

# Guidelines in Relation to the Recognition of Appropriately Qualified Experts for the Purposes of a Documentary Review

Under the European Union (Official Controls in Relation to Food Legislation) Regulations, 2020 (S.I. No. 79 of 2020)



# **Guidelines in Relation to the Recognition of Appropriately Qualified Experts for the Purposes of a Documentary Review under the European Union (Official Controls in Relation to Food Legislation) Regulations, 2020 (S.I. No. 79 of 2020)**

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## **1. Background**

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. The Regulation came into force in Ireland on the 14 December 2019.

For food businesses supervised by the Health Service Executive (HSE), Regulation (EU) 2017/625 is given effect in Ireland by the [European Union \(Official Controls in Relation to Food Legislation\) Regulations, 2020 \(S.I. No. 79 of 2020\)](#).

In accordance with Article 35 of Regulation (EU) 2017/625 and Regulation 12 of S.I. No. 79 of 2020, an authorised officer of the Health Service Executive shall when purchasing or taking a sample (in the context of official controls), and if so requested by the operator or the person in apparent charge or control of the food or relevant thing, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the documentary review referred to in Article 35(1) and (3) of Regulation (EU) 2017/625, should that prove necessary.

For the purposes of a documentary review, a food business has to appoint and use their own recognised and appropriately qualified expert at their own expense. Neither Regulation (EU) 2017/625 nor S.I. No. 79 of 2020 define what a recognised and appropriately qualified expert is, or the required educational background, professional qualities, training or experience required to undertake such a role.

However, under Regulation 12(3) of the European Union (Official Controls in Relation to Food Legislation) Regulations, 2020 (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 a documentary review. This short guidance is designed to assist a food business in appointing their own recognised and appropriately qualified expert for the purposes of documentary review.

## 2. Best Practice Criteria

Criteria are set out below to assist food businesses in choosing a recognised and appropriately qualified expert <sup>1</sup> for the purpose of a documentary review under the European Union (Official Controls in Relation to Food Legislation) Regulations, 2020 (S.I. No. 79 of 2020).

- a) A person who has a relevant scientific qualification
- b) A person who is or has been trained and has practical experience or knowledge of (*criteria as appropriate to the specific documentary review*):
  - Food sampling, analysis, test or diagnosis
  - 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
  - A laboratory which operates in accordance with the standard ISO/IEC 17025:2017 and is accredited in accordance with that standard by a national accreditation body operating in accordance with [Regulation \(EC\) No. 765/2008](#).

**Note 1:** The above criteria do not preclude the food business from being the expert themselves.

**Note 2:** The official agency reserves the right to determine, on the basis of the criteria laid out in this document, if an expert appointed by a food business for the purpose of second expert opinion is a recognised and appropriately qualified expert. Any objections to the appointed expert will be noted by the official agency and communicated to the food business before the second expert opinion process begins. This objection does not preclude the food business from using the said expert.

**Note 3:** The official agency will record all correspondence with a food business related to the recognition of an expert for the purpose of documentary review. This will ensure detail is captured correctly in relation to any objection to an expert by the official agency.

**Note 4:** The food business may only appoint one expert for the purposes of documentary review as per Article 35 (1) of Regulation (EU) 2017/625.

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<sup>1</sup> An official certificate given in accordance with Regulation 16(1) of S.I. No. 79 of 2020 shall be evidence of the matters contained therein until the contrary is shown. The official result provided by the official laboratory shall be regarded as the prima facie evidence and that result forms the basis for the actions taken by the Health Service Executive and/or the Food Safety Authority of Ireland in managing the non-compliance.

### 3. Recognised and Appropriately Qualified Experts

Examples of persons who might meet the criteria for a recognised and appropriately qualified expert could include a person belonging to a EU Member State professional body with competencies in the concerned area, retired staff from official laboratories or a person with an auditing background who would be familiar with auditing systems, examining documents and protocols.

Some examples (non-exhaustive list) are given below of persons who might fit the proposed criteria:

- An approved examiner<sup>2</sup> as defined in S.I. No. 79 of 2020, including approved examiners from the Official Laboratories and from the National Reference Laboratories
- An equivalent approved examiner in other equivalent legislation *e.g. approved examiners from the State Laboratory, Marine Institute etc.*
- An international expert with qualifications equivalent to the above
- A retired approved examiner qualified as above
- A scientist with equivalent qualifications and experience to an approved examiner working in an accredited laboratory conducting similar analysis and reporting in a similar manner *i.e. in line with legislation*
- A subject-matter expert akin to the regular accreditation specialists the official laboratories deal with on a regular basis.

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<sup>2</sup> An approved examiner means a chief medical scientist located at an official laboratory, a consultant microbiologist located at an official laboratory, a deputy public analyst located at a public analyst's laboratory, an executive analytical chemist located at a public analyst's laboratory or a public analyst located at a public analyst's laboratory or a person, or member of a class of persons, designated by the Minister pursuant to Regulation 17 of S.I. No. 79 of 2020.



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