

DATED this 1st day of March 2019

Service Contract

between

THE FOOD SAFETY AUTHORITY OF IRELAND

- and -

THE STATE LABORATORY

THIS SERVICE CONTRACT is made this 1st day of March 2019 **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, Irish Financial Services Centre, Dublin 1 and **THE STATE LABORATORY** having its principal place of business at Backweston Laboratory Campus Celbridge Co. Kildare

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;

"Official Agency" means the State Laboratory;

"Commencement Date" means the 1st March 2019;

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

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

2. The Authority is the Competent Authority responsible for the enforcement of all food legislation. The Official Agency, carrying out functions under this Service Contract, shall be acting on behalf of and as an agent for the Authority.
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 until the 28th of February 2022.
The Service Contract may be subject to review, modification or amendment, and may be extended by agreement.
4. In accordance with section 11 (2) of the Act, and in order to ensure the safety of food, the Official Agency will consider all aspects of the food production chain in so far as it relates to food safety within the meaning of the Act.
5. For the purposes of section 11 of the Act, it is agreed that the Official Agency shall carry out in its functional area on behalf of and as an agent for the Authority the following –
 - (a) the determination of compliance with food legislation by means of sampling and analysis of food, including food ingredients.

6. 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 sampling and analysis it 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.

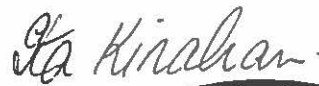
7. The Official Agency has indicated to the Authority that, for the purposes of section 48(4) of the Act, the means by which it proposes to meet the matters specified by the Authority in Schedule 2 of this Service Contract are those set out in Schedule 3 of this Service Contract. The Official Agency agrees to collect data and report to the Authority in the form set out in Schedule 4.
8. In accordance with the provisions of Official Controls Regulation (EC) No. 882/2004 and its replacement Regulation (EU) No. 2017/625, in so far as a task or function comes within Section 46 of the Act, the Official Agency may delegate a task or function to a third party subject to the agreement of the Authority.
9. 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, 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.
10. The Authority and the Official Agency agree to review and amend this contract in the event of changing circumstances.

IN WITNESS WHEREOF the Authority and the State Laboratory 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 STATE LABORATORY** was affixed hereto by
Ms. Ita Kinahan, State Chemist
a person duly authorised by the State Laboratory in that behalf:-



SCHEDULE 1

List of the food legislation contained in the First Schedule to the Act for which the Official Agency has responsibility.

Duties and responsibilities for food safety activities for the Official Agency will derive from the following list of legislation in so far as that legislation relates to Section 46 of the Act.

When the Minister for Health makes an order amending the First Schedule of the Act, or any Act passed by the Oireachtas or any statutory instrument made thereunder or regulation made under the European Communities Act, 1972, which is deemed to be food legislation for the purposes of the Food Safety Authority of Ireland Act, 1998, the new legislation may be inserted by the Authority into this Schedule.

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

A reference to a statutory instrument shall be construed as a reference to that instrument as amended, adapted, extended or replaced by any subsequent statutory instrument.

FOOD LEGISLATION	Acts and Statutory Instruments (where applicable)
1. General	
Food Safety Authority of Ireland Act 1998	<u>No. 29 of 1998</u> <u>S.I. No. 184 of 2000</u> <u>S.I. No. 580 of 2002</u> <u>S.I. No. 735 of 2003</u> <u>S.I. No. 210 of 2004</u> <u>S.I. No. 827 of 2005</u> <u>S.I. 320 of 2006</u> <u>S.I. 839 of 2007</u> <u>S.I. No. 494 of 2010</u> <u>S.I. No. 724 of 2011</u> <u>S.I. No. 346 of 2012</u> <u>S.I. No. 390 of 2014</u> <u>S.I. No. 107 of 2017</u> <u>S.I. No. 568 of 2018</u>
District Court (Food Safety) Rules 2004	<u>S.I. No. 700 of 2004</u>
2. Food Information	
EU (Provision of Food Information to Consumers) Regulations, 2014 & 2016	<u>S.I. No. 556 of 2014</u> <u>S.I. No. 389 of 2016</u> <u>S.I. No. 559 of 2016</u>
3. General Food Law	
E.C. (General Food Law) Regulations 2007 to 2013	<u>S.I. No. 747 of 2007</u> <u>S.I. No. 498 of 2010</u> <u>S.I. No. 500 of 2011</u> <u>S.I. No. 473 of 2012</u> <u>S.I. No. 383 of 2013</u>

FOOD LEGISLATION	Acts and Statutory Instruments (where applicable)
4. Official Controls Regulations	
E.C. (Official Control of Foodstuffs) Regulations 2010 and 2011	<u>S.I. No. 117 of 2010</u> <u>S.I. No. 344 of 2011</u>
Regulation (EU) 2017/625 of the European Parliament and of the Council, 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 (as amended).	<u>Regulation (EU) No. 2017/625</u>
5. Animal Remedies	
Animal Remedies Act, 1993 (Other than Section 4-5)	<u>No. 23 of 1993</u>
European Communities (Control of Animal Remedies and their Residues) Regulations, 2009 (excluding Regulations 3, 8, 9-12, 16, 20 and 26)	<u>S.I. No. 183 of 2009</u> <u>S.I. No. 263 of 2012</u>
6. Food Additives and Flavourings	
European Union (Food Additives) Regulations 2015 & 2016	<u>S.I. No. 330 of 2015</u> <u>S.I. No. 484 of 2016</u>
European Communities (Flavourings for use in foodstuffs for human consumption) Regulations, 1992	<u>S.I. No. 22 of 1992</u>
Regulation (EC) No 1334/2008 of the 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC as amended.	<u>Regulation (EC) No 1334/2008</u> <u>Regulation (EC) No 2065/2003</u>
Regulation (EC) No 2065/2003 of the 10 November 2003 on smoke flavourings used or intended for use in or on foods as amended	<u>Regulation (EC) No 627/2006</u>
Commission Regulation (EC) No 627/2006 of 21 April 2006 implementing Regulation (EC) No 2065/2003 of the European Parliament and of the Council as regards quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke product	<u>Regulation (EU) No 1321/2013</u>
Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings	
7. Food Supplements	
European Communities (Food Supplements) Regulations 2007 to 2018)	<u>S.I. No. 506 of 2007</u> <u>S.I. No. 355 of 2010</u> <u>S.I. No. 282 of 2015</u> <u>S.I. No. 225 of 2018</u>
8. Contaminants	
European Communities (Certain Contaminants in Foodstuffs) Regulations 2010 -2017	<u>S.I. No. 218 of 2010</u> <u>S.I. No. 276 of 2012</u> <u>S.I. No. 348 of 2012</u> <u>S.I. No. 380 of 2013</u> <u>S.I. No. 143 of 2014</u> <u>S.I. No. 329 of 2016</u> <u>S.I. No. 377 of 2017</u>
Commission Regulation (EU) 2017/1237 of 7 July 2017 amending Regulation (EC) No 1881/2006 as regards a maximum level of hydrocyanic acid in unprocessed whole, ground, milled, cracked, chopped apricot kernels placed	<u>Regulation (EU) No. 2017/1237</u>

FOOD LEGISLATION	Acts and Statutory Instruments (where applicable)
on the market for the final consumer	
Commission Regulation (EU) 2018/290 of 26 February 2018 amending Regulation (EC) No 1881/2006 as regards maximum levels of glycidyl fatty acid esters in vegetable oils and fats, infant formula, follow-on formula and foods for special medical purposes intended for infants and young children	<u>Regulation (EU) No. 2018/290</u>
Commission Regulation (EU) 2017/644 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin like PCBs in certain foodstuffs and repealing Regulation 589/2014.	<u>Regulation (EU) No. 2017/644</u>

SCHEDULE 2

The objectives, targets, timeframe and other matters relating to food sampling and analysis which the Authority has specified to the Official Agency

Section 1 of this schedule applies to all areas of this service contract.

1. GENERAL REQUIREMENTS

1.1 Introduction

The Official Agency will fulfil all obligations regarding food safety and authenticity (as an Official Laboratory and National Reference Laboratory) as agreed with the Authority from time to time. The Official Agency will work in partnership with the Authority and its other Official Agencies to enhance consumer protection and interests and ensure effective official controls.

Within this context the State Laboratory as an Official Agency of the Authority agrees to fulfil all obligations regarding food safety and authenticity testing, as may be agreed with the Authority.

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.

1.2 Official Controls

The Official Agency will carry out official controls on food products of non-animal origin and animal origin as appropriate to ensure compliance by food business operators with food legislation and by agreement with the Authority.

In the performance of official controls, the Official Agency shall comply with the relevant requirements of Regulation (EC) No. 882/2004 or the provisions of Regulation (EU) No. 2017/625, when in force.

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 competence and expertise of the Official Agency.

The Official Agency will work with the Authority to develop performance measures to ensure official controls are efficient, effective and are suitable to achieve the objectives of the relevant legislation.

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.

1.3 Legislation

Duties and responsibilities for food safety activities for the Official Agency will derive from the legislation listed in Schedule 1. All staff involved in food control activities shall be provided with access to this legislation or to the Legislation Section of the Authority's Website (www.fsai.ie/legislation.html).

1.4 Multi Annual National Control Plan for Ireland (MANCP).

The Official Agency shall have regard to the importance of achieving the aims of the Multi Annual National Control Plan for Ireland in accordance with Articles 41-44 of Regulation (EC) No. 882/2004 and articles 109-111 of Regulation (EU) No. 2017/625, when in force.

1.5 Participation on Working Groups

The Official Agency will participate as agreed in Food Safety Authority of Ireland, inter-agency or expert working groups, or committees to: -

- Produce Guidance Notes and Codes of Practice.
- Evaluate implications of existing and proposed legislation.
- Evaluate relevant food safety/scientific information.
- Participate in the Food Fraud Task Force (or subgroup).
- Participate in a working group on official control data.
- Produce other outputs as required.

The Authority and the Official Agency will establish objectives, terms of reference and timeframes for each working group.

1.6 Service Plan/Service Level Agreement

The Official Agency will prepare and send a Service Plan/Service Level Agreement (SLA) to the Authority from the relevant Official Agency Divisions by the end of the first quarter of each calendar year. The SLA will include details of official control testing, analysis and NRL activities to be carried out, to ensure delivery of service contract requirements, and compliance with the relevant legislation.

The content of the SLA will be reviewed by the Authority and the Official Agency at liaison meetings.

Note: Where SLAs are already in place between the Official Agency and the Department of Agriculture, Food and the Marine for residues analysis under the national residues monitoring programme, the provisions of clause 3.1 of Schedule 2 will apply.

1.7 Data collection and reporting

The Official Agency by agreement will collect data regarding activities carried out under this contract and share subject to the Data Protection Acts with the Authority as necessary. The Official Agency will provide reports and other information on official controls and enforcement activities under this contract to the Authority in the format and frequency agreed with the Authority annually, and in accordance with Schedule 4 of the Contract and the Multi Annual National Control Plan reporting requirements.

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

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's database in a format and at a frequency to be agreed annually with the Authority.

For all other areas of the Official Agency's food safety activities the Official Agency will aim to develop, in collaboration with the Authority, a computerised system, subject to resources. The Official Agency agrees to work with the Authority to progress within the period of this contract development in the following areas:

- Agree a standardised format for data transfer between the Official Agency laboratory IT systems and the FSAI national all-official agency systems in line with national & EU data standards.
- The revision of the National Sample Submission Form and its electronic capture.
- The standardisation of recording in LIMS of sub-contracted samples.
- The classification and description of samples taken by the Official Agency or analysed by them according to the FOODEX2 and overall SSD2 system.

The Official Agency will advise the Authority on its progress in meeting the aims of this Clause.

Note: Where data is generated under the national residue monitoring programme, results will continue to be provided to the Department of Agriculture, Food and the Marine in the required SSD2 format as per clause 3.1 of Schedule 2.

1.9 Continuing Professional Development

The Official Agency shall provide appropriate training for staff performing official controls enabling them to undertake their duties competently and to carry out official controls in a consistent manner, as per legislative requirements.

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

1.10 Out of Hours Emergency Service

The Official Agency shall provide official control services between 09:00 – 17:00 (Monday to Friday).

The Official Agency will also provide an emergency contact point outside of normal working hours to deal effectively with any emergency or crisis situations and including significant food safety incidents (as defined in the Authority's Code of Practice No. 5, and collectively referred to hereafter as "incidents").

Official control services outside of normal working hours will be agreed with the Official Agency and can be discussed at liaison meetings.

1.11 Contingency Planning

The Official Agency, in conjunction with the Authority, will ensure that there are contingency plans in place at appropriate levels for dealing with crises and incidents.

1.12 Rapid Alert System for Food and Feed.

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

1.13 Investigation of Food Incidents

The Official Agency shall co-operate with the Authority, other Official Agencies and / or the Outbreak Control Team in the investigation of incidents, and provide such information as requested by the Authority for the management of incidents, in a timely manner, and these can be reviewed at liaison meetings with the Authority.

1.14 Authenticity Surveillance, Intentional Violations of Food, and Integrity of the food supply chain

The Official Agency and the Authority will on an ongoing basis, and as required, agree a programme of proactive and reactive work relating to authenticity surveillance of food products and the agri-food chain.

These official controls can be used to verify:

- fair practices,
- the protection of consumer interests and information,
- the identification of intentional violations of food potentially perpetrated through fraudulent or deceptive practices,
- Appropriate safeguards to the safety and integrity of the food supply chain.

These activities will be carried out as may be required and by agreement with the Authority, insofar as they relate to the legislation in Schedule I, and in line with agreed procedures.

Official controls can also take into account of:

- The use of products, processes, materials or substances that may influence food safety, integrity and wholesomeness, of food.
- Any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of food.

1.15 Complaints regarding the implementation of this Service Contract

The Official Agency shall provide information to the Authority on complaints regarding the implementation of this Service Contract. The Official Agency shall cooperate with the Authority in any investigation regarding these complaints.

1.16 Boundaries of the service

The Official Agency contracts for provision of services within its administrative area. Where requested by the Authority, assistance may be provided to another Official Agency.

1.17 Food Complaints

Where the Official Agency is requested to provide analysis as part of the investigation of food complaints these shall be managed in a timely fashion and these can be reviewed at liaison meetings with the Authority.

1.18 Missions from the European Commission and/or other External Audits of Official Controls

The Authority and the Official Agency will cooperate with regard to Missions from the European Commission that are relevant to this service contract.

1.19 Food Law Enforcement Policy

The Official Agency will have due regard to the FSAI's enforcement policy.

The Official Agency agrees to support enforcement activities carried out by FSAI or other official agencies and may be requested to provide expert testimony or advice as may be required on a case by case basis.

1.20 EU Official Control Activities

The Official Agency shall carry out control activities having regard to the EU Coordinated Control Plans and European Food Safety Authority co-ordinated studies, as agreed with the Authority.

1.21 Administrative assistance and co-operation

The Official Agency shall agree with the Authority the procedures for administrative assistance and co-operation required under Articles 36-40 of Regulation (EC) No 882/2004 (or the provisions of Article 102-108 of Regulation (EU) No. 2017/625, when in force) 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 of Regulation (EC) No. 882/2004, (or under Article 106 of Regulation (EU) No. 2017/625, when in force) where a risk to human health or a serious infringement of food law is identified, shall be notified to the Authority in a timely manner.

1.22 Additional Activities

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

2.0 FOOD SAFETY, AUTHENTICITY AND NATIONAL REFERENCE LABORATORY SERVICES, SAMPLING AND ANALYSIS

2.1 Introduction

The food safety, authenticity and National Reference Laboratory services provided by the Official Agency, are listed in Schedule 3.

Additional official control laboratory or National Reference Laboratory capability, capacity and expertise may be developed over the term of the service contract in response to new legislation or new areas in relation to food control and authenticity testing and analysis as appropriate, and by agreement with the Authority.

Food control services outside of normal working hours will be provided by the Official Agency by agreement and within resources to deal effectively with outbreaks and food incidents.

2.2 Scope of the National Reference Laboratory Activities

Members States are required to designate National Reference Laboratories in accordance with the requirements of article 100 of Regulation (EU) 2017/625.

The Minister for Health and the Minister for Agriculture, Food and the Marine designate laboratories in Ireland as National Reference Laboratories.

The Official Agency has been designated as a National Reference Laboratory for:

- (a) Monitoring for Residues in food of animal origin
- (b) Monitoring for Persistent Organic Pollutants (POPs) in Food, including brominated, fluorinated and chlorinated POPs, Dioxins and PCBs

Additional NRL areas and activities may be developed over the duration of this service contract, as appropriate and by agreement with the Authority.

2.3 Scope of the Official Laboratory Activities

The Official Agency shall function as an 'Official laboratory' as defined in Regulation (EC) No. 882/2004 and as per procedures agreed with the Authority. Official control laboratories shall comply with the relevant requirements of Regulation (EU) 2017/625, when in force.

The Official Agency shall co-operate with the relevant National Reference Laboratories for food testing in Ireland in the discharge of their functions under and as per agreed protocols with the Authority.

Additional official control methodologies and analytical capability may be developed over the duration of this service contract, as appropriate and by agreement with the Authority.

2.4 Sampling and analysis

The Official Agency, in consultation with the Authority, will prepare annual control programmes for each of the laboratory control areas.

The Official Agency shall agree annual national chemical testing plans with the Authority in the final quarter preceding the year to which they apply. The annual chemical testing plans will include analysis to determine compliance with food legislation.

Note: For testing carried out under the national residue monitoring programme, testing plans will continue to be agreed with the Department of Agriculture, Food and the Marine as per clause 3.1 of Schedule 2.

Over the course of the service contract the Official Agency agrees to explore possibilities to develop capacity for sampling e.g. for surveys and similar chemical testing requests. The majority of sampling is however likely to come from other Official Agencies and/or FSAI.

Where samples are taken under this contract, the Official Agency shall ensure that these samples are taken as part of official controls and are sampled and analysed in accordance with legislative requirements.

2.5 Accreditation

The Official Agency will maintain accreditation to ISO/IEC 17025 for relevant test methods, which are currently included in its scope of accreditation and used for official controls in its National Reference Laboratories and official laboratories.

The Official Agency will keep the scope of accreditation under review and will work towards ensuring that core methods are accredited, and that the scope is expanded, as resources permit, in line with the requirements of Article 11 (2) and (3) of Regulation (EC) No. 882/2004, or the requirements of article 34 of Regulation (EU) 2017/625, when in force.

The Official Agency will seek accreditation to ISO/IEC 17025 for test methods used for official controls, which are not currently included in its scope of accreditation, in all cases where accreditation is deemed necessary.

The Official Agency will consider the views of the Authority regarding the scope of accreditation, in so far as it relates to activities in this Contract. Changes to the scope of accreditation will be discussed at liaison meetings.

Where the Official Agency uses a method for official controls for which accreditation has not yet been obtained, the method must be included in the laboratory quality assurance system to ensure sound and reliable results from the use of the method for official control purposes.

In accordance with ISO/IEC 17025, the Official Agency will include, within its review procedures, reference to the current service contract with FSAI.

2.6 Turnaround Times

The Official Agency will ensure that turnaround times for samples taken as part of official controls allow efficient follow up of non-compliant samples. Turnaround times for routine analyses will be reviewed at liaison meetings.

2.7 Laboratory methods

Laboratories shall use methods that comply with Article 11 of Regulation (EC) No. 882/2004 or the requirements of article 34 of Regulation (EU) 2017/625, when in force.

2.8 Subcontracted testing

The Official Agency will ensure that external laboratories used for the analysis of official control samples are in compliance with relevant legislative requirements, including accreditation of test methods to ISO/IEC 17025. The official agency will inform FSAI of any proposed outsourcing or subcontracting of testing for the purpose of this contract which will be subject to agreement with FSAI.

2.9 Duties of the Official Agency as a National Reference Laboratory

1. Duties arise from Article 101 of Regulation (EU) 2017/625

- (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 designated official laboratories 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 and of coordinated control programmes;
- (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.

2. The Official Agency as an NRL, agrees to fulfil the requirements of Art. 100.3 of Reg. (EU) No. 2017/625:

- (a) be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as national reference laboratories;
- (b) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;
- (c) possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;
- (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;
- (e) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and
- (f) where relevant, be equipped to comply with relevant biosecurity standards.

2.10 Authority Support

The Authority will actively support the Official Agency in its various National Reference Laboratory roles.

3.0 CHEMICAL ANALYSIS

Requests for developing chemical methods, sampling, analysis and reporting under this service contract will be discussed at liaison meetings between the Official Agency and the Authority. A plan for chemical testing will be developed in consultation with Official Agency for each year to include:

- The development and validation of analytical methods
- Analysis of samples
- Participation in surveys agreed with FSAI
- Additional testing as may be agreed from time to time

The parameters will be agreed from the categories of substances described in this section.

3.1 Residues Analysis

In accordance with Council Directive 96/23/EC (and replacement delegated and implementing acts in accordance with article 19 of Regulation (EU) 2017/625), when in force, the Official Agency shall fulfil all obligations regarding the national residues monitoring programme in accordance with the annual national residue control plan (NRCP) for Ireland.

The Official Agency agrees to continue to provide results of residue monitoring to the Department of Agriculture, Food and the Marine as per the SLAs already agreed.

The range of parameters currently tested for are outlined in Table 1, Schedule 3 of the service contract. Additional parameters may be requested by DAFM as appropriate, following the annual review of the NRCP by the European Commission, EURLs, DAFM, and the Authority.

3.2 Analysis of Halogenated Persistent Organic Pollutants (POPs)

3.2.1 Polychlorinated Dibenzodioxins (PCDDS), Polychlorinated Dibenzo furans (PCDFS) and Polychlorinated Biphenyls (PCBS)

The Official Agency agrees to develop and provide analytical testing over the course of the service contract and as agreed with the Authority, as part of the national dioxin monitoring programme, in accordance with Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs (as amended).

This includes:

- The use of analytical methods in accordance with Commission Regulation (EU) 2017/644 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin like PCBs in certain foodstuffs and repealing Regulation 589/2014.
- Analysis of samples submitted as part of the annual national dioxin monitoring programme.
- Monitoring in accordance with Commission Recommendations and additional testing, as may be agreed from time to time subject to resources. This includes Commission Recommendation 2013/711/EU on the reduction of the presence of dioxins, furans and PCBs in feed and food, and Commission Recommendation 2006/794/EC on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin like PCBs in foodstuffs.
- Participation in Dioxin and PCB surveys agreed with FSAI.

3.2.2 Persistent organic pollutants

The Official Agency agrees to develop and provide analytical testing over the course of the service contract as part of the implementation of a national monitoring programme, of traces of the following substances in food and as agreed with the Authority, subject to resources.

- brominated flame retardants including Polybrominated diphenyl ethers in food in accordance with Commission Recommendation (2014/118/EU)
- perfluoralkylated substances (PFAS)
- other halogenated persistent organic pollutants, (i.e. not already covered above), in order to meet the requirements of Commission Regulation (EU) 2018/192

3.3. Food Supplements

The Official Agency may be requested to develop methods for the additional analysis of food supplements for the detection of unauthorised substances or substances likely to cause adverse health effects over the term of the current service contract and as agreed with the Authority. These include the detection and analysis of the following substances:

- Anabolic androgenic steroids (AAS)

- Selective androgen receptor modulators (SARMs)
- Other anabolic agents marketed as SARMs
- Products containing Anabolic Agents and Stimulants
- Stimulants (These could include psychoactive substances, such as amphetamines and its derivatives, as well as other substances including cocaine, caffeine and nicotine. For dietary supplements, some stimulants of concern include; ephedrine, pseudoephedrine, phenylpropanolamine, norephedrine, synephrine, 1,3-Dimethylamylamine (1,3-DMAA), 1,3-Dimethylbutylamine (1,3-DMBA) and 1,5-Dimethylhexylamine (1,5-DMHA)).
- Alpha Lipoic Acid
- Yohimbe (Pausinystalia Yohimbe (K. Schum) Pierre ex Beille)
- Synephrine and Caffeine Combination
- Hydroxyanthracene Derivatives

3.4 Botanical weight loss supplements

The Official Agency may be requested to develop and provide analysis of Botanical weight loss supplements for the presence of the following substances Sibutramine, Phenolphthalein, Sildenafil, Tadalafil, Fluoxetine, Orlistat and Lorcaserine. Additional testing requirements may be added by agreement with the Authority and the Official Agency.

3.5 Monitoring of Hemp products and Cannabidiol

Tetrahydrocannabinol (THC)

The Official Agency may be requested to develop and provide methods of analysis for the monitoring of THC, its precursors and other cannabinoids in food of animal origin, hemp derived foods and foods containing hemp or hemp derived ingredients including cannabis oil type products.

Development of these methods and analysis would be over the term of the current service contract as agreed with the Authority.

3.6 Spirits and Counterfeit alcohol

The Official Agency has already developed methods covering the following specific areas and products. The Official Agency may be requested to develop and provide analysis of spirit drinks as agreed with the Authority.

Spirits-adulteration, dilution, counterfeit, methanol, industrial alcohol.

Parameters to test include:

- Alcohol content
- Methanol
- Denaturants e.g. 2-Propanol, Propan-1-ol, 2-Methylpropan-1-ol, 3-methyl-1-butanol, 2-(2-Hydroxyethoxy) ethan-1-ol, 2-Methyl-1-butanol, 3-methyl-1-butanol, Ethyl Acetate, Propan-2-one, Ethane-1,2-diol...etc.
- Aldehydes
- Sugar marker – in Vodka only
- Conductivity

3.7 Organic Foods

The Official Agency may be requested to develop and provide methods of analysis for the testing of Organic Foods for the presence/level of residues of veterinary medicines, as agreed with the Authority.

The Official Agency may be requested to fulfil an NRL role over the designated Organic Official Control Laboratories testing Organic Foods for the presence/level of residues of veterinary medicines, as agreed with the Authority.

3.8 Flavourings

The Official Agency may be requested to develop methods and provide analysis of flavourings over the course of the service contract and as agreed with the Authority. These are outlined below.

- **Annex III substances:**
e.g. (1-allyl-4-methoxybenzene (estragole), hydrocyanic acid, menthofuran, 4-allyl-1,2-dimethoxybenzene (methyleugenol), pulegone, quassin, 1-allyl-3,4-methylene dioxy benzene (safrole), teucrin A, and thujone (alpha and beta).
- **Smoke flavourings:**

There are ten primary products and derived products thereof. These are listed in Regulation (EU) No 1321/2013 which established the European Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings.

- **Annex I flavourings with restrictions of use:**
e.g. rebaudioide A, glyzhirizic acid (and its ammoniated salt), ammonium chloride, caffeine, quinine and its several salts, theobromine, neohesperidin dihydrochalcone, p-Mentha-1,8-dien-7-ol, Myrtenol, Deca-2,4-dien-1-ol, Hepta-2,4-dien-1-ol , Hexa-2,4-dien-1-ol, Nona-2,4-dien-1-ol, Hexa-2(trans),4(trans)- dienal, Trideca- 2(trans),4(cis),7(cis)-trienal and others.
- **Flavouring substances in Annex I with no restrictions of use**
- **Flavouring preparations and other ingredients not subject to premarketing authorisation**

3.9 Food Additives

The Official Agency may be requested to develop and provide analysis of food additives over the course of the service contract as agreed with the Authority.

3.9.1 Analysis of colours, sweeteners, antioxidants, preservatives, emulsifiers etc.

The Official Agency may be requested to develop capability and methodologies for testing of some of these additives e.g. natural colours, in order to meet the requirements of Commission Regulation (EC) 1333/2008, as may be agreed with the Authority.

3.9.2 Analysis of biocides, (e.g. chlorate)

The Official Agency may be requested to develop methods and provide analysis of these substances over the course of the service contract and as agreed with the Authority.

3.9.3 Allergen Testing

The Official Agency may be requested to develop methods for analysis of these substances over the course of the service contract and as agreed with the Authority.

3.9.4 Additional Considerations

Considerations could include determination of geographic origin, DNA analysis (meat), stable isotope and elemental analysis of foods, alcohol congener analysis (e.g. detection of industrial alcohols used in spirit manufacture), HTMS, FTIR, etc. Methodologies could also be developed to detect the use of animal by-products in the food chain.

The Official Agency may be requested to develop and provide chemical testing in these areas over the course of the service contract and as agreed with the Authority.

4.0 MONITORING

4.1 Liaison

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

The Official Agency shall nominate a person or persons to liaise with the Enforcement Policy Manager in the Food Safety Authority of Ireland.

4.2 Access

The Official Agency carrying out functions under this service contract shall be acting on behalf of and as an agent for the Authority and will provide the Authority with access as required through the liaison link to the staff referred to in Schedule 3 and to all records, data and sites relevant to food safety duties. The Authority will provide Officers of the Official Agency access as required through the liaison link to records relevant to the Official Agency.

4.3 Review

The Authority will review the delivery of this Service Contract and provide feedback to the Official Agency.

The Official Agency will provide the Authority at quarterly intervals with updates on close out actions taken in response to findings of:

- The Authority's audits
- European Commission (SANTÉ F) and other external audits

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

4.4 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 details of any external audits of its service covered by the service contract.

SCHEDULE 3

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

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

Staffing Resource

(a) List of all staff involved for the purposes of this contract.

(b) List of Liaison Officer(s):-

The Official Agency will also submit to the Authority within the first quarter of each year, in the format outlined in the 48(8) Annual Report the personnel resources it proposes to deploy in the performance of the Service Contract

Table 1: National Reference Laboratory Services provided by the Official Agency

Matrix/parameter	Name / Address of NRL
<p>Residues in food of animal origin:</p> <p><u>Group A:</u></p> <p>A 1 Stilbenes; A 3 Steroids; A 4 Resorcylic acid lactones including Zeranol</p> <p>A 6 Compounds included in Annex IV Council Reg. 2377/90 [Nitromidazoles, Chlorpromazine only]</p> <p><u>Group B:</u></p> <p>B 2 (d) Sedatives B 2 (e) Non-steroidal Anti-inflammatory Drugs (NSAIDs) B 2 (f) Other Pharmacologically active substances [corticosteroids only]; B3 (d) Mycotoxins</p>	<p>The State Laboratory Backweston Campus Celbridge Co. Kildare Ireland</p>
<p>Persistent Organic Pollutants (POPs) in Food</p>	

Table 2: Official Control Laboratory Services provided by the State Laboratory

Matrix/parameter	Name / Address of NRL
<p>Official Control Laboratory Service may be expanded over the course of the service contract by agreement with the FSAI.</p>	

SCHEDULE 4

Data Collection and Reporting

1. General Requirements for data collection and reporting

The Official Agency shall collect and store information generated from activities specified in Schedule 2. The data collected is to be maintained and all records are to be kept up to date.

An agreed dataset is to be electronically transferred to the Authority in an agreed format and via an agreed mechanism. The Official Agency and the Authority will jointly develop a project to implement this arrangement.

The frequency of electronic transfer will be agreed with the Authority.

The format and content of the forms developed for this Schedule shall be developed and agreed with the Authority annually until the agreed dataset is transmitted electronically.

2. Resources

The Official Agency shall maintain a current electronic list of Liaison Officers for the purpose of the service contract. The list shall include names, contact addresses, telephone numbers and email addresses for all Liaison Officers.

The Schedule 3 list shall be updated as changes arise and submitted to the Authority bi-annually.

3. Activities undertaken outside of returns outlined at 1.0 in Schedule 2

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

- a) Participation on Food Safety Authority of Ireland, interagency and expert working groups and committees, and any other similar activity.
- b) Continuing Professional Development undertaken by staff (as set out in paragraph 1.9 of Schedule 2).
- c) Other food safety and authenticity activities as agreed.

SCHEDULE 5

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's audits will verify conformance by the Official Agency with the Service Contract including the food legislation and the relevant requirements of the Multi Annual National Control Plan for Ireland. The Authority will take cognisance of the work performed by the Official Agency Internal Audit Units in its audit programme.

Audits will be conducted in accordance with the Authority's Audit Charter and documented procedures.

3. Audit Programmes

The Authority shall provide details of the audits it intends to carry out on the Official Agency's activities through the circulation of its Audit Programmes. 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.

5. Access

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

6. Corrective Action

Where audit findings indicate deficiencies in the controls, a corrective action plan shall be developed by the Official Agency in liaison with the Authority.

The Authority will monitor implementation of the plan to ensure corrective action 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.