Dated this 1st day of March 2021

Service Contract Between

The Food Safety Authority of Ireland

and

The Health Service Executive

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This Service Contract is made this 1st day of March 2021 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 **HEALTH SERVICE EXECUTIVE** having its principal place of business at Oak House, Millennium Park, Naas, W91 KDC2, Co. Kildare (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 1st day of March 2021;
"Food Legislation" means the Food Legislation set out in Schedule 1 of this Service Contract;
"Official Agency" means the **HEALTH SERVICE EXECUTIVE**
"Establishment" means any unit of a food business;
"Operator" means any natural or legal person subject to one or more of the obligations provided for in food legislation, including a food business operator.

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.

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 1st day of March 2026. The Service Contract may be subject to review, modification, or amendment, and may be extended by agreement.

4. For the purposes of Section 11(2) of the Act, it is agreed that the Official Agency shall carry out in its functional area on behalf of and as an agent for the Authority the following:

(a) The determination of compliance with food legislation by means of:

(i) The inspection, approval, licensing and/or registration of premises and equipment, including premises or equipment used in connection with the manufacture, processing, disposal, transport, and storage of food,

(ii) The inspection, sampling and analysis of food including food ingredients, and

(iii) The inspection and analysis of food labelling,

(b) The provision of food safety and food hygiene education to producers, manufacturers, distributors, retailers, and caterers.

So as to ensure that food produced in the State (whether or not distributed or marketed in the State) and food distributed or marketed in the State complies with any relevant food legislation.

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) 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) Other matters which the Authority considers necessary.

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

6. The Official Agency has indicated to the Authority that, for the purposes of section 48(4) of the Act, the means by which it proposes to meet the matters specified by the Authority in Schedule 2 of this Service Contract are those set out in Schedule 3 of this Service Contract. 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 and food inspections to be undertaken on behalf of the Authority shall be directed towards bringing about a general acceptance amongst producers, manufacturers, distributors, retailers and caterers of the principle that, in respect of any food placed on the market, the primary responsibility for the safety and suitability of the food for human consumption is borne by them individually or, as appropriate, collectively and as a consequence, each of the persons mentioned shall take all reasonable steps to ensure, in so far as that person is concerned, the safety and hygienic standard of that food.

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

PRESENT when the Official Seal of

THE FOOD SAFETY AUTHORITY OF IRELAND
was affixed hereto: -

Dr Pamela Byrne, Chief Executive Officer

PRESENT when the Official Seal of

THE HEALTH SERVICE EXECUTIVE
was affixed hereto: -

Mr. Paul Reid, Chief Executive Officer

Schedule 1

List of the Food Legislation contained in the First Schedule to the Act for which the Official Agency has responsibility.
The Schedule 1 has been updated to incorporate new Food Legislation, as of November 2023.

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 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. The implications of new legislation for the Official Agency will be considered and enforcement priorities recommended by the Service Contract Committee on Food Legislation. Enforcement priorities will be agreed in the annual work plans and through the management liaison process following revision of this Schedule. In this context, both parties to the Service Contract accept that any increase in workload for the Official Agency will require the provision of adequate resources.

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

The legislation is listed overleaf:

FOOD LEGISLATION ** See EC legislation which has direct effect in Member States below*	**Acts and Statutory Instruments**
1. General	
Food Safety Authority of Ireland Act 1998	Act No. 29 of 1998 S.I. No. 184 of 2000 S.I. No. 580 of 2002 S.I. No. 735 of 2003 S.I. No. 210 of 2004 S.I No. 827 of 2005 S.I. No. 320 of 2006 S.I. No. 839 of 2007 S.I. No. 494 of 2010 S.I. No. 724 of 2011 S.I. No. 346 of 2012 S.I. No. 390 of 2014 S.I. No. 107 of 2017 S.I. No. 568 of 2018 S.I. No. 173 of 2020 S.I. No. 152 of 2021 S.I. No. 543 of 2021 S.I. No. 310/2022
2. General Food Hygiene	
Health Act 1947	Act No. 28 of 1947
Food Hygiene Regulations 1950 to 1989	S.I. No. 205 of 1950 S.I. No. 270 of 1951 S.I. No. 289 of 1952 S.I. No. 24 of 1961 S.I. No. 32 of 1971 S.I. No. 21 of 1986 S.I. No. 62 of 1989
Food Hygiene (Revocation of certain provisions) Regulations 2017 *Note: Regulations 9, 10, 11, 25 paragraphs 21 and 22, 26B, 26C, 26D and Part IV of S.I. 205 of 1950 have been revoked*	S.I. No. 528 of 2017
3. Hygiene Package	
E.C. (General Food Law) Regulations 2007 to 2013	S.I. No. 747 of 2007 S.I. No. 498 of 2010 S.I. No. 500 of 2011 S.I. No. 473 of 2012 S.I. No. 383 of 2013
E.U. (Official Controls in Relation to Food Legislation) Regulations 2020	S.I. No. 79 of 2020

E.C. (Hygiene of Foodstuffs) Regulations 2006 to 2020	S.I. No. 369 of 2006 S.I. No. 380 of 2009 S.I. No. 497 of 2010 S.I. No. 453 of 2014 S.I. No. 82 of 2018 S.I. No. 47 of 2020
E.U. (Food and Feed Hygiene) Regulations 2020	S.I. No. 22 of 2020 S.I. No. 660 of 2020
Health (Definition of Marginal, Localised and Restricted Activity) (Butcher Shop) Regulations 2010	S.I. No. 340 of 2010
Health (Definition of Marginal, Localised and Restricted Activity) (Retail Catering Establishments) Regulations 2012	S.I. No. 168 of 2012
4. Microbiological Criteria	
E.U. (Microbiological Criteria for Foodstuffs) Regulations 2012 to 2020 *Note: For approved food business operators S.I. No. 22 of 2020 is the relevant legislation for microbiological criteria*	S.I. No. 474 of 2012 S.I. No. 301 of 2013 S.I. No. 15 of 2014 S.I. No. 425 of 2020
5. Import Controls, Temporary Increased Controls and Emergency Measures	
EU (Official Controls in relation to Food Legislation) (Imports of Food of Non-Animal Origin) Regulations 2020	S.I. No. 575 of 2020
E.U. (Emergency Measures Regarding Unauthorised Genetically Modified Rice in Rice Products for Food Use Originating in or Consigned from China) Regulations 2015	S.I. No. 138 of 2015
European Union (Imports of Animals and Animal Products from Third Countries) Regulations 2020	S.I. No. 656 of 2020
European Communities (Plastics and other materials) (Contact with food) Regulations 2017	S.I. No. 49 of 2017
Designation Under Regulation 17 of the European Union (Official Controls in Relation to Food Legislation) Regulations 2020	S.I. No. 79 of 2020 S.I. No. 329 of 2022 S.I. No. 586 of 2022
European Union (Organic Farming) Regulations 2022	S.I. No. 494 of 2022

Commission Delegated Regulation (EU) 2020/2190 of 29 October 2020 amending Delegated Regulation (EU) 2019/2124 as regards official controls at the border control post where goods leave the Union and certain provisions on transit and transshipment.	Commission Delegated Regulation (EU) 2020/2190
Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products, and products of animal origin.	Commission Delegated Regulation (EU) 2020/692
Commission Delegated Regulation (EU) 2021/573 of 1 February 2021 amending Delegated Regulation (EU) 2019/625 as regards import conditions for live snails, for composite products and for casings placed on the market for human consumption.	Commission Delegated Regulation (EU) 2021/573
Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC.	Commission Delegated Regulation (EU) 2021/630
Commission Implementing Regulation (EU) 2021/632 of 13 April 2021 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Commission Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC.	Commission Implementing Regulation (EU) 2021/632
Commission Delegated Regulation (EU) 2021/1934 of 30 July 2021 amending Delegated Regulation (EU) 2015/2446 as regards certain provisions relating to the origin of goods.	Commission Delegated Regulation (EU) 2021/1934
Commission Implementing Regulation (EU) 2021/2246 of 15 December 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No. 178/2002 of the European Parliament and of the Council.	Commission Implementing Regulation (EU) 2021/2246
Commission Implementing Regulation (EU) 2021/1533 of 17 September 2021 imposing special conditions governing the import of feed and food originating in or dispatched from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) 2016/6.	Commission Implementing Regulation (EU) 2021/1533

Commission Implementing Regulation (EU) 2020/1158 of 5 August 2020 on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station.	Commission Implementing Regulation (EU) 2020/1158
Commission Delegated Regulation (EU) 2020/1275 of 6 July 2020 amending Delegated Regulation (EU) 2020/592 on temporary exceptional measures derogating from certain provisions of Regulation (EU) No. 1308/2013 of the European Parliament and of the Council to address the market disturbance in the fruit and vegetables and wine sectors caused by the COVID-19 pandemic and measures linked to it.	Commission Delegated Regulation (EU) 2020/1275
Commission Delegated Regulation (EU) 2020/592 of 30 April 2020 on temporary exceptional measures derogating from certain provisions of Regulation (EU) No. 1308/2013 of the European Parliament and of the Council to address the market disturbance in the fruit and vegetables and wine sectors caused by the COVID-19 pandemic and measures linked to it.	Commission Delegated Regulation (EU) 2020/592
Commission Implementing Regulation (EU) 2020/600 of 30 April 2020 derogating from Implementing Regulation (EU) 2017/892, Implementing Regulation (EU) 2016/1150, Implementing Regulation (EU) No. 615/2014, Implementing Regulation (EU) 2015/1368 and Implementing Regulation (EU) 2017/39 as regards certain measures to address the crisis caused by the COVID-19 pandemic.	Commission Implementing Regulation (EU) 2020/600
Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No. 599/2004, Implementing Regulations (EU) No. 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC.	Commission Implementing Regulation (EU) 2020/2235
Commission Implementing Regulation (EU) 2015/949 of 19 June 2015 approving the pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins	Commission Implementing Regulation (EU) No 2015/949
Commission Implementing Regulation (EU) 2017/1269 of 13 July 2017 amending Implementing Regulation (EU) 2015/949 as regards withdrawal of groundnuts (peanuts) from the United States of America from the list of approved pre-export checks as regards aflatoxins	Commission Implementing Regulation (EU) 2017/1269

Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council.	Commission Implementing Regulation (EU) 2021/405
Commission Implementing Regulation (EU) 2020/1641 of 5 November 2020 regarding imports of live, chilled, frozen, or processed bivalve molluscs, echinoderms, tunicates, and marine gastropods for human consumption from the United States of America.	Commission Implementing Regulation (EU) 2020/1641
Commission Implementing Regulation (EU) 2021/645 of 15 April 2021 amending Annex I to Regulation (EU) No. 605/2010 as regards the list of third countries or parts thereof from which the introduction into the European Union of consignments of raw milk, dairy products, colostrum, and colostrum-based products is authorised.	Commission Implementing Regulation (EU) 2021/645.
Commission Delegated Regulation (EU) 2020/2192 of 7 December 2020 amending Annex II to Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards the identification mark to be used for certain products of animal origin in the United Kingdom in respect of Northern Ireland.	Commission Delegated Regulation (EU) 2020/2192
Commission Implementing Regulation (EU) 2020/1667 of 10 November 2020 amending Implementing Regulation (EU) 2020/977 as regards the period of application of the temporary measures in relation to controls on the production of organic products.	Commission Implementing Regulation (EU) 2020/1667
6. Specified Risk Material (SRM)	
E.U. (Transmissible Spongiform Encephalopathies) Regulations 2015 to 2018	S.I. No. 532 of 2015 S.I. No. 156 of 2018
7. Food Information	
E.U. (Provision of Food Information to Consumers) Regulations 2014 -2021	S.I. No. 556 of 2014 S.I. No. 389 of 2016 S.I. No. 559 of 2016 S.I. No. 542 of 2021
Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations 2014	S.I. No. 489 of 2014
E.U. (Nutrition and Health Claims made on Foods)	S.I. No. 11 of 2014

Regulations 2014-2021	S.I. No. 458 of 2015 S.I. No. 154 of 2017 S.I. No. 176 of 2018 S.I. No. 243 of 2021
E.C. (Identification of Foodstuff Lot) Regulations 1992	S.I. No. 110 of 1992
8. Meat and Fish Labelling	
E.C. (Labelling of Beef and Beef Products) Regulations 2000 to 2015	S.I. No. 435 of 2000 S.I. No. 485 of 2002 S.I. No. 404 of 2015
Health (Country of Origin of Beef) Regulations 2006 to 2007	S.I. No. 307 of 2006 S.I. No. 85 of 2007
E.C. (Marketing of meat of bovine animals aged 12 months or less) Regulations 2008	S.I. No. 245 of 2008
E.C. (Origin Labelling of Meat) Regulations 2015	S.I. No. 113 of 2015
E.U. (Labelling of Fishery and Aquaculture Products) Regulations 2016	S.I. No. 121 of 2016
9. Olive Oil Labelling	
E.C. (Marketing Standards) (Crops and oils) Regulations 2011	S.I. No. 378 of 2011
10. Alcohol labelling	
Irish Whiskey Act, 1980	Act No. 33 of 1980
E.C. (Definition, Description and Presentation of Aromatised Wines, Aromatised Wine – based drinks and Aromatised Wine – product Cocktails) Regulations 1998	S.I. No. 254 of 1998
E.U. (Spirit Drinks) Regulations 2015	S.I. No. 316 of 2015 S.I. No. 468 of 2015
E.C. (Labelling, Presentation and Marketing of Wines) Regulations 2010	S.I. No. 507 of 2010
11. Miscellaneous Product Labelling	

E.C (Marketing of Fruit Jams, Jellies, Marmalades and Sweetened Chestnut Puree) Regulations 2003	S.I. No. 294 of 2003
E.C. (Marketing of Coffee Extracts and Chicory Extracts) Regulations, 2000	S.I. No. 281 of 2000
European Union (Marketing of fruit juices and certain similar products) Regulations 2013	S.I. No. 410 of 2013
E.C. (Marketing of Cocoa and Chocolate Products) Regulations 2003	S.I. No. 236 of 2003
E.C. (Marketing of Honey) Regulations 2003 and 2015	S.I. No. 367 of 2003 S.I. No. 261 of 2015
E.C. (Marketing of Sugar Products) Regulations 2003	S.I. No. 289 of 2003
E.C. (Dehydrated Preserved Milk) Regulations 2003 and 2008	S.I. No. 298 of 2003 S.I. No. 124 of 2008
12. Zoonoses	
E.C. (Monitoring of Zoonoses) Regulations 2004	S.I. No. 154 of 2004
E.U. (Animal Health) (Adaption) Regulations 2014	S.I. No. 112 of 2014
13. Contaminants	
Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006	Commission Regulation (EU) 2023/915
Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.	Commission Regulation (EU) 2017/2158
Corrigendum to Commission Regulation (EU) No 519/2014 of 16 May 2014 amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis.	Corrigendum to Commission Regulation (EU) No 519/2014
Commission Regulation (EU) 2017/644 of 5 April 2017 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 (EU) No 589/2014	Commission Regulation (EU) 2017/644
Commission Implementing Regulation 2019/2093 of 29 November 2019 amending Regulation (EC) No 333/2007 as regards the analysis of 3-monochloropropane-1,2-diol (3-MCPD) fatty acid esters, glycidyl fatty	Commission Implementing Regulation 2019/2093

acid esters, perchlorate and acrylamide. Commission Regulation (EU) 2021/155 of 9 February 2021 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products. Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation. Health (Arsenic and Lead in Food) Regulations 1972 and 1992 Health (Tin in Food) Regulations 1993 Health (Mineral Hydrocarbons in Food) Regulations 1972 and 1992 E.C. (Vinyl Chloride in Food) (Method of Analysis) Regulations 1984 E.C. (Vinyl Chloride in Food) Regulations 1984 and 1992 E.C. (Certain Contaminants in Foodstuffs) Regulation 2010 to 2017	Commission Regulation (EU) 2021/155 Commission Delegated Regulation (EU) 2022/931 Commission Implementing Regulation (EU) 2022/932 S.I. No. 44 of 1972 S.I. No. 72 of 1992 S.I. No. 389 of 1993 S.I. No. 45 of 1972 S.I. No. 71 of 1992 S.I. No. 92 of 1984 S.I. No. 95 of 1984 S.I. No. 65 of 1992 S.I. No. 218 of 2010 S.I. No. 276 of 2012 S.I. No. 348 of 2012 S.I. No. 380 of 2013 S.I. No. 143 of 2014 S.I. No. 329 of 2016 S.I. No. 377 of 2017
14. Additives and Flavourings	
E.C. (Flavourings for use in Foodstuffs for Human Consumption) Regulations 1992 *Note: The above legislation transposes the previous EU legislation which was repealed by Regulation (EC) No 1334/2008)*	S.I. No. 22 of 1992

E.U. (Food Additives) Regulations 2015 to 2019	S.I. No. 330 of 2015 S.I. No. 484 of 2016 S.I. No. 413 of 2018 S.I. No. 240 of 2019
15. Food Contact Materials	
E.U. (Plastics and other materials) (Contact with food) Regulations 2017 to 2019	S.I. No. 49 of 2017 S.I. No. 257 of 2018 S.I. No. 278 of 2019
16. Food Supplements	
E.C. (Food Supplements) Regulations 2007 to 2021	S.I. No. 506 of 2007 S.I. No. 355 of 2010 S.I. No. 282 of 2015 S.I. No. 225 of 2018 S.I. No. 540 of 2021
17. Foods for Specific Groups	
European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 *Note: S.I. No. 425 of 2019 is the overarching legislation for Regulation 609/2013 Foods for Specific Groups and Commission Delegated Regulation 2016/128 on for food for special medical purposes. The S.I. is repeated below where it is relevant.*	S.I. No. 425 of 2019
18. Infant Formula	
E.C. (Infant Formulae and Follow-on Formulae) 2007 and 2014	S.I. No. 852 of 2007 S.I. No. 209 of 2009 S.I. No. 92 of 2014
19. Processed Cereal-Based Baby Foods	
E.C. (Processed Cereal-based Foods and Baby Foods for Infants and Young Children) Regulations 2007 E.U. (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019	S.I. No. 776 of 2007 S.I. No. 425 of 2019
20. Foods Intended for Use in Energy - Restricted Diets	
	S.I. No. 784 of 2007

E.C. (Foods intended for use in energy-restricted diets for weight reduction) Regulations 2007 E.U. (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019	S.I. No. 425 of 2019
21. Foods for Special Medical Purposes	
E.U. (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019	S.I. No. 425 of 2019
22. Foodstuffs treated with Ionising Radiation	
E.C. (Foodstuffs Treated with Ionising Radiation) Regulations 2000	S.I. No. 297 of 2000
23. Bottled water	
E.U. (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016 and 2020	S.I. No. 282 of 2016 S.I. No. 55 of 2020
24. Food Fortification	
E.U. (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) Regulations 2017 and 2018	S.I. No. 376 of 2017
25. Miscellaneous	
Food Standards Act 1974 *Note: Now superseded by more recent legislation* Poisons Act 1961 Poisons Regulations 2008 Animal Remedies (Poisons Act 1961) Regulations 2007 Sale of Food and Drugs Act, 1899 <u>Sale of Food and Drugs Acts 1875 – 1936</u> (a) Margarine Act 1887 (b) Butter and Margarine Act 1907	Act No. 11 of 1974 Act No. 12 of 1961 S.I. No. 511 of 2008 S.I. No. 861 of 2007 Sale of Food and Drugs Act, 1899 2008 1887 50 and 51 Vict. 1907 7 Edw. 7

E.C. (Quick Frozen Foodstuffs) Regulations 1992	S.I. No. 290 of 1992
E.C. (Monitoring of Temperature in The Means of Transport, Warehousing and Storage of Quick-Frozen Foodstuffs and Sampling Procedure and Methods of Analysis for Control of the Temperatures of Quick-Frozen Foods Intended for Human Consumption) Regulations, 1995	S.I. No. 370 of 1995
E.C. (Extraction Solvents used in the Production of Foodstuffs and Food Ingredients) Regulations 2010 to 2018	S.I. No. 119 of 2010 S.I. No. 129 of 2011 S.I. No. 190 of 2018
District Court (Food Safety) Rules 2004	S.I. No. 700 of 2004
EC Legislation Which has Direct Effect in Member States	**Not Transposed but Deemed Food Law**
26. Hygiene Package and General Food Law	
Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.	Regulation (EU) 2019/1381
Corrigendum to Commission Regulation (EU) No 1086/2011 of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards salmonella in fresh poultry meat	Corrigendum to Commission Regulation (EU) No 1086/2011
Corrigendum to Commission Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.	Corrigendum to Commission Regulation (EC) No 1441/2007
Corrigendum to Commission Regulation (EU) No 1019/2013 of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamines in fishery products	Corrigendum to Commission Regulation (EU) No 1019/2013
Commission Delegated Regulation (EU) 2021/1374 of 12 April 2021 amending Annex III to Regulation (EC) No. 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin.	Commission Delegated Regulation (EU) 2021/1374
27. Official Controls Legislation	

Commission Implementing Regulation (EU) 2019/723 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the standard model form to be use in the annual reports submitted by Member States	Commission Implementing Regulation (EU) 2019/723
28. Food Information	
Commission Implementing Regulation (EU) 2018/775 of 28 May 2018 laying down rules for the application of Article 26(3) of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards the rules for indicating the country of origin or place of provenance of the primary ingredient of a food. Commission Regulation (EU) 2021/382 of 3 March 2021 amending the Annexes to Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture.	Commission Implementing Regulation (EU) 2018/775 Commission Regulation (EU) 2021/382
29. Meat and Fish Labelling	
Commission Implementing Regulation (EU) No. 576/2011 of 16 June 2011 amending Regulation (EC) No. 543/2008 laying down detailed rules for the application of Council Regulation (EC) No. 1234/2007 as regards The Marketing Standards for Poultry Meat	Commission Implementing Regulation (EU) No. 576/2011
30. Olive Oil Labelling	
Commission Regulation (EU) No. 61/2011 of 24 January 2011 amending Regulation (EEC) No. 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis. Commission Delegated Regulation (EU) 2016/1226 of 4 May 2016 amending Annex IX to Regulation (EU) No. 1308/2013 of the European Parliament and of the Council as regards the optional reserved terms for olive oil Commission Delegated Regulation (EU) 2022/2104 of 29 July 2022 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards marketing standards for olive oil, and repealing Commission Regulation (EEC) No 2568/91 and Commission Implementing Regulation (EU) No 29/2012 Commission Implementing Regulation (EU) 2022/2105 of 29 July 2022 laying down rules on conformity checks of marketing standards for olive oil and methods of analysis of the characteristics of olive oil	Commission Regulation (EU) No. 61/2011 Commission Delegated Regulation (EU) 2016/1226 Commission Delegated Regulation (EU) 2022/2104 Commission Implementing Regulation (EU) 2022/2105
31. Alcohol Labelling	

Commission Regulation (EC) No. 113/2009 of 6 February 2009 concerning the use of certain traditional terms on labels for wine imported from the United States of America	Commission Regulation (EC) No. 113/2009
Regulation (EU) No. 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No. 1601/91	Regulation (EU) No. 251/2014
Commission Delegated Regulation (EU) 2017/670 of 31 January 2017 supplementing Regulation (EU) No. 251/2014 of the European Parliament and of the Council as regards the authorised production processes for obtaining aromatised wine products	Commission Delegated Regulation (EU) 2017/670
Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No. 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation.	Commission Delegated Regulation (EU) 2019/33
Commission Implementing Regulation (EU) 2019/34 of 17 October 2018 laying down rules for the application of Regulation (EU) No. 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, amendments to product specifications, the register of protected names, cancellation of protection and use of symbols, and of Regulation (EU) No. 1306/2013 of the European Parliament and of the Council as regards an appropriate system of checks	Commission Implementing Regulation (EU) 2019/34
Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No. 110/2008	Regulation (EU) 2019/787
Corrigendum to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl	Corrigendum to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17

alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No. 110/2008 (OJ No. L 178, 20.5.2021, p. 4).	April 2019 (OJ No. L 178, 20.5.2021, p. 4).
Commission Implementing Regulation (EU) 2021/724 of 3 March 2021 laying down rules for the application of Regulation (EU) 2019/787 of the European Parliament and of the Council as regards the communications to be made by Member States to the Commission with regard to the bodies appointed to supervise ageing processes for spirit drinks and the competent authorities responsible for ensuring compliance with that Regulation.	Commission Implementing Regulation (EU) 2021/724 of 3 March 2021
Commission Delegated Regulation (EU) 2021/1334 of 27 May 2021 amending Regulation (EU) 2019/787 of the European Parliament and of the Council as regards allusions to legal names of spirit drinks or geographical indications for spirit drinks in the description, presentation and labelling of other spirit drinks.	Commission Delegated Regulation (EU) 2021/1334 of 27 May 2021
Commission Delegated Regulation (EU) 2021/1335 of 27 May 2021 amending Regulation (EU) 2019/787 of the European Parliament and of the Council as regards the labelling of spirit drinks resulting from the combination of a spirit drink with one or more foodstuffs.	Commission Delegated Regulation (EU) 2021/1335 of 27 May 2021
Commission Delegated Regulation (EU) 2021/1465 of 6 July 2021 amending Regulation (EU) 2019/787 of the European Parliament and of the Council as regards the definition of allusions to legal names of spirit drinks or geographical indications for spirit drinks and their use in the description, presentation and labelling of spirit drinks other than the spirit drinks to which allusion is made.	Commission Delegated Regulation (EU) 2021/1465 of 6 July 2021
32. Miscellaneous Product Labelling	
Commission Implementing Regulation (EU) No. 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No. 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sector.	Commission Implementing Regulation (EU) No. 543/2011
Commission Delegated Regulation (EU) No. 1040/2014 of 25 July 2014 amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption to adapt its Annex I to technical progress.	Commission Delegated Regulation (EU) No. 1040/2014
Commission Regulation (EU) 2021/77 of 27 January 2021 refusing to authorise certain health claims made on foods, other than those	Commission Regulation (EU) 2021/77

referring to the reduction of disease risk and to children's development and health. Commission Delegated Regulation (EU) 2021/1890 of 2 August 2021 amending Implementing Regulation (EU) No. 543/2011 as regards marketing standards in the fruit and vegetables sector.	Commission Delegated Regulation (EU) 2021/1890
33. Novel Foods	
Commission Implementing Regulation (EU) 2020/1634 of 4 November 2020 authorising the placing on the market of sugars obtained from cocoa (Theobroma cacao L.) pulp as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470	Commission Implementing Regulation (EU) 2020/1634
Commission Implementing Regulation (EU) 2021/50 of 22 January 2021 authorising an extension of use and a change in the specifications of the novel food '2'-fucosyllactose/difucosyllactose mixture' and amending Implementing Regulation (EU) 2017/2470	Commission Implementing Regulation (EU) 2021/50
Commission Implementing Regulation (EU) 2021/51 of 22 January 2021 authorising a change of the conditions of use of the novel food 'trans-resveratrol' under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance).	Commission Implementing Regulation (EU) 2021/51
Commission Implementing Regulation (EU) 2021/82 of 27 January 2021 authorising the placing on the market of 6'-sialyllactose sodium salt as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance)	Commission Implementing Regulation (EU) 2021/82
Commission Implementing Regulation (EU) 2021/96 of 28 January 2021 authorising the placing on the market of 3'-sialyllactose sodium salt as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470	Commission Implementing Regulation (EU) 2021/96
Commission Implementing Regulation (EU) 2021/2079 of 26 November 2021 authorising the placing on the market of vitamin D2 mushroom powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.	Commission Implementing Regulation (EU) 2021/2079
European Union (Novel Foods) Regulations 2022	S.I. 253/2022

35. Additives and Flavourings	
Commission Regulation (EU) 2020/1419 of 7 October 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of ascorbic acid (E 300) and citric acid (E 330) on white vegetables intended for further processing.	Commission Regulation (EU) 2020/1419
Commission Implementing Regulation (EU) 2021/148 of 8 February 2021 amending Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.	Commission Implementing Regulation (EU) 2021/148
Commission Regulation (EU) 2019/800 of 17 May 2019 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the extension of the use of carminic acid, carmine (E 120) in certain meat products traditional in French Overseas Territories	Commission Regulation (EU) 2019/800
Commission Regulation (EU) 2020/1819 of 2 December 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of colours in salmon substitutes	Commission Regulation (EU) 2020/1819
Commission Regulation (EU) 2020/279 of 27 February 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of soybean hemicellulose (E 426)	Commission Regulation (EU) 2020/279
Commission Regulation (EU) 2020/351 of 28 February 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of citric acid (E 330) in cocoa and chocolate products	Commission Regulation (EU) 2020/351
Commission Regulation (EU) 2020/355 of 26 February 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) in liquid vegetable oil emulsions	Commission Regulation (EU) 2020/355
Commission Regulation (EU) 2020/356 of 4 March 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polysorbates (E 432-436) in carbonated beverages	Commission Regulation (EU) 2020/356
Commission Regulation (EU) 2020/771 of 11 June 2020 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b)	Commission Regulation (EU) 2020/771

Commission Regulation (EU) 2019/801 of 17 May 2019 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of mono- and diglycerides of fatty acids (E 471) on certain fresh fruits.	Commission Regulation (EU) 2019/801
Commission Regulation (EU) 2019/891 of 28 May 2019 amending Annexes I and II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the functional class of 'stabilisers' and the use of ferrous lactate (E 585) on the mushroom Albatrellus ovinus as a food ingredient in Swedish liver pâtés.	Commission Regulation (EU) 2019/891
Commission Regulation (EU) 2019/1676 of 7 October 2019 correcting certain language versions of Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.	Commission Regulation (EU) 2019/1676
Commission Regulation (EU) 2020/268 of 26 February 2020 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sorbic acid (E 200) in liquid colour preparations for the decorative colouring of eggshells.	Commission Regulation (EU) 2020/268
Commission Regulation (EU) 2018/1472 of 28 September 2018 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No. 231/2012 as regards Cochineal, Carminic acid, Carmines (E 120).	Commission Regulation (EU) 2018/1472
Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 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.	Regulation (EC) No. 1334/2008
Commission Regulation (EU) 2019/799 of 17 May 2019 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards the removal from the Union list of the flavouring substance furan-2(5H)-one.	Commission Regulation (EU) 2019/799
Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC.	Commission Implementing Regulation (EU) No 872/2012
Commission Regulation (EU) 2020/1681 of 12 November 2020 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances	Commission Regulation (EU) 2020/1681
Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary	Commission Implementing

products for use as such in or on foods and/or for the production of derived smoke flavourings.	Regulation (EU) No 1321/2013
Commission Regulation (EU) 2017/378 of 3 March 2017 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances	Commission Regulation (EU) 2017/378
Commission Regulation (EU) 2018/678 of 3 May 2018 amending and correcting Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances	Commission Regulation (EU) 2018/678
Regulation (EC) No. 2065/2003 of the European Parliament and Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods.	Regulation (EC) No. 2065/2003
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 products.	Commission Regulation (EC) No. 627/2006
Commission Regulation (EU) 2022/63 of 14 January 2022 amending Annexes II and III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E 171).	Commission Regulation (EU) 2022/63
Commission Implementing Regulation (EU) 2021/148 of 8 February 2021 amending Regulation (EU) No. 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives.	Commission Implementing Regulation (EU) 2021/148
Commission Regulation (EU) No. 246/2014 of 13 March 2014 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances	Commission Regulation (EU) No. 246/2014
Commission Regulation (EU) No. 1098/2014 of 17 October 2014 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances	Commission Regulation (EU) No. 1098/2014
Commission Regulation (EU) 2015/648 of 24 April 2015 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance of N-Ethyl (2E,6Z)-nonadienamide	Commission Regulation (EU) 2015/648
Commission Regulation (EU) 2015/1102 of 8 July 2015 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances	Commission Regulation (EU) 2015/1102

Commission Regulation (EU) 2017/1250 of 11 July 2017 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance 4,5-epoxydec-2(trans)-enal.	Commission Regulation (EU) 2017/1250
Commission Regulation (EU) 2015/1760 of 1 October 2015 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance pmentha-1,8- dien-7-al	Commission Regulation (EU) 2015/1760
Commission Regulation (EU) 2016/54 of 19 January 2016 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards inclusion of gamma-glutamyl-valylglycine in the Union list of flavouring substances	Commission Regulation (EU) 2016/54
Commission Regulation (EU) 2016/55 of 19 January 2016 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances	Commission Regulation (EU) 2016/55
Commission Regulation (EU) 2016/178 of 10 February 2016 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances	Commission Regulation (EU) 2016/178
Commission Regulation (EU) 2016/637 of 22 April 2016 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances	Commission Regulation (EU) 2016/637
Commission Regulation (EU) 2016/692 of 4 May 2016 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances	Commission Regulation (EU) 2016/692
Commission Regulation (EU) 2016/1244 of 28 July 2016 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances from a group related with an alpha beta unsaturation structure.	Commission Regulation (EU) 2016/1244
Commission Regulation (EU) 2018/1246 of 18 September 2018 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards the inclusion of pyroligneous distillate in the Union list of flavourings	Commission Regulation (EU) 2018/1246
Commission Regulation (EU) 2018/1259 of 20 September 2018 amending Regulation (EU) No. 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the	Commission Regulation (EU) 2018/1259

Council as regards the extension of the transition period of Article 4 concerning the flavouring 'grill flavour concentrate (vegetable)'	
Commission Regulation (EU) 2018/1482 of 4 October 2018 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards caffeine and theobromine.	Commission Regulation (EU) 2018/1482
Commission Regulation (EU) 2018/1649 of 5 November 2018 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances.	Commission Regulation (EU) 2018/1649
Commission Regulation (EU) 2019/36 of 10 January 2019 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards the substance N-(2-methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide.	Commission Regulation (EU) 2019/36
Commission Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council	Commission Regulation (EU) No 873/2012
Commission Regulation (EU) No 545/2013 of 14 June 2013 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the flavouring substance 3-acetyl-2,5-dimethylthiophene	Commission Regulation (EU) No 545/2013
Commission Regulation (EU) No 985/2013 of 14 October 2013 amending and correcting Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances	Commission Regulation (EU) No 985/2013
Commission Regulation (EU) 2020/279 of 27 February 2020 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of soybean hemicellulose (E 426).	Commission Regulation (EU) 2020/279
Commission Regulation (EU) 2020/351 of 28 February 2020 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of citric acid (E 330) in cocoa and chocolate products.	Commission Regulation (EU) 2020/351
Commission Regulation (EU) 2020/355 of 26 February 2020 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) in liquid vegetable oil emulsions.	Commission Regulation (EU) 2020/355
Commission Regulation (EU) 2020/356 of 4 March 2020 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of polysorbates (E 432-436) in carbonated beverages.	Commission Regulation (EU) 2020/356
	Commission Regulation (EU) 2020/763

Commission Regulation (EU) 2020/763 of 9 June 2020 amending the Annex to Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards specifications for tricalcium phosphate (E 341 (iii)).	Commission Regulation (EU) 2020/771
Commission Regulation (EU) 2020/771 of 11 June 2020 amending Annexes II and III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No. 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b).	Commission Implementing Regulation (EU) 2020/869
Commission Implementing Regulation (EU) 2020/869 of 24 June 2020 amending Implementing Regulation (EU) No. 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor.	Commission Regulation (EU) 2020/1419
Commission Regulation (EU) 2020/1419 of 7 October 2020 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of ascorbic acid (E 300) and citric acid (E 330) on white vegetables intended for further processing.	Commission Regulation (EU) 2020/1681
Commission Regulation (EU) 2020/1681 of 12 November 2020 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances.	Commission Regulation (EU) 2020/1819
Commission Regulation (EU) 2020/1819 of 2 December 2020 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of colours in salmon substitutes.	Commission Regulation (EU) 2021/1156
Commission Regulation (EU) 2021/1156 of 13 July 2021 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No. 231/2012 as regards steviol glycosides (E 960) and rebaudioside M produced via enzyme modification of steviol glycosides from Stevia.	Commission Regulation (EU) 2021/1175
Commission Regulation (EU) 2021/1175 of 16 July 2021 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the use of polyols in certain energy-reduced confectionery products.	Commission Regulation (EU) 2021/1532
Commission Regulation (EU) 2021/1532 of 17 September 2021 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards the inclusion of 3-(1-((3,5-dimethylisoxazol-	

4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione in the Union list of flavouring substances. Commission Regulation (EU) 2021/1916 of 3 November 2021 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards the inclusion of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid in the Union list of flavourings. Commission Regulation (EU) 2021/1917 of 3 November 2021 amending Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council as regards the inclusion of 2-(4-methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide in the Union list of flavourings.	Commission Regulation (EU) 2021/1916 Commission Regulation (EU) 2021/1917
36. Foods for Particular Groups	
Commission Delegated Regulation (EU) 2019/828 of 14 March 2019 amending delegated regulation (EU)2016/127 with regard to Vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula. Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control Commission Delegated Regulation (EU) 2018/561 of 29 January 2018 amending Delegated Regulation (EU) 2016/127 with regard to protein requirements for follow-on formula. Commission Delegated Regulation (EU) 2021/571 of 20 January 2021 amending the Annex to Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the list of substances that may be added to infant and follow-on formula, baby food and processed cereal-based food. Commission Delegated Regulation (EU) 2021/572 of 20 January 2021 amending Delegated Regulation (EU) 2016/127 as regards the date of application of certain of its provisions. //formula	Commission Delegated Regulation (EU) 2019/828 Commission Delegated Regulation (EU) 2016/127 Commission Delegated Regulation (EU) 2017/1798 Commission Delegated Regulation (EU) 2018/561 Commission Delegated Regulation (EU) 2021/571 Commission Delegated Regulation (EU) 2021/572

Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021 amending Delegated Regulation (EU) 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula.	Commission Delegated Regulation (EU) 2021/1041
37. Food Enzymes	
Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97	Regulation (EC) No 1332/2008
Commission Regulation (EU) No 1056/2012 of 12 November 2012 amending Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures.	Commission Regulation (EU) No 1056/2012
Commission Implementing Regulation (EU) 2020/1823 of 2 December 2020 amending Regulation (EU) No. 234/2011 implementing Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.	Commission Implementing Regulation (EU) 2020/1823
38. Food Contact Materials	
Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.	Commission Regulation (EU) 2019/1338
Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials	Commission Regulation (EU) 2018/213
Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.	Commission Regulation (EU) 2020/1245
39. Food Fortification	

Schedule 2

1. General Requirements

Section 1 outlines the objectives, targets and other matters relating to official controls and other official activities which the Authority has specified to the Official Agency.

Section 1 applies to official controls and other official activities related to food safety of the Environmental Health Service (EHS) and the Food Safety Laboratory Service (FSLS) comprised of the Public Analysts Laboratories (PAL) and the Official Food Microbiology Laboratories (OFML).

1.1 Introduction

The Official Agency will fulfil all obligations regarding food safety and integrity as agreed with the Authority under the terms of this 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.

Both parties to the service contract accept that staffing levels over the period of this contract will vary. Consequently, enforcement will have to be considered in the context of available resources and may require the objectives and targets set out in this schedule to be reviewed and reprioritised. To this end the Official Agency and the Authority will review and amend objectives and targets set under this contract as part of the agreement of the annual work plans (Section 1.15), to take account of available resources and any unforeseen external challenges.

In recognition of this, implementation of service contract requirements will be reflected in the Official Agency's National Service Plans, National Sampling and Analysis Programs and Environmental Health Service Operational Plan.

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 in the agencies remit at any stage of production, processing, distribution and sale as agreed under this contract. Official controls and other official activities shall be carried out as appropriate, at any of the stages of production, processing, distribution and sale of food. They shall 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.

Within its area of competence, the Official Agency shall ensure that 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.

The Official Agency shall have due regard to recognised guidance notes, codes of best

practice, Standard Operating Systems or accreditation systems; in addition to any advice which may be issued by the Authority as agreed between the Official Agency and the Authority.

The frequency of official controls shall be determined in line with the requirements of Article 9 of Regulation (EU) 2017/625 and these official controls shall be conducted in line with the methods and techniques for official controls outlined in Article 14 of Regulation (EU) 2017/625.

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, operational plan and resourcing of the Official Agency. These inter-agency activities include, but are not limited to:

- Sharing of information on food businesses
- Provision of reasonable assistance as appropriate
- Participation in cross-agency meetings
- Inter-agency training
- Multi-disciplinary working.

1.3 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 and Regulation 19 of S.I. No. 79 of 2020. 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.

Where there are reasonable grounds to suspect that a food may present a risk to public 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. When the Official Laboratories are required by law or authorised by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

The Official Agency shall put procedures in place to ensure any inaccuracies in information made available to the public are appropriately rectified and the Authority will be advised.

1.4 Multi Annual National Control Plan (MANCP)

The Official Agency shall work 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 shall co-operate with the Authority in updating Ireland's MANCP and in the preparation of the annual reports for Ireland. By the 31st of 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.

1.5 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 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 procedures and arrangements in place facilitate the implementation of official controls and other official activities that are effective and appropriate.

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 will provide the Authority with updates as specified in Schedule 4.

The Official Agency and the Authority agree to work to ensure there is efficient and effective coordination involved in carrying out official controls and other official activities and to ensure that, as far as is practicable, there is consistency and effectiveness of official controls and other official activities.

1.6 Documented Control Procedures

The Official Agency shall carry out official controls in accordance with national documented control procedures. 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 Authority will on request, be provided with all current documented procedures relating to service contract activities.

1.7 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.

As part of these plans, the Environmental Health Service will provide the Authority with dedicated contact points for both office hours and out of office hours contact for emergency and crisis situations, including foodborne outbreaks and food incidents.

The Food Safety Laboratory Service will, when necessary, endeavour to provide the Authority with dedicated contact points for both office hours and out of office hours contact for emergency and crisis situations, including foodborne outbreaks and food 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 out of hours arrangements.

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 [MOFI] as per Section 1.8.

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

1.8 Investigation of Foodborne Outbreaks

The Official Agency, in conjunction with the Authority, shall implement the agreed protocol(s) to manage and deal effectively with foodborne outbreaks in particular the current guidance on Management of Outbreaks of Foodborne Illness as published on the FSAI website.

The Authority and the Official Agency shall notify each other without undue delay of foodborne outbreaks and the outcome of investigations in accordance with the above protocol(s).

1.9 Investigation of Food Incidents

Provisions shall be made by the Official Agency to deal effectively with food incidents. The Authority and the Official Agency shall notify each other without undue delay of food incidents when food is found to pose a serious risk to human health or food fraud.

Where a product recall or withdrawal is required, the Official Agency shall aim to ensure that food business operators it supervises follow the procedures set out in the latest version of the Authority's Guidance Note 10: Product Recall and Traceability.

The Official Agency shall co-operate with the Authority and other Official Agencies in the investigation of food incidents and provide such information as requested by the Authority for the management of food incidents, in a timely manner.

The Official Agency shall notify the Authority without delay of the outcome of investigations.

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

The Official Agency shall maintain dedicated contact points for the Environmental Health Service and Food Safety Laboratory Service for exchange of information relating to food incidents during normal office hours as outlined in the latest version of Authority's Code of Practice No. 5.

1.10 Coordinated Monitoring, Coordinated Control Programmes, Information and Data Collection

The Official Agency shall participate in EU coordinated monitoring, 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.

1.11 Administrative Assistance and Cooperation

The Official Agency shall 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 noncompliance with food law is identified or suspected shall be notified to the Authority in a timely manner.

The Authority shall act as the contact point responsible for facilitating the exchange of communications between competent authorities in accordance with Articles 104 to 107 of Regulation (EU) 2017/625 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.

1.12 Legislation

Duties and responsibilities of the Official Agency for the performance of official controls and other official activities related to food safety, food integrity, protection of consumers' interests and information will derive from the legislation listed in Schedule 1. All staff involved in official controls and other official activities shall be provided with access to this legislation.

1.13 Participation on Working Groups

The Authority and the Official Agency will agree Service Contract Committees and working groups and establish objectives, terms of reference and timeframes for each. The terms of reference will outline the purpose and scope and reporting lines of these groups and will be agreed by the Official agencies concerned. The terms of reference will be reviewed annually or as required. The role of Service Contract Committees and working groups is to make recommendations to management. The current service contract, cross-agency and ad-hoc Committees and Groups are:

Service Contract Committees

- Service Contract Committee on Food Legislation
- Service Contract Committee on Enforcement Consistency
- Service Contract Committee on Microbiological Sampling (FSAI-EHS-OFML Group)
- Service Contract Committee on Chemical Sampling (FSAI-EHS-PAL Group)

The terms of reference of these committees will be reviewed as required.

Cross-agency Committees and Working Groups

- Cross-Agency Supervisory Arrangements Group
- Cross-Agency Import Control Group
- FSAI LIMS Administrators Working Group
- Food Fraud
  - Food Fraud Task Force
  - Food Fraud official agencies sub-group.

Ad-hoc Working Groups/Expert Groups:

- Spirit drinks working group.
- Allergens working group.
- Cross-Agency Laboratory working group.
- Enforcement Tools working group.
- Second Expert Opinion working group.

The Official Agency will, on request to the agreed contact point provide nominees to include staff from the Food Safety Laboratory Service, Environmental Health Service and other relevant staff to participate in the Authority's Service Contract committees, ad hoc working groups, bilateral and cross-agency working groups and expert working groups as appropriate to:

- Produce, review and amend Guidance Notes, Codes of Practice and Guides to Good Hygiene Practice
- Evaluate implications of existing and proposed legislation
- Evaluate relevant food safety/scientific information.
- Produce other outputs including meeting reports, as agreed.

1.14 Fraudulent and Deceptive Practices Related to the Food Chain

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.

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.

1.15 Annual Work Plans

The Official Agency will prepare annual work plans for the official controls and other official activities performed under this service contract to be met. This will include both the Environmental Health Service and the Food Safety Laboratory Service. These plans will incorporate the requirements of Article 9(1) and Article 9(2) of Regulation (EU) 2017/625.

The Environmental Health Service annual work plan as it relates to food safety, will be agreed with the Authority for each calendar year by February 28th. The work plan will specify targets and measurable outcomes for the requirements of the service contract.

The National sampling plans (chemical and microbiological) will be agreed as per Section 3.3 of Schedule 2.

The implementation of the work plans will be reviewed by the Authority and the Official Agency through the FSAI-HSE Management. The work plans and their implementation against the agreed targets will be used to monitor the performance of the contract.

1.16 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.

The Food Safety Laboratory Service shall share data on individual food samples taken under this contract, electronically to the Authority from the laboratory LIMS. The specifics of the LIMS data transmission shall be agreed in a controlled document defining content, format, frequency and transmission mechanism.

The Official Agency shall within the period of this contract and with respect to the activities specified in the contract, progress:

- The interface of the EHIS and the Official Agency laboratory IT systems
- Consistency of recording in LIMS of sub-contracted samples
- The consistency of recording in LIMS of designations for microbiological samples analysed.
- The discussion with the Authority regarding the classification and description of samples taken by the Environmental Health Service or analysed by the Food Safety Laboratory Service according to the FOODEX2 system.

The Authority and the Official Agency will progress the convergence of data fields to facilitate data sharing and compatibility with agreed national data standards.

The Authority shall collate and analyse national data based on the data transmissions from Food Safety Laboratory Service.

The Authority shall provide best efforts underpinned by resource capacity to support the FSAI developed systems used by the Official Agency for the fulfillment of this contract.

The Official Agency will co-operate with the Authority in ensuring national implementation of national and EU data standards.

1.17 Data Collection, Information and Reporting

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

- Enforcement of food law (both hygiene and non-hygiene) in the food businesses under its supervision, and
- Sampling and analysis of food and materials and articles in contact with food.

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 (MANCP), 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 (MANCP) 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 will respond in a timely fashion to data requests and for clarifications from the Authority.

The Official Agency shall ensure the reporting suite in the national Environmental Health Service IT system is flexible enough to facilitate agreed ad-hoc reporting to the Authority with respect to any data field captured in the system which relates to activities carried out under this contract.

1.18 Import Controls for Products of Non-Animal Origin and Food Contact Materials

The Official Agency, in consultation with the Authority, shall maintain and develop its import control capacity to ensure it meets its obligations as a Competent Authority under relevant food safety legislation.

Data regarding consignments inspected by the Official Agency shall be transmitted to the Authority as detailed in Schedule 4.

The Official Agency will operate import controls in line with legislative requirements in liaison with other Official Agencies and the Office of the Revenue Commissioner's Customs officials as appropriate.

The Official Agency will carry out official controls on food products of non-animal origin and current increased controls on food contact materials, as agreed with the Authority to meet the requirements of Articles 43 to 77 of Regulation (EU) 2017/625.

The Official Agency, in consultation with the Authority, shall maintain and develop its import control capacity to ensure it meets its obligations as a Competent Authority under relevant food safety legislation.

1.19 Third Party Complaints Regarding the Implementation of this Service Contract

The Official Agency shall provide information to the Authority on food business operator or public complaints regarding the implementation of the service contract. Complaints will be managed in accordance with the Official Agency's procedures. The Official Agency shall 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 managed through the liaison process.

1.20 Designated Officers

The Official Agency shall nominate officers for designation by the Board of the Authority to carry out the consultation function outlined in Section 52, 53 and 54 of the Act and Regulations 27, 28, 29 and 30 of the European Union (Official Controls in Relation to Food Legislation) Regulations, 2020.

1.21 Authorisation

The Official Agency shall ensure that all relevant staff are authorised appropriately by the Official Agency for the official controls and other official activities they carry out.

1.22 Training and Continuous Professional Development

The Official Agency shall provide appropriate training, including induction training for staff performing official controls and other official activities 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 Annex II, Chapter I, 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 will endeavour 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, through surveys, liaison meetings, working groups and feedback from training or other events. 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 shall 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 will provide training and e-learning resources for staff involved in official controls and/or other official activities. These resources will aim to:

- Inform staff performing official controls and/or other official activities on the requirements of existing and new/revised legislation.
- Disseminate and clarify the application of guidance material.
- 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 shall 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 BTSF philosophy is to ensure that participants for each course are drawn from food control staff from several EU Member States. This gives participants a chance to learn of experience in different jurisdictions, thereby promoting consistency of approach across the EU. To facilitate this the Official Agency shall support participants in disseminating knowledge or skills acquired and encourage the application of learning gained through BTSF training programmes.

The Official Agency shall 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 shall ensure that any contractors used in the performance of the Service Contract provide evidence of appropriate training.

1.23 Commission Controls and Third Country Audits

The Official Agency will cooperate 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 shall take effective actions to address audit report recommendations (if any) in a timely manner, and as agreed with the Authority. The Official Agency will keep the Authority informed on the progress to implement such actions upon request.

The Official Agency shall nominate a coordinator(s) for European Commission (DG SANTE Health and Food Audits and Analysis, Directorate F), or audits by third countries relevant to this contract. Depending on the scope of the audit this may require nominees from the Environmental Health Service and/or the Food Safety Laboratory Service.

1.24 Internal Audit

The Official Agency shall carry out internal audits or have audits carried out on themselves of its official controls and other official activities related to this service contract and shall take appropriate measures in the light of the results of those internal audits as per Article 6(1) of Regulation (EU) 2017/625.

Internal audits and their programming will be conducted in accordance with relevant guidelines issued by the European Commission. All aspects of internal audit activities are to be carried out in a transparent manner and be subject to independent scrutiny as per Article 6(2) of Regulation (EU) 2017/625.

The Official Agency shall provide the Authority annually with its audit programmes, audit reports, corrective action plans and any other documentation related to its internal audit function that falls within the remit of this service contract.

For the Official Agency services accredited to ISO/IEC 17025:2017 documentation on internal audits that fall within the remit of the contract will be provided on request. The Authority and the Official Agency will, collaboratively assess the extent to which audits carried out in relation to ISO/IEC 17025:2017 satisfy the requirement of official controls legislation.

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

1.25 Boundaries of the Service

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

1.26 Zoonoses

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

The Official Agency shall facilitate appropriate staff (to include food microbiology laboratory staff, public analyst laboratory staff, environmental health staff and other relevant staff) to be members of and attend regional and the national zoonoses committees**.**

1.27 Official Certification

Certificates for Export

The Environmental Health Service of the Official Agency will issue certificates for export of Products of Non-Animal Origin in line with agreed procedures. The Food Safety Laboratory Service will test samples relating to certificates for export on request.

The Official Agency in collaboration with the Authority and other Official Agencies will agree and implement a process for issuing official certificates for other exports, as required. Such official certificates will be issued in line with Articles 86 to 91 of Regulation (EU) 2017/625 and its associated tertiary legislation and procedures agreed with the Authority.

1.28 Written Records of Official Controls

In line with Article 13 of Regulation (EU) 2017/625 the Official Agency shall draw up written reports on each 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 food business operator concerned is to take.

In accordance with Article 13(2) of Regulation (EU) 2017/625 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.

1.29 Follow-Up on Non-Compliances

In line with Article 138 of Regulation (EU) 2017/625 the Official Agency shall initiate follow-up action following detection of non-compliances to ensure that the operator concerned rectifies the non-compliance and takes steps to avoid further occurrences of such non-compliance.

Where appropriate the Official Agency may consult with the Authority regarding follow-up to non-compliances.

1.30 Enforcement Action

The Official Agency will ensure that enforcement action taken is in accordance with Articles 137 and 138 of Regulation (EU) 2017/625. The Official Agency shall ensure the effective and appropriate use of enforcement powers under national food legislation while having due regard for:

- The use of available enforcement tools under the Act
- Food law enforcement policy published by the Authority and
- Any enforcement guidance agreed between the Authority and the Official Agency.

1.31 Second Expert Opinion

In line with Article 35 of Regulation (EU) 2017/625 and Regulation 12 of S.I. No. 79 of 2020 the Authority in conjunction with the Official Agency will develop guidance and procedures to ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense.

1.32 Distance Communication

In line with Article 36 of Regulation (EU) 2017/625 the Official Agency in conjunction with the Authority will develop procedures to sample goods offered for sale by means of distance communication.

1.33 Financing of Official Controls and Other Official Activities

The Official Agency shall collect fees/charges for official controls and other official activities in line with Articles 78-85 of Regulation (EU) 2017/625 and Regulations 4 and 5 of S.I. No. 79 of 2020. The basis for fees or charges applied by the Official Agency shall be in line with Regulation (EU) 2017/625.

The Official Agency shall identify those responsible for the collection of these fees or charges and provide proof of payment of such fees or charges to food business operators on request in accordance with Article 85(2) and Article 84 of Regulation (EU) 2017/625.

The Official Agency will work in partnership with the Authority and other Official Agencies to develop a consistent national approach to charging of fees for areas within the remit of this contract.

1.34 Information and Supports for Food Business Operators

The primary responsibility for training of food industry staff remains with the food industry. The Official Agency shall provide information to stakeholders on services related to its food safety activities. The information will be provided as appropriate through seminars, presentations, handbooks, leaflets and the Official Agency's website.

Where resources allow the Official Agency may provide food safety training to food establishments under their supervision. Such provision will be primarily focused on food businesses that are managed, funded, supported or operated by the Official Agency. When training is provided the Official Agency shall ensure that there is no conflict of interest.

Where possible the Official Agency will contribute to the development of and the provision of information to food businesses under its supervision related to food safety activities of the Authority, including details of webinars, e-Learning activities and other materials or tools as appropriate.

1.35 Voluntary National Guides

The Authority and the Official Agency shall encourage and facilitate the development of guides to good practice on hygiene and HACCP principles by the food industry in line with the procedures laid down in the Authority's Guidance Note No. 23 on Development and

Assessment of Recognised National Voluntary Guides to Good Hygiene Practice and the Application of HACCP Principles.

1.36 Additional Tasks

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

2. Environmental Health Service

2.1 Introduction

The Environmental Health Service is provided by the various grades of Environmental Health Officer and administrative support personnel employed by the Official Agency. The service shall operate during normal office hours Monday to Friday, with programmed out of hours activity.

The Official Agency shall perform official controls and other official activities as per legislative requirements, the agreed cross-agency supervisory arrangements and the Official Agency's documented procedures.

The Official Agency shall 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 Official Controls and Other Official Activities to be Provided

The Official Agency will perform official controls and other official activities in the context of the legislation outlined in Schedule 1 including the determination of compliance with food legislation by means of:

(i) Inspection, registration and/or approval of establishments and equipment, including establishments or equipment used in connection with the manufacture, processing, disposal, transport and storage of food.
(ii) Inspection and sampling of food including food ingredients.
(iii) Assessment of water after the point of compliance referred to in Article 6 of Directive 98/83/EC, as amended.
(iv) Inspection and examination of food labelling so as to protect consumer health / interests and ensure compliance with food legislation.

2.2.1 Food Business Establishments and Operators Subject to Official Controls and Other Official Activities

The Official Agency will perform official controls and/or other official activities on categories of food business establishments and/or operators as determined by the Scope of Schedule 1. The food business establishments and operators will include those subject to Regulation (EC) No. 853/2004 and Regulation (EC) No. 852/2004.

The Official Agency shall supervise food business establishments and/or operators in line with the agreed, latest version of the supervisory arrangements document.

The Authority may, if necessary, determine responsibility for provision of official controls and other official activities for specific food business establishments and operators. The Authority, the Official Agency and other agencies will agree criteria for the allocation of supervising agency for certain establishments.

Official controls and other official activities in food business establishments, and/or on operators shall be carried out by a single Official Agency and the Official Agency shall supervise all activities undertaken by the food business operator in relation to the food business (s). Where single agency supervision is not possible and the Official Agency shares responsibility for performing official controls and other official activities on food business establishments and/or operators with other Official Agencies, local arrangements will be made to coordinate appropriate supervision arrangements in consultation with the Authority in line with the agreed, latest version of the supervisory arrangements document.

The Official Agency will ensure that the activities undertaken by the food business establishments and/or operators are reviewed on a regular basis as part of the official controls performed.

2.2.2 Inspections of Food Business Establishments and/or Operators Subject to Notification under Regulation (EC) No 852/2004

Official controls including risk profiling, inspections and follow up shall be carried out in accordance with the latest version of the Authority's Guidance Note No.1. The Authority will be consulted in advance of any national planned change to the frequency of inspections in the Authority's Guidance Note No. 1. The Official Agency shall work toward ensuring consistency of frequency of inspection nationally.

Official Controls in catering/other food businesses operated by or on behalf of the HSE/Official Agency must be carried out and notified to the Authority in accordance with the Authority's Guidance Note No. 1.

2.2.3 Inspections of Food Business Establishments and/or Operators Subject to Approval under Regulation (EC) No 853/2004

Official controls of food businesses subject to under Regulation (EC) No. 853/2004 must be carried out in line with the Authority guidance on approvals under Regulation (EC) No 853/2004 of establishments supervised by HSE consistent with similar / equivalent official controls carried out by other Official Agencies, as coordinated through the Authority.

2.2.3.1 Approval and Notification of Food Business Establishments

The Official Agency shall grant/withdraw/suspend/amend the approval in accordance with the provisions of food legislation, The Authority's guidance and Official Agency procedures. The Official Agency shall notify the Authority without delay of changes to establishment approvals to facilitate publication of an up-to-date list on the Authority's website.

2.2.3.2 Risk Categorisation and Inspection of Approved Food Business Establishments

Approved establishments must be risk categorised to determine the frequency of inspection in accordance with legislative requirements. The Authority will be consulted in advance of any national planned change to the frequency of inspections in Guidance Note No.1.

Inspections must be carried out in accordance with legislative requirements, The Authority guidance and Official Agency procedures. The inspection process should be carried out in accordance with the Authority's Guidance Note No. 1. The Official Agency shall keep the approval of establishments under review when carrying out official controls.

2.2.4 Food Legislation *(See Categories in Schedule 1)*
Official controls in respect of food legislation listed in Schedule 1, will primarily be implemented through inspection and/or through the Official Agency national sampling programmes. Where practicable such official controls will be undertaken early in the production/distribution chain to maximise effectiveness and avoid duplication. These targeted inspection/sampling programmes will be agreed annually in the format of the template provided in Appendix 2.

2.2.5 Miscellaneous
The Authority and the Official Agency will agree an appropriate level of controls in respect of any other food legislation using the template in the Appendix 2.

2.2.6 Specialisation
It is recognised that due to the scope and complexity of food legislation that it is not always necessary, feasible or practical that all Official Agency staff be fully trained in enforcement of all food legislation. The Official Agency may make arrangements where relevant and feasible to have in place subsets of Official Agency staff trained in specific areas of non-food hygiene legislation.

2.2.7 Other Services
The Official Agency shall make arrangements for official controls to be undertaken in areas not covered by Schedule 2 by agreement with the Authority.

3. Sampling for Analysis

3.1 Introduction

Within the Official Agency, official control for microbiological and chemical sampling is carried out by the Environmental Health Service and analysis is carried out by the Food Safety Laboratory Service of the Official Agency.

The Environmental Health Service and Food Safety Laboratory Service shall collaborate in matters of mutual interest, in conjunction with the Authority as appropriate, to ensure the effective and efficient operation of the sampling and analysis activities under this service contract.

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

- Sampled for analysis and testing in accordance with the requirements of Articles 34 to 36 of Regulation (EU) 2017/625
- Submitted to an official laboratory of the Food Safety Laboratory Service designated for that purpose in accordance with the requirements of Articles 37 and 38 of Regulation (EU) 2017/625.

3.2 Coordination of Sampling and Analysis

The Official Agency shall co-ordinate sampling and analysis between the Environmental Health Service and Food Safety Laboratory Service. Issues relating to coordination of sampling and analysis will primarily be dealt with through the EHS-OFML and EHS-PAL sampling groups in conjunction with the Authority. The Official Agency shall ensure national implementation of sampling and analysis decisions.

3.3 Sampling Plans

The Official Agency shall agree annual national sampling plans both microbiological and chemical with the Authority. The chemical national sampling plan will be agreed in the final quarter preceding the year to which the plan applies. The annual microbiology sampling plan consists of routine sampling according to the Risk Based Guidance Document and an agreed survey. The topic for the survey will be agreed in the final quarter preceding the year in which the survey takes place. The sampling plans will include the various food sampling programmes undertaken by the Official Agency, including EU coordinated control plans and pilot programmes, EU coordinated monitoring and National Microbiological/Chemical Surveillance Programmes which also includes monitoring recommendations.

The plan will outline the numbers of samples to be taken, the parameters to be analysed and where appropriate the sampling points, this plan will also include, where relevant, sampling information, including, where relevant, information relating to the provisions of Article 35 of Regulation (EU) 2017/625. The priorities for each year shall also be detailed in these sampling plans. Sampling should be carried out in accordance with the relevant legislative requirements, sampling guidelines and/or sampling protocols.

Sampling shall be focused on appropriate areas in the food supply chain from production/importation to retail/catering as an aid to the determination of compliance of food and food businesses with food legislation, to provide optimal data for protection of the consumer and as part of agreed focused surveys. The timing and delivery of samples shall be agreed at local level.

The Official Agency shall monitor the delivery of the sampling plan throughout the year in particular with a view to ensuring sample numbers and sample types are achieved and adjustments are made to the sampling plan where necessary. This will be discussed through the EHS-OFML and EHS-PAL sampling groups in conjunction with the Authority.

3.4 National Sampling Submission Form

The Official Agency shall implement the current single agreed national sample submission form for all official controls for microbiological and chemical sampling relevant to the service contract. The single agreed form will be used by all areas.

3.5 Surveys

The Official Agency will participate in national surveys as agreed with the Authority. The timing and organisation of national surveys will be agreed with the Authority, the Food Safety Laboratory Service and the Environmental Health Service. Where practicable such surveys should be included in the Official Agency annual food sampling and analysis programmes.

4. Food Safety Laboratory Service

4.1 Introduction

The Food Safety Laboratory Service (FSLS) is provided by the Official Agency through the Official Food Microbiology Laboratories (OFMLs) and the Public Analysts' Laboratories (PALs), listed in Schedule 3.

The Food Safety Laboratory Service shall provide food control services during normal working hours. Out of hours activities may be provided by agreement with the Food Safety Laboratory Service having regard to staffing issues and financial resources.

4.2 National Management System for the Food Safety Laboratory Service

Both parties to the service contract recognise the importance of establishing an integrated management system for the Food Safety Laboratory Service within the framework of the Official Agency that will provide for the overall management and coordination of the Food Safety Laboratory Service. The Official Agency will review the existing management structures and implement an appropriate national structure for the Food Safety Laboratory Service during the term of the contract.

4.3 Official Laboratories

The Food Safety Laboratory Service shall function as 'Official laboratories' as defined in Regulation (EU) 2017/625 and as listed in S.I. No. 79 of 2020 (as amended) and as per procedures agreed with the Authority.

Samples taken during official controls and/or other official activities shall be analysed or tested in designated official laboratories listed in Regulation 2(1) of S.I. No 79 of 2020.

The Food Safety Laboratory Service shall cooperate with the National Reference Laboratories (NRLs) for testing food in Ireland in the discharge of their functions under Article 100 of Regulation (EU) 2017/625 and as per agreed protocols with the Authority.

The Food Safety Laboratory Service will participate in audits for the purposes of Article 39 of Regulation (EU) 2017/625.

Where laboratories external to the Food Safety Laboratory Service perform analysis and testing of samples taken as part of official controls and/or other official activities the Official Agency and/or the Authority, as relevant, will ensure that this is done in accordance with Regulation 2017/625.

The Official Agency shall work with the Authority in the discharge of the Authority's functions for designated Official laboratories, in accordance with Articles 37(3), 38(3) and (4), 39(1), 42(2)(c) of Regulation (EU) 2017/625 and S.I. No. 79 of 2020.

4.4 Services to be Provided

The specific Official laboratories within the Food Safety Laboratory Service shall carry out specific analysis and testing, and any other tasks as per their written designation under Article 37(3) of Regulation (EU) 2017/625.

The Food Safety Laboratory Service shall co-operate as relevant with the National Reference Laboratories (NRLs) in the discharge of their functions under Articles 100 and 101 of Regulation (EU) 2017/625 and as agreed with the Authority.

4.4.1 Sample Analysis

The Food Safety Laboratory Service shall provide services for microbiological, chemical and other testing of foodstuffs for parameters including contaminants, additives, flavourings, and compositional parameters. Analysis shall be carried out in accordance with Section 3, taking into account the relevant legislative requirements, guidelines and/or protocols.

It is recognised that sampling and analysis may be required outside the agreed national/regional sampling programmes. In this regard the Authority and the Environmental Health Service will firstly request the assistance of the Food Safety Laboratory Service.

In the event of a food-poisoning outbreak, food incident and any unforeseen external challenges, the routine testing programme may have to be adjusted, to this end the sampling and testing regime may need to be amended, to allow for emergency analysis as required.

4.4.2 Accreditation

The Food Safety Laboratory Service of the Official Agency shall operate in accordance with the standard ISO/IEC 17025:2017 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.

Over the duration of this contract, the Food Safety Laboratory Service will work toward expanding accreditation for all the methods used by the laboratories when testing Official control samples in the scope of this contract in so far as is possible.

The Official laboratories within the Food Safety Laboratory Service will provide the Authority with up-to-date information on the scope and the status of their accreditation. The Food Safety Laboratory Service will consider the views of the Authority regarding the scope of accreditation, in so far as it relates to activities in this Contract.

In accordance with ISO/IEC 17025:2017 requirements, the Authority will be referenced as a customer in the Quality Management Systems of the specific Official laboratories of the Food Safety Laboratory Service.

In line with the requirements of ISO/IEC 17025:2017, Statements of Conformity to a specification or standard, where supplied by the Official laboratories of the Food Safety Laboratory Service, either as a result of a requirement in the specific standard/legislation or at the request of the customer, will be included with the result. The decision rule(s) used to determine these statements shall be clearly defined, unless inherent in the requested specification or standard. The rule selected shall be communicated to, and agreed with, the Authority or customer.

4.4.3 Turnaround Time

In line with the requirements of Article 37(4)(d) of Regulation (EU) 2017/625, the Food Safety Laboratory Service will ensure that turnaround times for programmed samples taken as part of official controls and other official activities allow for efficient follow-up of non-compliant samples.

Turnaround times for analysis of programmed samples in the Food Safety Laboratory Service will be discussed and reviewed as necessary at FSAI/OFML/PAL/EHS liaison meetings.

4.4.4 Laboratory Methods

The official laboratories shall use methods that comply with Article 34 of Regulation (EU) 2017/625. Official laboratories within the Food Safety Laboratory Service performing the same analysis should strive to use comparable methods to ensure consistency of results nationally or adopt other strategies to ensure this consistency. Where similar methods are undertaken, there should also be consistency with regard to the sample quantities requested by the Food Safety Laboratory Service, sample storage and preparation**.**

4.4.5 Reporting, Designation and Certification

Having regard to the requirements pertaining to approved examiners under food law, the OFMLs shall implement a consistent approach to the reporting of results of analysis at national level, including designation, based on agreed decision rules, observations, and certification; taking into account the requirements of the Environmental Health Service and the Authority.

The Public Analyst Laboratories (PAL) shall operate to the agreed procedures as outlined in the 'Public Analysts' National Policy on Designation and Reporting of Analytical Results for Official Food samples".

For the purposes of this Service Contract, 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 laboratories within the Food Safety Laboratory Service shall notify immediately the Official Agency and/or the Authority that submitted the sample for analysis as appropriate, in line with the requirements of Article 38(1) of Regulation (EU) 2017/625 and S.I. No. 79 of 2020.

Notifications to the Authority shall be as per procedures agreed with the Authority.

4.4.6 Specialisation
The Food Safety Laboratory Service shall agree and implement the specialisations within the Food Safety Laboratory Service. This shall be done having taken into account the sampling and analytical requirements of the Environmental Health Service and the Authority.

4.4.7 Subcontracted Testing
The Food Safety Laboratory Service shall work to ensure any arrangements for subcontracting are in line with the requirements of Regulation (EU) 2017/625 and ISO/IEC 17025:2017. Where subcontracting is carried out the Food Safety Laboratory Service will subcontract to another official laboratory where available. The Authority shall be informed of such subcontracting.

Where an Official laboratory of the Food Safety Laboratory Service subcontracts testing to another laboratory the official laboratory shall have a written agreement with the subcontracted laboratory detailing the services and standards to be provided in accordance with its documented procedures for sub-contract testing in their quality management system.

Results from subcontracted tests shall be reported through the LIMS extracts in line with the procedures agreed through the LIMS Administrators Working Group. The Authority shall be informed of such subcontracting and subcontracted tests should be clearly identifiable on the extract to the Authority.

4.4.8 Retrospective Surveillance Data
The Official Agency shall provide relevant retrospective surveillance data to the Authority, in the context of requests from the EU Commission.

4.4.9 Method Development
The Official laboratories of the Food Safety Laboratory Service shall, in agreement with the Authority and subject to available resources, contribute to 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.

The Authority shall receive regular updates on parameters that are undergoing method development or proposals for method development through a standing agenda item for the planned FSAI/PAL and FSAI/OFML Liaison meetings.

4.4.10 Cross Agency Laboratory Working
The official laboratories will work with the Authority, other official laboratories and national reference laboratories on a cross agency basis to implement Regulation (EU) 2017/625.

4.4.11 Audits of Official Laboratories
The official laboratories of the Food Safety Laboratory Service will 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 status as an official laboratory.

4.4.12 Other Tasks

The Official Agency shall make arrangements for official controls or other official activities to be undertaken in areas not covered by Schedule 2 by agreement with the Authority.

4.5 National Reference Laboratories

4.5.1 Introduction

National Reference Laboratories (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.

4.5.2 Designated National Reference Laboratories

The National Reference Laboratories designated by the Official Agency shall carry out the responsibilities and tasks of National Reference Laboratories as per Clause 4.5.3.

The Minister for Health has designated the National Reference Laboratories in accordance with Article 100 of Regulation (EU) 2017/625. The National Reference Laboratories are listed in Section 2 of Schedule 3.

4.5.3 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.

4.5.3 Authority Support

The Authority will actively support the Food Safety Laboratory Service in its various official control and National Reference Laboratory roles.

5. Monitoring

Section 5 outlines 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 shall nominate person(s) responsible for the operation of the Official Agency's contract to liaise with the Enforcement Policy Manager in the Authority who shall be the Official Agency's contact point(s) 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 the Official Agency's contact point(s), the Enforcement Policy Manager and/or the Director. Issues may be escalated as required up to the Chief Executive of the Authority or equivalent for the Official Agency.

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:

- FSAI-HSE Management Liaison Meetings: **Three per year**
- FSAI-FSLS OFML Group: **Two per year**
- FSAI-EHS-FSLS OFML Group: **Two per year**
- FSAI-FSLS PAL Group: **Two per year**
- FSAI-EHS-FSLS PAL Group: **Two per year**
- FSAI-EHS Audit Group: **Two per year**
- FSAI-National PEHO Meeting: **One per year**
- FSAI-HSE Public Health Nutrition meeting: **One per year**
- FSAI-EHS Training Group: **One per year**
- FSAI-EHS Technical Liaison Meeting: **One per year**
- Bilateral and Cross Agency Meetings: **Frequency by agreement**
- Ad-Hoc and Expert Working Groups: **Frequency by agreement.**

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

5.2 Access

The Official Agency carrying out functions under this service contract shall be acting on behalf of and as an agent for the Authority. 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. Officers of the Official Agency shall have access as required through the liaison link to records relevant to the Official Agency held by the Authority.

5.3 Verification

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

For those services accredited in line with ISO/IEC 17025:2017, the Food Safety Laboratory Service of the Official Agency will inform the Authority on request of the results of the external audits of those services, insofar as they relate to this Service Contract.

Results of external audits of other services relevant to the contract will be provided by the Official Agency to the Authority if requested. The Authority will take account of these external audits.

5.4 Review

The Authority will review the delivery of this service contract and provide feedback to the Official Agency in an appropriate manner which will include a report on the delivery of the service contract measures of performance in Appendix 1, the outcomes of the service contract work plans in Appendix 2 and the results of audits. Recommendations made by the Authority regarding the scope for better co-ordination and delivery of those food control services will be considered by the Official Agency management.

Schedule 3

1. Resources

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

1.1 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 will provide staff and all resources required to ensure delivery of service outputs/activity as outlined in Schedule 2 subject to the provisions of Schedule 2, Section 1.1.

The Official Agency shall ensure that they:

(i) Have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and other official control duties can be carried out efficiently and effectively.

(ii) Have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official control duties efficiently and effectively.

1.2 Staffing Resources

The Official Agency shall detail the staffing resources to be provided annually for the purposes of this Service Contract in the following tables.

1.3 Environmental Health Service

The Environmental Health Service staffing resources are as follows:

Table 1: Environmental Health Service

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
EHS National		
PEHO		
SEHO		
EHO		
Administrative		
Total:		

1.4 Food Safety Laboratory Service

1.4.1 The Public Analyst Laboratories

The Public Analyst Laboratories included in this service contract are listed below:

Table 1: Public Analyst's Laboratory, Sir Patrick Duns Hospital, Grand Canal Street, Dublin
Table 2: Public Analyst's Laboratory, St. Finbarr's Hospital, Cork
Table 3: Public Analyst's Laboratory, Galway University Hospital.

Table 1: Public Analyst's Laboratory, Dublin

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 2: Public Analyst's Laboratory, Cork

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 3: Public Analyst's Laboratory, Galway

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

1.4.2 The Official Food Microbiology Laboratories

The Official Food Microbiology Laboratories included in this service contract are listed below:

Table 1: Public Health Laboratory, Limerick,
Table 2: Public Health Laboratory, Sligo University Hospital
Table 3: Public Health Laboratory, Waterford Regional Hospital, Waterford
Table 4: Public Analyst`s Laboratory, Sir Patrick Duns Hospital, Grand Canal Street, Dublin
Table 5: Public Health Microbiology Laboratory, St Finbarr's Hospital, Cork
Table 6: Public Health Microbiology Laboratory, Cherry Orchard Hospital, Dublin
Table 7: Public Health Microbiology Laboratory, Galway University Hospital

Table 1: Public Health Laboratory, Limerick

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 2: Public Health Laboratory, Sligo University Hospital

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 3: Public Health Laboratory, Waterford Regional Hospital, Waterford

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 4: Public Analyst`s Laboratory, Sir Patrick Duns Hospital, Grand Canal Street, Dublin

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 5: Public Health Microbiology Laboratory, St Finbarr's Hospital, Cork

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 6: Public Health Microbiology Laboratory, Cherry Orchard Hospital, Dublin

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

Table 7: Public Health Microbiology Laboratory, Galway University Hospital

Grade/Title *(Please List)*	**Staff Engaged in any Food Safety/Control Activities**	
	Total *(Number of Staff)*	**Whole Time Equivalent** *(WTE)*
Management (Scientific)		
Scientific/Technical		
Administration		
Ancillary		
Total		

2. National Reference Laboratories

The Minister for Health has designated the following laboratories outlined in Table 1 from the Food Safety Laboratory Service as National Reference Laboratories (NRLs) in accordance with Article 100 of Regulation (EU) 2017/625:

Table 1: Laboratories from the Food Safety Laboratory Service Designated as National Reference Laboratories

Laboratory	National Reference Laboratory with Responsibility For:
Public Analyst's Laboratory, HSE, Dublin	Materials and articles intended to come into contact with foodstuffs
	Mycotoxins and Plant Toxins in food
	Processing Contaminants in food
Public Analyst's Laboratory, HSE Cork	Metals and Nitrogenous Compounds

Schedule 4

1. Data and Information Collection and Reporting

1.1 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 with the Authority (subject to the Data Protection Acts).

A file is to be maintained for each food business under the supervision of the Official Agency. The Official Agency shall maintain an electronic up to date national list of all food establishments which are under HSE supervision. This list will record the registration or approval status of each establishment. Data collected shall be maintained and all records kept up to date. Records relevant to this Service Contract will be kept for a minimum of five years.

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 by the Official Agency are as follows, unless otherwise agreed:

(i) Notify and submit copies to the Authority of enforcement notices and orders served under the Food Safety Authority of Ireland Act 1998, S.I. No. 79 of 2020 or other food legislation, and outcomes of legal proceedings in line with agreed procedures and legislative requirements

(ii) Section 48(8) annual report as specified in the agreed controlled document by 31st March each year

(iii) The national list of all establishments under the Official Agency supervision as outlined above will be provided to the Authority in Excel, at six monthly intervals.

(iv) The Food Safety Laboratory Service shall provide the Authority with the agreed electronic LIMS dataset transmissions including all tests/analysis undertaken for the purposes of this Service Contract. The frequency of the LIMS transmissions will remain weekly as agreed.

(v) Data on safeguard and emergency measures as required under EU legislation.

(vi) Summary Reports in the format specified in the agreed controlled document.

(vii) Ad-hoc reports, where necessary, on activities carried out under the contract shall be provided without undue delay.

(viii) Updates on corrective actions taken in response to findings of audits by the Authority, third countries and the European Commission's DG Health and Food Safety, to be provided at agreed intervals.

(ix) Annual report on the internal audit activities of the HSE services covered by this Service Contract as outlined in Schedule 2, Clause 1.24

(x) The annual work plans as they relate to this Service Contract which will be agreed with the Authority for each calendar year to which a plan applies.

1.2 Resources

Schedule 3 shall be updated and submitted to the Authority on an annual basis.

The Official Agency shall maintain a current electronic list of authorised, designated and liaison officers. The list shall include names, contact addresses, telephone numbers and email addresses for all officers.

The Official Agency shall maintain an up-to-date list of laboratories (Food Safety Laboratory Service) used for testing and analysis under the legislation listed in Schedule 1. This list shall be provided to the Authority and amended as changes arise.

2. Reporting on Food Related Official Controls and Other Official Activities Undertaken Outside of Returns Outlined under Sections 1.1 and 1.2 of Schedule 4

The Official Agency will record and submit to the Authority annually, in a format to be agreed through the national liaison committee details of:

a. Food complaints
b. Food poisoning incidents – sporadic and outbreaks
c. Staff training and development undertaken by staff.
d. Hygiene education activities undertaken.
e. Complaints regarding implementation of this Service Contract
f. Outdoor events
g. Additional food control activities as agreed.

All dataset requirements to be agreed.

a. Safeguard decisions.

The Official Agency will record and submit to the Authority as necessary details of activity relating to:

a. Foodborne outbreaks
b. Food incidents
c. Food alerts
d. Administrative assistance.

Schedule 5

1. Auditing the Service Contract

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

1.1 Legal Basis

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

1.2 General Requirements

The Authority's audits will verify 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 (MANCP) 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. Where the Official Laboratories have been audited by INAB the outcome of these audits will be shared with the Authority where relevant and every effort will be made to ensure no cross-over or duplication between these audits.

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

1.3 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. As part of its planning process the Authority will take due regard of internal audits planned or carried out by the Official Agency as detailed in Clause 1.24 of Schedule 2 of the contract.

The Authority's audit programmes shall be circulated at a minimum of every 12 months following the commencement of the contract.

1.4 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.

1.5 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.

1.6 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 by food business

operators 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.

Appendix 1: Measures of Performance of the Service Contract

Clause Number	Title	Key Deliverable
1.2	Official Controls and Other Official Activities	Inspections and audits carried out in accordance with prescribed frequencies
1.4	Multi Annual National Control Plan (MANCP)	Official Agency input received for MANCP, and annual report produced on time and in correct format
1.5	Effectiveness and Appropriateness of Official Controls and Other Official Activities	Control verification procedures in place
1.6	Documented Control Procedures	Relevant procedures provided to the Authority on request
1.10	Coordinated Monitoring, Coordinated Control Programmes, Information and Data Collection	Official Agency activities carried out as specified
1.13	Participation on Working Groups	Official Agency staff participate as specified
1.14	Fraudulent and Deceptive Practices Related to the Food Chain	Programme agreed and implemented
1.15	Annual Work Plans	Work plan in Appendix 2 (as applicable) agreed and implemented
1.16	Information Systems	Data shared as specified
1.17	Data Collection and Information and Reporting	Data shared as specified
1.18	Import Controls for Products of Non-Animal Origin and Food Contact Materials	Official controls carried out and reported on as specified
1.20	Designated Officers	Official Agency staff nominated and notified to the Authority
1.21	Authorisation	Official Agency staff authorised

1.22	Training and Continuous Professional Development	• Annual training plans in place • Annual meeting held with Environmental Health Service at which training plans reviewed • HSE staff participates in e-learning as appropriate to their area.
1.23	Commission Controls and Third Country Audits	• Official Agency to participate in missions and audits by third countries where appropriate • Official Agency to close out and/or implement recommendations as appropriate.
1.27	Official Certification	Certs issued and reported as per Schedule 4
1.31	Second Expert Opinion	In conjunction with the Authority develop procedures and guidelines to facilitate the provision of second expert opinion
1.32	Distance Communication	In conjunction with the Authority develop procedures to sample goods offered for sale by means of distance communication
2.2.2	Inspections of Food Business Establishments and/or Operators Subject to Notification under Regulation (EC) No 852/2004	Inspections carried out as specified and reported as per Schedule 4
2.2.3	Inspections of Food Business Establishments and/or Operators Subject to Approval under Regulation (EC) No 853/2004	
3.3	Sampling Plans	• Annual sampling plans in place • Sampling and testing carried out as per sampling plans
4.4.2	Accreditation	• Accreditation maintained as per ISO/IEC 17025:2017 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 • Updates provided to the Authority.

4.4.5	Reporting, Designation and Certification	• Consistent approach among OFMLs developed and implemented in all laboratories • The PALs shall operate to the agreed procedures as outlined in "*Public Analysts' National Policy on Designation and Reporting of Analytical Results for Official Food samples"*.
Schedule 3	Resources	• Staff and resources provided as per Schedule 3 • Updates provided to the Authority as per Schedule 4
Schedule 4	Data Collection and Reporting	Data and reports provided to the Authority as specified.

Appendix 2: Service Contract Annual Work Plans - Template for Official Controls of Schedule 1 Food Legislation (Schedule 2, 2.2.4)

Food Legislation Category *(may be revised by agreement)*	**Business Type(s)** *(where legislation is applicable)*	**Point at which Official Controls and Other Official Activities should take place**		
		Inspection	**Sampling**	**Frequency of Official Control to be Specified in Annual Work Plans**
Microbiological Criteria				
Emergency Measures and Import Control				
Specified Risk Material				
Food Information for Consumers (FIC)				
Meat Labelling				
Fish Labelling				
Olive Oil Labelling				
Alcohol Labelling				
Miscellaneous Products Labelling				
Zoonoses				
Contaminants				
Food Additives				
Food Flavourings				
Food Enzymes				

Materials in Contact with Foods (Food Contact Materials)				
Food Supplements				
Food Fortification				
Foods for Specific Groups: • Infant formula and follow-on formula • Processed cereal based food and baby food • Food for special medical purposes • Total diet replacement for weight control.				
Foodstuffs Treated with Ionising Radiation				
Novel Foods				
GMOs				
Nutrition and Health Claims				
Packaged Water				
Animal by Products				
Food Authenticity				