data and information fall within the scope of Section 16 of the Act and will be treated as such.

The Official Agency shall provide the Authority with data and information on its food related official controls and other official activities as set down in Schedule 4 of the contract and the Multi Annual National Control Plan reporting requirements.

Both the Authority and the Official Agency acknowledge each other's respective responsibilities under Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (the "General Data Protection Regulation").

Specifically, the Authority and the Official Agency agree to share with each other their respective policies on the retention of personal data; data use; data sharing; and, data reporting.

The Official Agency agrees to respond in a timely fashion to data requests and for clarifications from the Authority.

### ***1.8 Information Systems***

The Official Agency in conjunction with the Authority will meet the relevant requirements of Articles 131 to 136 of Regulation (EU) 2017/625 and Implementing Regulation (EU) 2019/1715 as appropriate to the Official Agency.

Digitisation of sampling, testing and analysis systems must have the functionality to allow data gathered in respect of Clause 1.7 of this Schedule to be transferred electronically to the Authority.

Details regarding the formatting, frequency, structure and content of such data transfers will be agreed, from time to time, by the Official Agency and the Authority. The prevailing agreement at any given time will reflect the operational needs of the Official Agency and the Authority, as well as the respective technological capabilities of both organisations.

### ***1.9 Legislation***

Duties and responsibilities for the performance of official controls and other official activities related to food and food safety and integrity and protection of consumers interests and information for the Official Agency will be consistent with Schedule 1. All staff

involved in official controls and other official activities shall be provided with access to relevant food law and food legislation.

#### **1.10 Authorisation**

The Official Agency agrees to ensure that all relevant staff are authorised appropriately and in accordance with the Act, for the official controls and other official activities they carry out.

#### **1.11 Service Plan/Annual Control Plan/Annual Work Programme/Budget Estimate and Service Plan**

The Official Agency agrees to prepare an annual business or service plan (or equivalent) for the official controls and other official activities performed under this Service Contract. These plans will incorporate the requirements of Article 9(1) and Article 9(2) of Regulation (EU) 2017/625.

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.

#### **1.12 Fraudulent and Deceptive Practices Related to the Food Chain**

Where, following the receipt of information or during the course of official controls, the Official Agency identifies circumstances which may indicate fraudulent/deceptive practices in so far as they relate to food legislation, these will be recorded and reported in line with agreed procedures, in a timely manner to the Authority.

The Official Agency and the Authority with the support of other Official Agencies and Law enforcement authorities as appropriate, will agree and implement a programme of proactive and reactive work to identify and investigate possible intentional violations perpetrated through fraudulent and deceptive practices.

#### **1.13 Follow Up on Non-Compliances**

Within its identified organisational competencies and in line with Article 138 of Regulation (EU) 2017/625 the Official Agency agrees to assist with follow up action associated with the detection of non-compliances, in consultation as necessary with the Authority or other Official Agencies.

#### **1.14 Designated Officer**

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.

#### **1.15 Internal Audit**

The Official Agency shall conduct internal audits on its official controls and other official activities related to this service contract and will ensure effective action is taken to address the results of these audits.

These internal audits will be conducted in accordance with relevant guidelines issued by the European Commission. Such audits are to be carried out in a transparent manner and are subject to independent scrutiny as per Article 6 of Regulation (EU) 2017/625.

When requested by the Authority, the Official Agency agrees to provide the Authority with its annual internal audit programme(s), internal audit reports, corrective action plans and any other documentation related to its internal audit function that falls within the remit of this contract in a timely manner.

Progress related to its internal audit activities will be reviewed at liaison meetings and normal communication channels with the Authority.

#### **1.16 Contingency Planning**

The Official Agency in conjunction with the Authority shall ensure that there are contingency plans in place at appropriate levels for dealing with food related crises and incidents. The contingency plan shall be in line with Article 115 of Regulation (EU) 2017/625 and include arrangements for activation of the plan, establishment of a crisis team, communication and information, out of hours contacts and on call services.

As part of these plans, the Official Agency will provide the Authority with contact points for both office hours and out of office hours contact for emergency and crisis situations.

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

The Official Agency shall implement the agreed *Inter-Agency Protocol for the Management of a Food Crisis* and guidance on *Management of Outbreaks of Foodborne Illness* as per Section 1.18.

### **1.17 Out of Hours Emergency/On Call Services**

The Official Agency agrees to provide the Authority with contact points for out of office hours contact for emergency and crisis situations.

The provision of official controls by the Official Agency outside office hours, and beyond the normal working arrangements of the Official Agency, will be determined on a situational basis. The Authority agrees that the provision of such services outside office hours, and beyond the normal working arrangements of the Official Agency, may, of necessity, be limited by the availability of, or access to, resources.

### **1.18 Food Incidents**

Provisions shall be made by the Official Agency to deal effectively with food incidents relevant to the Official Agency. The Authority and the Official Agency agree to notify each other without undue delay of all matters relating to such food incidents or food fraud where there is a real or potential risk to food, food safety or integrity, human health, an infringement of food law or involving international food trade.

The Official Agency in conjunction with the Authority, agree to implement the agreed protocol(s) to manage and deal effectively with food borne outbreaks in particular the guidance on “*Management of Outbreaks of Foodborne Illness*” as published on Safetynet.

The Official Agency agrees to co-operate with the Authority, other Official Agencies and / or the Outbreak Control team in the investigation of relevant incidents and provide such information as requested by the Authority for the management of incidents, in a timely manner.

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

### **1.19 Food Complaints**

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

### **1.20 Commission Controls and Third Country Audits**

The Official Agency agrees to cooperate with, and participate (as required) in, the preparation and conduct of audits to Ireland carried out by the European Commission (DG SANTE Health and Food Audits and Analysis, Directorate F), or audits by third countries as may arise, and for the completion of questionnaires requested by the Commission and/or other services.

The Official Agency agrees to take effective actions to address mission report recommendations (if any) in a timely manner, and as agreed with the Authority. The Official Agency agrees to keep the Authority informed on the progress to implement actions to be taken or proposed and upon request.

### **1.21 Coordinated Control Programmes and Information and Data Collection**

The Official Agency agrees to participate in relevant EU coordinated control programmes and/or provide information and data requested in line with the requirements of Article 112 of Regulation (EU) 2017/625 as agreed with the Authority.

### **1.22 Administrative Assistance and Cooperation**

The Authority agrees to act as the contact point responsible for facilitating the exchange of communications between competent authorities in accordance with Articles 104 to 107 in all matters relating to food incidents or food fraud where a risk to human health, a possible non-compliance with food law or fraudulent or deceptive practices is suspected.

The Official Agency will agree with the Authority the procedures for administrative assistance and co-operation required under Articles 102 to 108 of Regulation (EU) 2017/625 and include such activity in its Section 48(8) report to the Authority.

Requests for assistance made or received by the Official Agency under Title IV of Regulation (EU) 2017/625, where a risk to human health or a possible non-compliance with food law is identified or suspected shall be notified to the Authority in a timely manner.

### **1.23 Multi Annual National Control Plan (MANCP)**

The Official Agency agrees to co-operate with the Authority and the other Official Agencies to achieve the objectives of the single integrated multi annual national control plan (MANCP) prepared in accordance with Regulation (EU) 2017/625.

The Official Agency agrees to co-operate with the Authority in updating Irelands MANCP and in the preparation of the annual reports for Ireland. By the 31<sup>st</sup> July each year the Official Agency shall provide the information and data for the MANCP in the format required by the Authority to meet the requirements of Implementing Regulation (EU) 2019/723.

Revisions to this Service Contract will be reflected in the MANCP.

### **1.24 Training and Continuous Professional Development**

The Official Agency agrees to provide appropriate training, including induction training for staff performing official controls enabling them to undertake their duties competently and to carry out official controls and other official activities in a consistent manner, in line with Article 5(4)(a) and Chapter I, Annex II of Regulation (EU) 2017/625.

While the provision of training is the primary responsibility of the Official Agency, the Authority may provide training interventions where the Official Agency has highlighted areas where training is required. The Authority agrees to facilitate networking and collaboration with other Official Agencies to assist in improving knowledge in such areas.

Training needs for official control staff will be identified by the Official Agency. These training needs shall form part of the annual training plans be completed by the Official

Agency, which should include details of appropriate training to be provided to staff listed in Schedule 3.

The Official Agency agrees to maintain training records for each member of staff involved in official controls and/or other official activities that are within the remit of this Service Contract.

The Authority agrees to provide training and e-learning resources for official control staff. These resources will aim to:

- (a) Inform staff performing official controls and/or other official activities on the requirements of existing and new/revised legislation
- (b) Disseminate and clarify the application of guidance material
- (c) Facilitate standardised approaches to official controls and other official activities to ensure a consistent understanding and application of existing and new/revised legislation, guidance or procedures.

Following any training resource provided by the Authority, the Official Agency agrees to support participants in using e-learning resources, disseminating knowledge or skills acquired and encourage the application of learning gained.

The Authority co-ordinates participation for Irish Official Agency staff on training courses run by the European Commission in the EU 'Better Training for Safer Food' (BTSF) training programme. The Official Agency agrees to support participants in disseminating knowledge or skills acquired and encourage the application of learning gained through BTSF training programmes.

The Official Agency agrees to ensure that staff carrying out official controls and/or other official activities are kept up to date in their area of competence. The Official Agency agrees ensure that any contractors used in the performance of the Service Contract provide evidence of appropriate training.

### ***1.25 Participation on Working Groups***

The Official Agency agrees to participate in FSAI working groups relevant to the Official Agency's work or operations and provide advice, within its competence. Relevant working groups includes, but is not limited to, interagency working groups and expert working groups established to:

- Produce the multi-annual national control plan for Ireland.
- Discuss data standardisation and laboratory information systems.
- Produce Guidance Notes and Codes of Practice.
- Evaluate implications of existing and proposed legislation.
- Evaluate relevant food safety/scientific information.
- Produce other outputs as agreed.

### **1.26 Food Hygiene Information Programme**

The Official Agency agrees to support, within its competence, Food Hygiene Information Programmes organised through or in partnership with the FSAI. Support provided by the Official Agency may include provision of advice or commentary on information material, or, by agreement, making subject-matter experts available to participate in events.

### **1.27 Voluntary National Guides**

The Official Agency agrees to support, within its competence, the development of Voluntary National Guides.

### **1.28 Third Party Complaints Regarding the Implementation of this Service Contract**

The Official Agency agrees to provide information to the Authority on complaints regarding the implementation of this Service Contract. Complaints will be managed in accordance with the Official Agency's procedures.

The Official Agency agrees to co-operate with the Authority in any investigation regarding these complaints.

Complaints regarding the implementation of the service contract received by the Authority will be notified to the Official Agency and managed through the liaison process.

### **1.29 Boundaries of Service**

The Official Agency agrees to provide services and activities, under this Service Contract, within its administrative and functional areas as defined by the Marine Institute Act 1991.

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.

### **1.30 Communication with Industry and Associated Interested Parties**

The Official Agency agrees to organise and run workshops on shellfish safety and other topics as agreed with the Authority.

The Authority agrees to support and participate in the organising and running of these events.



### **1.31 Molluscan Shellfish Safety Committee (MSSC)**

The Official Agency agrees to participate in all MSSC meetings, and the associated Management Cell. The Official Agency further agrees to 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.

### **1.32 Integrated Marine Plan for Ireland**

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.

### **1.33 Additional Tasks**

The Official Agency agrees to participate in activities relating to food safety that may be agreed with the Authority, in collaboration with the Authority or other official agencies as appropriate.

## **Schedule 2 – Section 2 (Monitoring Programmes)**

### **2.0 Monitoring Programmes**

**Section 2 applies to the specific monitoring programmes that the Official Agency is responsible for related to food safety.**

#### **2.1 Introduction**

The Marine Institute is responsible for the implementation and maintenance of a number of monitoring programmes relating to the safety of fish and fishery products.

These monitoring programmes aim to ensure the safety, integrity and authenticity of the food chain by verifying compliance with food legislation requirements, detecting, deterring and preventing breaches of food law, and taking appropriate action to protect consumers health and interests.

#### **2.2 Shellfish Biotoxin Monitoring Programmes**

The Official Agency agrees to provide, within its competence and expertise, scientific advice to the Authority.

The Official Agency agrees to participate in the Shellfish Biotoxin Monitoring Programmes, in accordance with the prevailing Molluscan Shellfish Safety Committee's Code of Practice.

The Official Agency agrees to 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 agrees to communicate regularly, by appropriate means, with the Authority, other relevant agencies, the shellfish industry and associated interested parties, and the Authority agrees to facilitate this communication, when requested. Communication will include e-mail and web-based services.

The Authority will, in collaboration 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 Biotoxin Monitoring Programmes. The Official Agency will assist the Authority in the provision of training for those involved in the Shellfish Biotoxin Monitoring Programmes.

### **2.3 Bacterial and Viral Monitoring of Bivalve Molluscs**

The Official Agency agrees to provide scientific advice to the Authority on the microbiological and virological safety and quality of shellfish and shellfish growing waters, and on related matters.

Furthermore, the Authority, in collaboration 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 agrees to provide representatives for and advice to the MSSC, and any other relevant working group or sub-committee of the MSSC.

The Official Agency agrees to 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.

### **2.4 Chemical Monitoring of Fish and Shellfish**

The Official Agency agrees to continue to carry out sampling and analysis for certain environmental contaminants in farmed and wild fish and shellfish in accordance with the legislation in force at the time. Farmed fish sampled under the National Residues Control Plan and tested for environmental contaminants will contribute to the delivery of the National Contaminants Control Plan.

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 agrees to report results of such monitoring to the Authority on an annual basis. The Official Agency agrees to 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.

## **2.5 Monitoring pharmacologically active substances and residues thereof in finfish aquaculture**

### **a) National risk-based control plan with respect to pharmacologically active substances and residues thereof**

The Official Agency agrees to undertake monitoring of finfish aquaculture as required under the National Risk-based Control Plan (NRCP) -. This includes sampling and analysis of samples of farmed fish for a range of veterinary substances and other treatments and reporting of results.

The Official Agency agrees to consult with the Authority, the Department of Agriculture Food and the Marine and the Sea-Fisheries Protection Authority in the preparation of the NRCP.

Extensions to the scope of work in this area, in the context of new regulatory requirements coming into force from 2023 and findings of the FVO audits, will be subject to discussion and agreement with the Authority and subject to the provision of additional resources, in the context of the national plan.

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 agree to advise the Authority.

In consideration of the manner in which the Residues Programme is organised and delivered, the Official Agency agrees to 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 agrees to 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.

### **b) National randomized surveillance plan**

The Official Agency agrees to provide farmed finfish samples as collected under the above programme to relevant agencies/laboratories/ Departments to support delivery of the National Randomized Surveillance Plan with the Authority, the Department of Agriculture Food and the Marine and the Sea-Fisheries Protection Authority in the preparation of the NRCP.

### **c) National Risk-based control plan for third- country imports**

The Official Agency agrees to undertake analysis of certain substances in seafood sampled at Border Control Posts, where the target substances form part of the MI contaminants and

residues testing programmes. Should sample numbers increase this testing programme will be subject to review.

## **2.6 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.

## **2.7 Emerging Risks**

The Authority and the Official Agency agree to collaborate and assist, where appropriate, in the identification and assessment of “emerging risks.” In this context, an emerging risk is defined as “a risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard.”

## **2.8 Fish and Shellfish Health Monitoring**

The Official Agency agrees to 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.

## **2.9 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 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 agrees to 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.

## Schedule 2 - Section 3 (Service Outputs and Key Performance Indicators)

### **3.1 Introduction**

The Official Agency agrees to 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.

The Official Agency agrees to take samples for analysis and testing as required by food legislation, the Official Agency's documented procedures and annual sampling plans. The Official Agency agrees to ensure that samples taken as part of official controls and/or other official activities are:

- sampled, analysed and tested in accordance with the requirements of Articles 34 to 42 of Regulation (EU) 2017/625.
- submitted to official laboratories for analysis.

### **3.2 National Marine Biotoxin Monitoring Programme**

The Official Agency and the Authority agree that:

- 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 of lab receipt for lipophilic toxins (DSP & AZP)
- 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 four working days of lab receipt for PSP and ASP
- the Official Agency will aim to analyse and report on water samples submitted to it as part of the National Marine Biotoxin Monitoring Programme within three working days of lab receipt for toxic phytoplankton species associated with the production of DSP, AZP, PSP and ASP toxins.

The Official Agency and the Authority agree that these targets will be achieved in respect of a minimum of 90% of samples. The Official Agency and the Authority agree that these are agreed key performance indicators.

### **3.3 Bacterial and viral monitoring of bivalve molluscs**

The Official Agency and the Authority agree that 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 three working days of lab receipt 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. The Official Agency and the Authority agree that this is an agreed key performance indicator.

The Official Agency and the Authority agree that the Official Agency will aim to analyse and report on samples received by it as part of the Bacterial and Viral Monitoring Programme for risk management purposes within five 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. The Official Agency and the Authority agree that these targets will be achieved in respect of a minimum of 90% of samples.

### **3.4 Chemical monitoring of fish and shellfish**

The Official Agency and the Authority agree that the Official Agency will report on an annual basis, to the Authority, contaminants in shellfish, wild finfish and farmed fish. The submitted report shall be consistent with the agreed Department of Agriculture, Food and the Marine reporting format for transmission to the EC.

### **3.5 Monitoring of certain substances and residues thereof**

The Official Agency and the Authority agree that 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 5 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.

## **Schedule 2 - Section 4 (Analysis and Testing)**

### **4.0 Analysis and Testing**

#### **4.1 Official Laboratories**

The Official Agency and the Authority agree that samples taken during official controls and other official activities shall be analysed or tested in designated official laboratories.

The MI shall function as an 'official laboratory' and a National Reference Laboratory as defined in Regulation (EU) 2017/625 and as per procedures agreed with the Authority.

As an official laboratory the Official Agency agrees to participate in audits for the purposes of Article 39 of Regulation (EU) 2017/625.

In the designation of official laboratories by the Authority, the Official Agency agrees to provide advice to the Authority on the suitability of official laboratories for approval.

#### **4.1.1 Services to be Provided**

As an official laboratory, the Official Agency shall carry out analysis and testing and any other tasks as per their written designation under Article 37(3) of Regulation (EU) 2017/625.

#### **4.1.2 Laboratory Methods**

As an official laboratory the Official Agency shall use methods that comply with Article 34 of Regulation (EU) 2017/625.

The Official Agency will work to revalidate all residue methods under the NRCP according to the new requirements of Commission Implementing Regulation 2021/808 by June 2026, subject to available resource and technical constraints, and will endeavour to ensure all third party laboratories employed meet this programme.

#### **4.1.3 Accreditation**

As an official laboratory the Official Agency agrees to operate in accordance with the standard EN ISO/IEC 17025 and be accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008. The scope of accreditation of the official laboratory shall be in accordance with Article 37(5) of Regulation (EU) 2017/625.

Derogations from mandatory accreditation may only apply where granted under the conditions in Articles 40-42 of Regulation (EU) 2017/625 as appropriate, in accordance with the written designation and with the agreement of the Authority.

#### **4.1.4 Audits of Official Laboratories**

As an official laboratory, the Official Agency agrees to immediately inform the Authority of the results of any external audits which may have an impact on its accreditation status or of any other circumstances which may have an impact on its accreditation status.

#### **4.1.5 Turnaround Time**

In line with the requirements of Article 37(4)(d) of Regulation (EU) 2017/625 the Official Agency will ensure that turnaround times for programmed samples taken as part of official controls and other official activities are timely and allow for efficient follow up of non-compliant samples. Turnaround times for routine analyses will be reviewed at liaison meetings.

#### **4.1.6 Reporting**

With regard to the results of analysis or testing carried out on samples taken during official controls or other official activities, where such results indicate a risk to human or animal health or point to the likelihood of non-compliance, the Official Agency acting as an official

laboratory agrees to inform immediately the competent authorities (which designated them for that analysis, test or diagnosis) and, where relevant, delegated bodies or natural persons to which tasks have been delegated (in line with the requirements of Article 38(1) of Regulation (EU) 2017/625), of that fact

The Official Agency acting as an official laboratory agrees to inform the Authority and the Official Agency that submitted the sample for analysis of such non-compliant results. The Official Agency agrees that notifications to the Authority shall be as per procedures agreed with the Authority.

#### ***4.1.7 Subcontracted testing***

The Official Agency acting as an official laboratory agrees to work to ensure any arrangements for subcontracting are in line with the requirements of Regulation (EU) 2017/625.

The Official Agency acting as an official laboratory agrees to subcontract to another official laboratory where available.

The Official Agency acting as an official laboratory agrees that any subcontracting will take place only following consultation with the Authority.

The Official Agency acting as an official laboratory agrees to have a service level agreement with any subcontracted laboratory detailing the services and standards to be provided.

#### ***4.1.8 Method Development***

The Official Agency agrees that, subject to available resources, to help in the development of new analytical capabilities for emerging risks as identified by the Authority, European Commission, the official laboratories, relevant National Reference Laboratories or other relevant bodies when required by Union rules for food safety parameters, to support official controls and/or other official control activities.

#### ***4.1.9 Cross Agency Laboratory Working***

The Official Agency acting as an official laboratory agrees to work with the Authority, other official laboratories and national reference laboratories on a cross agency basis to implement Regulation (EU) 2017/625.

#### ***4.1.10 Retrospective Surveillance Data***

The Official Agency acting as an official laboratory agrees to provide relevant retrospective surveillance data to the Authority, in the context of specific requests from the EU Commission.



## **4.2 National Reference Laboratories**

### **4.2.1 Introduction**

Member States are required to designate one or more National Reference Laboratories (hereinafter referred to as “NRLs”) for each European Union reference laboratory referred to in Article 93(1) of Regulation (EU) 2017/625.

NRLs shall in their area of responsibility coordinate the activities of official laboratories designated with a view to harmonise and improve the methods of laboratory analysis. The Authority will agree the practical arrangements of these requirements with the NRLs, including the interactions with official laboratories in other Official Agencies.

### **4.2.2 Designated National Reference Laboratories**

The Minister for Health and the Minister for Agriculture, Food and the Marine have designated the National Reference Laboratories in accordance with Article 100 of Regulation (EU) 2017/625. The National Reference Laboratories are listed in Schedule 3.

### **4.2.3 National Reference Laboratory Responsibilities and Tasks**

The National Reference Laboratories shall for their area of competence fulfil the responsibilities and tasks in accordance with the requirements of Article 101 of Regulation (EU) 2017/625 and any delegated acts adopted thereunder and the agreed Guidelines for National Reference Laboratories and official laboratories.

In accordance with Article 101 of Regulation (EU) 2017/625 the Official Agency as a National Reference Laboratory, agrees to:

- (a) collaborate with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories;
- (b) coordinate the activities of official laboratories designated in accordance with Article 37(1) with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use;
- (c) where appropriate, organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;
- (d) ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies;
- (e) provide within the scope of their mission scientific and technical assistance to the competent authorities for the implementation of MANCPs referred to in Article 109 and of coordinated control programmes adopted in accordance with Article 112;

(f) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

(g) where necessary, conduct training courses for the staff of official laboratories designated under Article 37(1); and

(h) assist actively the Member State having designated them in the diagnosis of relevant outbreaks of foodborne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens.

The requirements provided for in point (e) of Article 37(4), Article 37(5), Article 39 and Article 42(1), points (a) and (b) of Article 42(2) and Article 42(3) of Regulation (EU) 2017/625 shall apply to national reference laboratories.

#### **4.2.4 Role and Scope of the Official Agency as a National Reference Laboratory**

The Official Agency agrees to act as the Irish National Reference Laboratory for:

- (a) Monitoring for Marine Biotoxins in Live Bivalve Molluscs.
- (b) Foodborne viruses (shellfish only)
- (c) *E. coli* (shellfish only)
- (d) Monitoring of Certain Substances and Residues thereof insofar as they apply to finfish aquaculture.

#### **4.2.5 Accreditation**

As a National Reference Laboratory, the Official Agency agrees to comply with Articles 37(4) and 37(5) of Regulation (EU) 2017/625 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."

The accreditation and assessment 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.

#### **4.2.6 Authority Support**

The Authority agrees to actively support the Official Agency acting in its NRL role. This includes the Authority supporting the provision of adequate resourcing of the Official Agency to fulfil its NRL role.

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

#### ***4.2.7 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 agrees to report to the Authority information or observations generated in the course of this work which may be relevant to food safety.

#### ***4.2.8 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.

### **Schedule 2 - Section 5 (Monitoring)**

#### **5.0 Monitoring**

The means by which the Authority monitors and communicates with the Official Agency regarding the performance of the service contract.

#### **5.1 – Liaison and Meetings**

The Official Agency agrees to nominate a person or persons to be responsible under this Service Contract for liaison with the Enforcement Policy Manager in the Authority designated as responsible for the management of this Service Contract.

The Authority agrees that the Enforcement Policy Manager designated by the Authority shall be the Official Agency’s contact point within the Authority on matters related to this Service Contract.

Any matter related to the Service Contract which becomes or is likely to become the subject of a disagreement between the Official Agency and the Authority shall in the first instance be dealt with through Official Agency’s contact point and the designated Enforcement Policy Manager. Issues may be, in the first instance be escalated as required up to the Authority’s Director of Enforcement Policy and the Official Agency’s Director – Marine Environment & Food Safety Services.

Should an issues remain unresolved following initial escalation then it may be brought to the attention of the Chief Executives of the Authority and the Official Agency for further instruction and guidance.

Liaison and review meetings shall be held according to an annual schedule developed by the Authority, in consultation with the Official Agency, and issued to the Official Agency.

The following meetings shall be held:

- Bilateral liaison meetings, between the Official Agency and the Authority, shall be held at least twice a year and more frequently as required by either party
- Trilateral liaison meetings with the Official Agency, the Authority and the Sea-Fisheries Protection Authority will be held at least twice a year to discuss areas of common interest
- Cross Agency meetings may also be arranged by the Authority to which the Official Agency will send representatives, when requested.

Additional meetings will be held as required by either party or as changing circumstances require.

## **5.2 Access**

The Official Agency agrees that it is carrying out functions under this service contract on behalf of and as an agent for the Authority. Consequently, the Official Agency agrees that the Authority shall have appropriate access to the Official Agency staff referred to in Schedule 3 through nominated persons and to all relevant records, data and sites relating to official controls and other official activities performed under this Service Contract.

The Authority agrees that the Official Agency shall have access as required through the liaison process outlined in section 7.1 of this Service Contract to records relevant to the Official Agency held by the Authority.

## **5.3 Verification**

The Official Agency agrees that the Authority may take such measures as it considers appropriate to determine compliance by the Official Agency with the requirements of this Service Contract. This will include audit activities to satisfy the requirements of Section 48(9) of the Act and in accordance with Schedule 5 of this Service Contract and the Official Agency agrees to cooperate with the Authority's audit activities.

## **5.4 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 agrees to 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.

### **Schedule 3 – Resources**

The means by which the Official Agency proposes to meet the requirements specified in this Service Contract.

#### **1.0 Introduction**

The Official Agency, as a competent authority performing official controls and other official activities shall meet the operational criteria set down in Articles 4, 5 and 6 as appropriate of Regulation (EU) 2017/625.

The Official Agency agrees to provide a sufficient number of suitably qualified and experienced staff and sufficient resources required for the 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.

#### **2.0 Staffing Resources**

The Official Agency shall detail the staffing resources to be provided annually for the purposes of this Service Contract as part of its annual report to the Authority under Section 48(8) of the Act.

## **Schedule 4 – Data and Information Collection and Reporting**

### **1.0 General requirements for data collection and reporting**

The Official Agency will collect and store electronically, information generated from food related official controls and other official activities specified in Schedule 2. Such information is to be electronically transmitted to the Authority by the Official Agency at the frequency and in the format agreed annually with the Authority (subject to the Data Protection Acts).

Additions and amendments to agreed specifications, may be agreed by the Official Agency and the Authority during the period of the contract with any such changes being noted at the subsequent Service Contract Liaison meeting. The specification for the data extract will be reviewed at each Service Contract Liaison meeting between the Authority and the Official Agency.

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.

Co-ordinated control programmes and information and data collected for the purposes of Article 112 of Regulation (EU) 2017/625 and National Surveillance Programme sampling and questionnaires shall be undertaken, completed and returned to the Authority as appropriate, in accordance with agreed protocols.

The Authority will acknowledge the source of data provided by the Official Agency in any publications.

The specific data to be provided to the Authority are as follows, unless otherwise agreed:

- 48(8) Annual report due by 31<sup>st</sup> March each year

## **2.0 Resources**

The Official Agency will provide an update on staffing resources in accordance with Schedule 3 and submit it to the Authority annually.

The Official Agency will maintain an up to date list of laboratories used for testing and analysis under the legislation listed in Schedule 1. This list should include official laboratories, National Reference Laboratories, approved laboratories (if any) and control bodies used to carry out functions under this contract. This list will be provided to the Authority annually and amended as changes arise.



## **Schedule 5 – Auditing the Service Contract**

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

### **1. Legal Basis**

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

### **2. General Requirements**

The Authority's audits will assess conformance by the Official Agency with the Service Contract including official controls and other official activities, food legislation and the relevant requirements of the Multi Annual National Control Plan for Ireland. The Authority will take cognisance in its audit programmes of internal audits performed by the Official Agency as required by Article 6 of EU Regulation 2017/625.

Audits will be conducted in accordance with the Authority's Audit Charter, documented procedures and guidance published by the EU Commission.

### **3. Audit Programmes**

The Authority shall provide details of the audits it intends to carry out on the Official Agency's official controls and other official activities through the circulation of its Audit Programmes. As part of its audit planning process the Authority will take due regard of internal audits planned by the Official Agency as detailed in Clause 1.18 of Schedule 2 of the contract.

The Authority's Audit Programmes shall be circulated at a minimum of every twelve months following the commencement of the contract.

### **4. Liaison**

Liaison for the purpose of audit shall be through a representative(s) nominated by the Official Agency. The liaison process will be the mechanism for the Authority and Official Agency to exchange information on audit programming and planning.

### **5. Access**

The Authority's audit team shall have access to Official Agency premises, personnel, documents, records or other information relevant to official controls and other official activities and/or food business operations applicable to the audit.

### **6. Corrective Action**

Where the audit generates findings in relation to official controls and/or other official activities a corrective action plan shall be developed by the Official Agency in liaison with the Authority. Findings generated in relation to noncompliance with food law will be documented as part of the audit reporting process for close out by the Official Agency. The Authority will monitor implementation of corrective action to ensure close out is adequate, appropriate and implemented in a timely manner. The Authority may, if it is deemed appropriate, verify closeout of findings through a supplementary audit.

**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 Service contract**

<b>Sch. 2 Clause</b>	<b>Clause Heading</b>	<b>Measureable outcome</b>	<b>Key Deliverable</b>
1.7	Data and Information collection and reporting	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. This data is held by MI and is available on request.
1.8	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. This data is held by MI and is available on request.
1.13	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.
1.18	Internal Audit	The Official Agency must maintain an appropriate Quality Management System	Details of the Official Agency's Internal Audit Programme
1.26	Commission Controls and Third Country Audits	The Official Agency will participate in SANTE F Missions  Mission recommendations to be closed out by the Official Agency	Participation in Missions, respond to SANTE F requests, and closeout of recommendations
3.2	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 from lab receipt for lipophilic toxins (DSP & AZP), and 4 days from lab receipt for 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.

Sch. 2 Clause	Clause Heading	Measureable outcome	Key Deliverable
3.2	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 three 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
3.3	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 from lab receipt 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
3.3	Bacterial and Viral Monitoring of Bivalve Molluscs, Norovirus	The Official Agency will 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 from lab receipt 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
3.4	Monitoring contaminants in wild and farmed fish and shellfish	The Official Agency will fulfil its obligations regarding the EU Coordinated Control Plan on Contaminants in Food insofar as it applies to the sampling and analysis of contaminants in fish and shellfish. The Official Agency will perform sampling and analysis in accordance with the relevant EU Regulations on sampling and analysis.	The official agency will report results for contaminants in fish and shellfish on an annual basis to the Authority and no later than 30 April for samples collected and analysed the previous year.
3.5	National Residue Control Plan (NRCP)	The Official Agency shall fulfil its obligations regarding National risk based Control Plan as regards pharmacologically active substances and residues thereof insofar as it applies to finfish aquaculture	Agreement on and implementation of the Annual NRCP. Annual Results Reported within 5 months of the end of the year to which it applies.

3.6	National Risk-based control plan for third-country imports	The Official Agency shall carry out testing of certain substances in seafood sampled at Border Control Posts	The Official Agency will report test results to the competent authority
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