

Consultation Information

Title: Consultation on the appropriate criteria for recognition of appropriately qualified experts for the purpose of documentary review for food businesses subject to official controls by the Health Service Executive, provided for in Article 35(1) of Regulation (EU) 2017/625.

Start date of consultation: 21/09/2020

Closing date: 12/10/2020

Consultation details: (Insert summary details/issues for comment)

[The Official Control Regulation \(EU\) 2017/625](#) provides the legal basis for how competent authorities in Ireland enforce food legislation, protect consumers and provide appropriate rights to food businesses. Regulation (EU) 2017/625 has applied since 14 December 2019 and replaces the existing official controls legislation, Regulation (EC) No 882/2004. Further detailed information on Regulation (EU) 2017/625 and official controls is available on the [FSAI website](#).

For food businesses supervised by the Health Service Executive (HSE), Regulation (EU) 2017/625 is implemented in Ireland under the [European Union \(Official Controls in Relation to Food Legislation\) Regulations 2010 - S.I. No. 79 of 2020](#). In accordance with Article 35 of Regulation (EU) 2017/625 and Regulation 12 of S.I. No. 79 of 2020, food businesses whose animals or goods are subject to sampling, analysis, testing or diagnosis in the context of official controls by an environmental health officer (EHO) of the Environmental Health Service (EHS) of the HSE should have the right to a second expert opinion (SEO), at their own expense:

Please note that the EHS of the HSE or the official laboratory as defined in Regulation 2 of S.I. No. 79 of 2020 will not charge food businesses for their time and cooperation in matters related to SEO. However, food businesses must appoint and if required, pay for their own recognised and appropriately qualified expert for the purposes of documentary review and pay for all their own expenses related to this. Additionally, should a food business have their own sample analysed, tested or diagnosed by another laboratory that expense is borne by the food business.

The right to a SEO shall allow the food business to request a documentary review by another recognised and appropriately qualified expert of the initial sampling, analysis, test or diagnosis, and a second analysis, test or diagnosis of the parts of the sampling material taken initially, unless any such second analysis, test or diagnosis is technically impossible or irrelevant.

When a SEO is requested by a food business, it will always involve a documentary review of the sampling, analysis, testing or diagnosis, by another recognised and appropriately qualified expert appointed by and at the expense of the food business. What this means in practice is that the food business can appoint their own expert to examine the documented procedures followed by the HSE involved in the sampling, analysis, testing or diagnosis of the sample *i.e. documentary review*.

Under Regulation 12(3) of S.I. No. 79 of 2020, the Food Safety Authority of Ireland (FSAI) is obliged to publish guidelines in relation to the recognition of appropriately qualified experts for the

purpose of documentary review. As such, the FSAI has deemed it necessary to seek views on what are the best practice criteria for the recognition of appropriately qualified experts for the purpose of documentary review provided for in Article 35(1) and 35(3) of Regulation (EU) 2017/625, for food businesses subject to official controls by the HSE.

The food businesses that are relevant for this consultation are all HSE supervised food businesses, including those operating in these areas:

- Food retail
- Food service and catering outlets including hotels, restaurants, hospitals, nursing homes and caterers
- Food wholesalers or distributors
- Manufacturers of foods of non-animal origin
- Third country importation of foods of non-animal origin, subject to HSE controls.

From the perspective of the FSAI and the HSE, a recognised and appropriately qualified expert is a person accepted as having the necessary qualifications and experience to complete a documentary review as part of second expert opinion on behalf of a food business.

Views are being sought by the FSAI on the following proposed best practice criteria to assist food businesses in choosing a recognised and appropriately qualified expert for the purpose of a documentary review.

Proposed Best Practice Criteria

Proposed best practice criteria are set out below to assist food businesses in choosing a recognised and appropriately qualified expert for the purpose of a documentary review.

- a) A person who has an appropriate scientific qualification
- b) A person who is or has been trained and has practical experience or knowledge. Criteria as appropriate to the specific documentary review include:
 - In food sampling
 - The specific method of analysis, test or diagnosis or group of such methods
 - The interpretation of legislation requirements and criteria, specific results and the appropriate follow-up action
 - The examination and auditing of sampling techniques and programmes
 - A laboratory which operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with [Regulation \(EC\) No. 765/2008](#).

Please note that the above proposed criteria do not preclude the food business from being the expert themselves. However, the FSAI and/or official agency reserves the right to object to the

appointment of an expert on the basis of their qualifications and experience, if it deems that the expert is not appropriately qualified.

Submissions to the consultation

If you are making a submission, please state whether the views expressed are personal or are being made on behalf of an organisation. If the views submitted are on behalf of an organisation, the name of the organisation should be clearly stated.

Submissions may be e-mailed to: consultation@fsai.ie

or

Posted to the following address:

Consultations
Food Safety Authority of Ireland
The Exchange
George's Dock
IFSC
Dublin 1
D01 P2V6

Feedback:

As set out under Regulation 12(3) of S.I. No. 79 of 2020, the FSAI will publish guidelines in relation to the recognition of appropriately qualified experts for the purpose of documentary review. These guidelines will be freely available on the FSAI website once agreed.

Personal Data

Any personal data, within the meaning of the General Data Protection Regulations, 2018, the Data Protection Act, 2018, and any Regulations made under that Act, submitted as part of the consultation process, will be treated in line with the requirements of these Regulations/Acts.

Personal identifying information contained in submissions will not be published in accordance with the General Data Protection Regulations, 2018, the Data Protection Act, 2018, and any Regulations made under that Act, as well as the Freedom of Information Act, 2014.