

**Guidance for Food Business
Operators Supervised by the Health
Service Executive on their Right to
Second Expert Opinion**

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

T +353 1 817 1300
E info@fsai.ie

www.fsai.ie

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Version History

Version	Date	Change
Final	03.05.2022	

Glossary

The following definitions are provided for the purposes of reading this guidance:

Approved examiner as per [Regulation 2 of S.I. No. 79 of 2020](#)

Authorised officer as per Regulation 2 of S.I. No. 79 of 2020

Another analysis means another analysis, test or diagnosis by another official laboratory as per Article 35(3) of Regulation (EU) 2017/625.

Analysis, test or diagnosis means all documents related to the laboratory report, in which the official laboratory reports the day, and the place where the analysis, test or diagnosis was performed. In addition, the analytical methods, results obtained, and findings related to those results as well as all other pertinent documents and details in relation to the analysis performed *e.g. receipt, handling, storage, analysis, reporting and designation of results*.

Dispute means cases where, following a documentary review under Article 35(1) of Regulation (EU) 2017/625, there is a request by a food business for a second documentary review of the initial analysis, test or diagnosis and where appropriate, another analysis, test or diagnosis by another official laboratory as per Article 35(3) of Regulation (EU) 2017/625.

Distance Communication as per [Article 2 of Regulation \(EU\) No. 1169/2011](#)

Food (or foodstuff) as per [Article 2 of Regulation \(EC\) No. 178/2002](#)

Food business means the food business operator or the person in apparent charge or control of a sample at the time of sampling.

Official Agency as per Regulation 2 of S.I. No. 79 of 2020

Official Laboratory as per Regulation 2 of S.I. No. 79 of 2020

Official Control Sample as per Regulation 11 of S.I. No. 79 of 2020

Own expense means a food business bearing all applicable costs associated with their right to a second expert opinion under Article 35 of Regulation (EU) 2017/625.

Operator as per Regulation 2 of S.I. No. 79 of 2020

Record as per Regulation 2 of S.I. No. 79 of 2020

Relevant thing as per Regulation 2 of S.I. No. 79 of 2020

Recognised and Appropriately Qualified Expert means an expert 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.

Sample means a food and/or a relevant thing.

Sampling and Analysis mean the sampling, analysis, test or diagnosis in the context of official controls.

Second analysis means a food business carrying out their own analysis, test or diagnosis at another laboratory of their choice, on a quantity of a sample which is taken on request by the food business by an authorised officer of the official agency.

Note: *The right to a second analysis is predicated on the authorised officer deeming it relevant, appropriate and technically feasible to take the additional quantity of the sample if requested to do so by the food business as per Article 35(2) of Regulation (EU) 2017/625.*

Sufficient Quantity means a quantity of sample which allows for a second analysis by a food business as per Article 35(2) of Regulation (EU) 2017/625 and another official analysis as per Article 35(3) of Regulation (EU) 2017/625, should this prove necessary.

Second Expert Opinion is providing a food business with their rights under Article 35 of Regulation (EU) 2017/625.

1. Scope

This guidance will provide food businesses with information about their right to a Second Expert Opinion (SEO) and how their right to a SEO is facilitated by the Health Service Executive (HSE).

This guidance is applicable to all food businesses supervised by the HSE.

This guidance is based on Article 35 of [Regulation \(EU\) 2017/625 on Official Controls and Other Official Activities \(OCR\)](#) and [Regulation 12 of the European Union \(Official Controls in Relation to Food Legislation\) Regulations 2020, S.I. No. 79 of 2020](#).

This guidance does not specifically address SEO as it applies to distance communication under Article 36 of the OCR.

Food businesses should always check the [Food Safety Authority of Ireland](#) (FSAI) website for the latest version of this guidance.

2. Background

The Official Controls Regulation (OCR) provides the legal basis for how the competent authorities in Ireland enforce food legislation, protect consumers and provide appropriate rights to food businesses. The OCR came into force in Ireland on the 14th of December 2019.

For food businesses supervised by HSE, the OCR is implemented in Ireland under the European Union (Official Controls in Relation to Food Legislation) Regulations 2020, S.I. No. 79 of 2020.

In the context of routine official controls carried out by Environmental Health Officers (EHOs) of the Environmental Health Service (EHS) of the HSE, *i.e. taking of samples under Regulation 11 and 14 of S.I. No. 79 of 2020* a consistent set of steps in relation to the right to a SEO for food businesses will be followed and is set out in this guidance.

3. Second expert opinion

A Second Expert Opinion (SEO) provides food businesses (at their own expense) with the right to:

1. A documentary review of the sampling, analysis, test or diagnosis by a recognised and appropriately qualified expert as per Article 35(1) of the OCR. This involves the food business appointing their own expert to carry out a review of documents and records related to how the official sampling, analysis, test or diagnosis was carried out by the HSE when carrying out official controls in that food business.
2. A request at the time of sampling where relevant, appropriate and technically feasible, that a sufficient quantity of sample is taken to allow for a second analysis by the food business and another analysis, test or diagnosis by another official laboratory should this prove necessary in the case of a dispute. As regards a food business request for a sufficient quantity of sample to be taken, to allow for a second analysis, the following should be noted:
 - (i) The food business is obliged to witness the sampling process if they request a second analysis.
 - (ii) The food business sample for a second analysis is not regarded as an official control sample.
 - (iii) The HSE official laboratory certificate of analysis is taken as '*Prima Facie*' evidence until the contrary is shown.
 - (iv) The food business is responsible for their sample and any storage, or disposal required including all costs incurred in having that sample analysed by a laboratory of their choice.
 - (v) The food business is advised to have their sample analysed by a laboratory that uses an accredited method for that analysis. The [Irish National Accreditation Board](#) (INAB) has a list of accredited laboratories available in Ireland on its website.
 - (vi) The food business is advised there will be circumstances when an EHO will not be able to facilitate a request for a sufficient quantity of sample for a second analysis to be taken. A non-exhaustive set of circumstances are outlined in Appendixes 1 to 3 of this document
 - (vii) As per Regulation 13 of S.I. No. 79 of 2020, when an EHO purchases or takes a sample of food pursuant to Regulation 11 of S.I. No. 79 of 2020 for the purpose of proceedings for an offence under food legislation and where the division of the sample is reasonably practicable, will divide the sample into three approximately equal parts called the enforcement, trade (defence) and referee samples. In this case for the purposes of SEO:

- a. The enforcement sample will be used for the official HSE analysis by the official control laboratory.
 - b. The trade (defence sample) will be provided to the food business to allow the food business to perform their own (second) analysis of the sample.
 - c. The referee sample is held by the authorised officer (EHO) to be used where another analysis by another official laboratory is required *e.g. requested by a court in legal proceedings*. The referee sample will also be used where another analysis test or diagnosis by another official laboratory is requested by the food business as per Article 35(3) of the OCR.
3. In the case of a dispute, a documentary review of the initial analysis, test or diagnosis and where appropriate another official analysis, test or diagnosis by another official laboratory as per Article 35(3) of the OCR will be carried out. This process will involve the food business requesting that another official laboratory examines relevant documents and records related to the initial analysis, test or diagnosis carried out by the HSE official laboratory involved in official controls and where appropriate, another analysis, test or diagnosis by another official laboratory.

Food businesses should note that in accordance with Article 35(4) of the OCR the application by a food business for a SEO under Article 35(1) of the OCR shall not affect the obligation of the competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or to animal welfare or, as regards GMOs and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2) of the OCR.

4. Expenses associated with second expert opinion

A key aspect to the right of a SEO under Article 35 of the OCR, is that the food business must bear all relevant expenses associated with using that right. These expenses include the following:

1. All expenses related to the food business appointing a recognised and appropriately qualified expert for the purposes of documentary review as per Article 35(1) of the OCR.
2. All expenses related to the food business having their own sample (Second sample) analysed, tested or diagnosed by another laboratory of their choice as per Article 35(2) of the OCR.
3. All expenses related to a food business requesting a documentary review of the initial analysis test or diagnosis and where appropriate another official analysis test or diagnosis by another official laboratory as per Article 35(3) of the OCR.

Food businesses should note that expenses will vary depending on expert chosen, laboratories used and the parameter(s) to be monitored. Food businesses should ensure that the work they commission is appropriate and fit for purpose.

5. Experts used in documentary review

To assist food businesses in appointing a recognised and appropriately qualified expert, the FSAI in line with Regulation 12(3) of S.I. 79 of 2020, has published [*Guidelines in relation to the recognition of appropriately qualified experts for the purposes of a documentary review.*](#)

Food businesses should always check the [FSAI website](#) for the latest version of this guidance.

Food businesses should note that the HSE reserves the right to object to a recognised and appropriately qualified expert appointed by the food business. Any objections to the recognised and appropriately qualified expert will be noted by the HSE and communicated in writing to the food business on receipt of the details of the expert and before the documentary review process begins. However, any HSE objection does not preclude the food business from using their chosen expert.

Food businesses should note that when a documentary review is requested, it is the responsibility of their appointed expert, or the other official laboratory to specify in writing what documents they'd like to examine in the course of the documentary review.

6. Documentary review

6.1 Documentary review under Article 35(1) of the OCR

In the context of the HSE, a documentary review under Article 35(1) of the OCR has two components:

- Review of the sampling carried out by the EHO and
- Review of the analysis, test or diagnosis by the HSE official laboratory.

Food businesses should note that the right to a documentary review will only be available during the timeframes outlined in this guidance. Where the food business does not follow the timeframes, it will be taken that the SEO process is complete and the rights of the food business in accordance with the OCR have been afforded (Section 6.3).

In relation to any uncontrolled copies of records and documents i.e. printed or physical copies of records and documents, these will only be available to the recognised and appropriately qualified expert to examine during the documentary review and duplication of any records will not be possible.

Food business should note that documents held by the HSE that could contain proprietary information will remain under the control of the HSE during the documentary review.

The relevant persons who will attend the documentary review will be agreed by the HSE and the recognised and appropriately qualified expert/food business. However, it is anticipated that the following would attend a documentary review related to a HSE supervised food business:

1. The recognised and appropriately qualified expert acting for the food business;
2. The food business or its representative;
3. The relevant authorised officer(s) of the EHS (if so required);
4. The Official laboratory involved in analysis, test or diagnosis (if so required);
5. The FSAI representative(s) and other HSE representative(s) (if so required).

Following completion of the documentary review under Article 35(1) of the OCR, the food business will within 10 working days confirm in writing to the Principal Environmental Health Officer (PEHO), that they accept the findings of the official agency or if they are in dispute. If a response is not received within the 10 working days, then it will be taken that the SEO process is complete.

If they are in dispute a documentary review of the initial analysis test or diagnosis, and where appropriate another official analysis test or diagnosis by another official laboratory, can be requested by the food business under Article 35(3) of the OCR (Section 6.2).

A summary of the steps and timelines in the documentary review process under Article 35(1) of the OCR is provided in Figure 1.

Food business should note that all timelines outlined in Figure 1 must be adhered to.

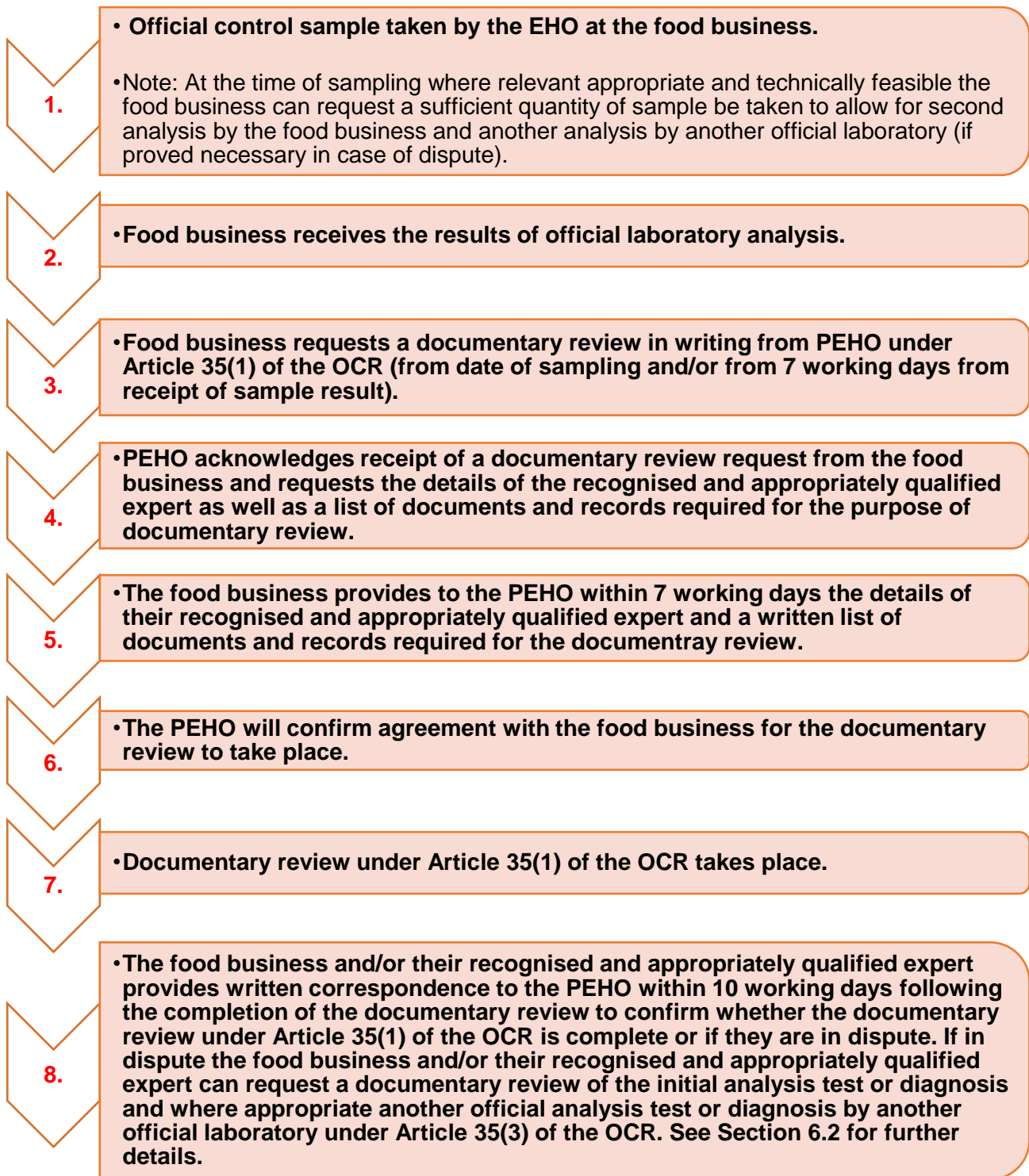


Figure 1 Summary of steps/timelines under Article 35(1) of the OCR

6.2 Documentary review under Article 35(3) of the OCR

In cases where, following a documentary review under Article 35(1) of the OCR, there is a dispute between the food business and the HSE, the food business has a right to request, at their own expense, a documentary review of the initial analysis, test or diagnosis and where appropriate, another official analysis, test or diagnosis by another official laboratory as per Article 35(3) of the OCR and Regulation 12(4) of S.I. 79 of 2020.

Following appropriate correspondence from the food business to the PEHO of a dispute (Section 6.1), the PEHO will make the necessary arrangements with the HSE official laboratory to continue the process of SEO under Article 35(3) of the OCR with the food business.

The HSE official laboratory will within 10 working days of notification of a dispute from the PEHO, provide the food business with details of another *i.e. Second* official laboratory for the purpose of a documentary review of the initial analysis, test or diagnosis and where appropriate, another analysis, test or diagnosis by that second official laboratory as per Article 35(3) of the OCR.

Food business should note that the HSE official laboratory reserves the right to inform and subsequently extend this period of 10 working days depending on the nature of the analysis test or diagnosis required and the process of identifying a suitable (second) official laboratory either in the State or another Member State.

Food business should note that the HSE official laboratory will not provide a choice of official laboratories for the purpose of a documentary review of the initial analysis, test or diagnosis and where appropriate, another official analysis, test or diagnosis under Article 35(3) of the OCR.

Following receipt of the details of a second official laboratory, the food business will have 10 working days to inform the HSE official laboratory in writing, if they wish to proceed with a documentary review by the second official laboratory of the initial analysis, test or diagnosis and where appropriate another analysis, test or diagnosis by that second official laboratory, as per Article 35(3) of the OCR.

Food business should note that if no correspondence is received by the HSE official laboratory from the food business within 10 working days, the process of SEO is complete as regards the HSE responsibilities under Article 35 of the OCR and Regulation 12 of S.I. 79 of 2020.

If correspondence is received by the HSE official laboratory from the food business within 10 working days, the HSE official laboratory will confirm the correspondence with the food business and make the necessary arrangements with the second official laboratory to facilitate Article 35(3) of the OCR.

Food business should note that if requested the HSE official laboratory will provide the food business with an opportunity to view the preparation of the sample to be sent to the second official laboratory or waive their opportunity thereafter.

Food businesses should note that the HSE official laboratory will outline any expenses payable by the food business related to Article 35(3) of the OCR and Regulation 12(4) of S.I. 79 of 2020.

Further details regarding the documentary review and where appropriate another analysis test or diagnosis as per Article 35(3) of the OCR and Regulation 12(4) of S.I. 79 of 2020 will be communicated by the HSE official laboratory to the food business when available.

Food businesses should note that the second official laboratory carrying out the documentary review of the initial analysis and where appropriate another analysis, test or diagnosis as per Article 35(3) of the OCR and Regulation 12(4) of S.I. 79 takes over the function of a 'referee' in cases where there is a dispute between the competent authority e.g. HSE and the food business based on the initial official control analysis and the documentary review under Article 35(1) of the OCR.

A summary of the steps and timelines in the documentary review process under Article 35(3) of the OCR is provided in Figure 2.

Food business should note that all timelines outlined in Figure 2 must be adhered to.

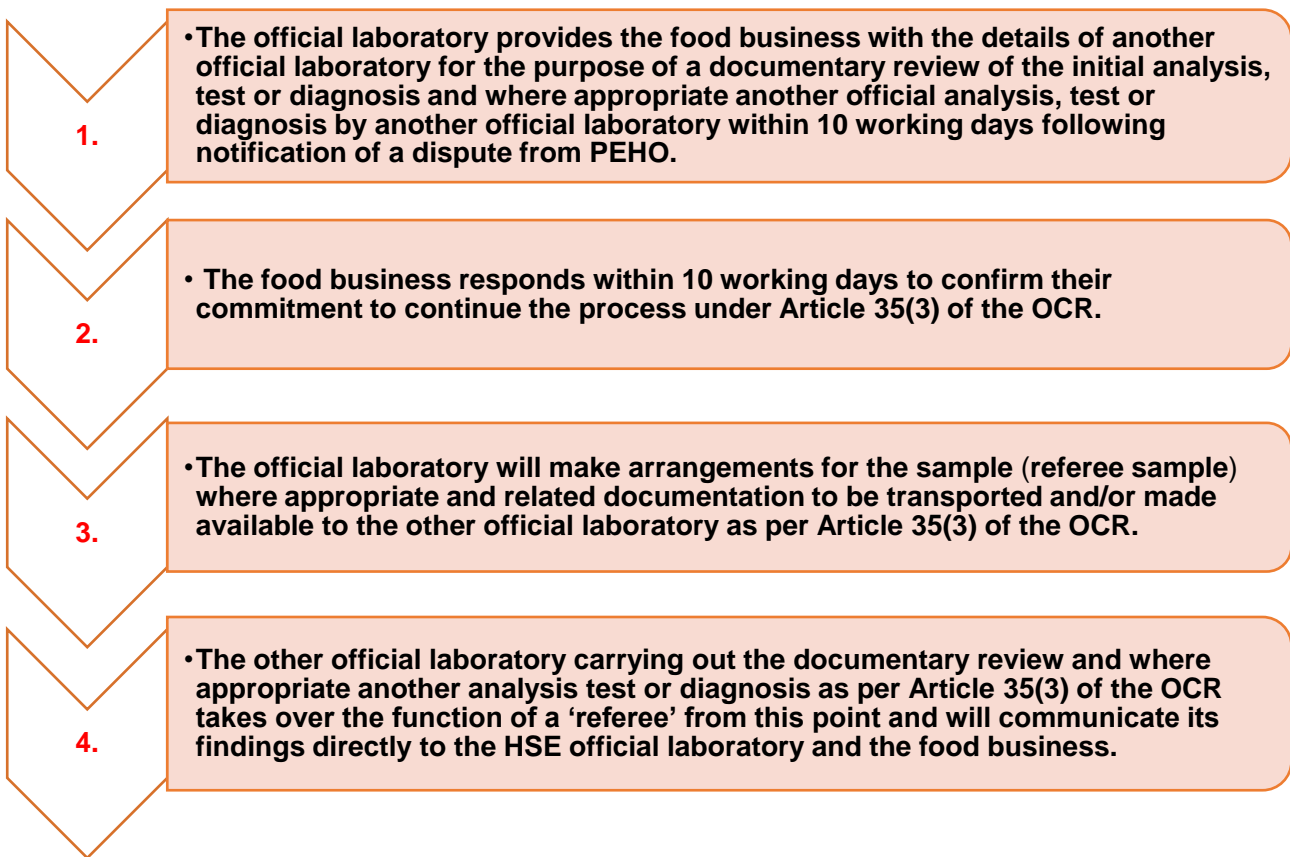


Figure 2 Summary of steps/timelines under Article 35(3) of the OCR

6.3 HSE responsibilities under Article 35 of the OCR

The process of SEO will be complete as regards HSE responsibilities under Article 35 of the OCR and Regulation 12 of S.I. 79 of 2020 if:

1. After receipt of the results of the analysis of the official control sample a request for a documentary review under Article 35(1) of OCR **is not** received by the PEHO within 7 working days.
2. After requesting a documentary review in accordance with Article 35(1) the details of the recognised appropriately qualified expert and a written list of documents and records which are required by the expert for the purposes of documentary review **are not** provided to the PEHO within 7 working days.
3. Following agreement for a documentary review process to take place under Article 35(1) of OCR, the recognised appropriately qualified expert and/or the food business does not attend for the documentary review.
4. No report or correspondence is received by the PEHO within 10 working days of completion of the documentary review in accordance with Article 35(1) of the OCR.
5. A report and/or correspondence is received by the HSE from the food business and/or their recognised appropriately qualified expert within 10 working days, **which does not request** a documentary review of the initial analysis, test or diagnosis and where appropriate, another official analysis, test or diagnosis by another official laboratory in accordance with Article 35(3) of the OCR.
6. Following a dispute, the food business requests a documentary review of the initial analysis, test or diagnosis and where appropriate, another official analysis, test or diagnosis by another official laboratory under Article 35(3) of the OCR and the HSE official laboratory has provided the sample and made available all relevant documentation to the second official laboratory.

Appendix 1 Circumstances under which a second analysis is not possible

This is not an exhaustive list and is provided for information and illustrative purposes only:

1. There is an insufficient quantity or insufficient availability of the sample to be taken by the EHO.
2. The sample is being taken for microbiological analysis.
3. The sample is an environmental or process hygiene swab.
4. A large quantity or number of units of the sample is required.
5. There are strict time and temperature requirements for completing analysis.

Example: Histamine analysis of fish and fishery products.

Note: This does not apply to sampling for histamine in cheese.

6. There are strict time, sampling and analysis requirements.

Example: Bottled water taken for radioactivity analysis which require sampling at the point of bottling and analyses to be completed within 24 hours.

Note: This does not apply to retail samples and the parameters analysed at that stage.

7. There are difficulties surrounding the location and/or circumstances under which the sample is taken.

Example: A delivery to a port or by a transport company where a representative from the food business is not available to decide on taking a sufficient quantity of sample to allow for a second analysis.

8. Where a sample is obtained by means of distance communication.

Note: In the case of these samples Article 36(2)(b) of the OCR only provides for the right to a documentary review of the sampling, analysis, test or diagnosis in accordance with Article 35(1).

9. The sampled material represents a risk if made available to the food business.

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Example: Diseased material or potential bioterrorism agents. However, the taking of sufficient sample quantity for a second official analysis may nevertheless be appropriate in such cases, if the sample is transported, stored and handled under the control of the competent authority and official laboratories.

Appendix 2 Circumstances under which chemical samples are considered not relevant, appropriate and technically feasible for second expert opinion involving a second analysis ¹

Parameter	Matrix	Comments
Alcohol (Ethanol)	Fermented non-alcoholic drinks	Alcohol content can increase over time.
Peanut (Allergen)	All food types	Samples will not be suitable for a second analysis where whole/chopped peanuts are present since there would be a homogeneity issue (i.e. an uneven distribution of peanut in the sample).
Ascorbic Acid (Vitamin C)	<ul style="list-style-type: none"> • Tuna (fresh/defrosted) • Pickled Herring • Sprat. 	Ascorbic acid content may decrease over time.

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Parameter	Matrix	Comments
Biogenic Amines	<ul style="list-style-type: none"> • Fresh and frozen fish • Packaged and canned fish products • Cheese. 	<p>Histamine content may increase during storage and on repeated freezing and re-thawing of samples (e.g. fish and cheese).</p> <p>Histamine may not be evenly distributed in a fish.</p>
Folic Acid	All	Folic acid content may decrease over time.
Food Complaints	All	<p>Examples of samples unsuitable for a second analysis: A sample containing a foreign object; an odour or taste from a sample, peanut in a sample etc.</p> <p>Note: These samples to be reviewed on a case-by-case basis. EHOs will contact the official laboratory for advice on suitability for a second analysis prior to taking the complaint sample.</p>

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Parameter	Matrix	Comments
Food Contact Materials	Some	A large quantity or number of units of the packaging and/or packaged food sample is required, making it not relevant, appropriate and technically feasible to provide the sample.
Freezing Point Depression	Raw, pasteurised, UHT and sterilised whole milk, partially skimmed milk and skimmed milk.	Note: Please see Titratable Acidity.
Furan	All	Due to the volatile nature of the analyte.
Nitrite and Nitrate	Bottled Water	Maximum storage time of 1 day.
Polycyclic Aromatic Hydrocarbons (PAHs)	Bottled Water	Maximum storage time of 7 days.
Sodium Nitrate Sodium Nitrite	Brines	Brine samples unsuitable for long term storage.

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Parameter	Matrix	Comments
Sulphur Dioxide	<ul style="list-style-type: none"> • Frozen Irish and imported prawns and shrimps • Processed potato products (not dehydrated) • Vacuum packed vegetable <i>i.e.</i> potatoes, carrots, parsnips, turnips and cabbage • Sausages including both wrapped/labelled and loose sausages • Minced meat, burgers • Fresh meats and meat products • Draught beers and ciders. 	Sulphur dioxide content decreases in these products over time
Titrateable Acidity	Liquid milk	<p>Note: This parameter will only arise in the case of a complaint or investigation etc. EHOs will contact the official laboratory to discuss the suitability for a second analysis before sampling. Lactic acid increases over time due to naturally occurring <i>Lactobacillus</i> bacteria which convert lactose into lactic acid. Fresh milk samples either in an open or unopened state will become unpalatable <i>i.e.</i> sour with time even under controlled refrigerated storage. The exceptions are UHT</p>

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Parameter	Matrix	Comments
		<p>and sterilised milk products which, if not opened, can have an ambient shelf life of 6-9 months.</p> <p>Note: A second analysis may be possible for UHT products due to their long shelf-life. However, it will be more difficult in the case of liquid milk samples which require refrigeration due to their short shelf-life. In both cases a second analysis would need to be carried out within the shelf-life of the sample and be taken from the same lot/batch stored under the appropriate conditions.</p>
Volatile Organic Compounds (VOCs)	Bottled Water	Volatile compounds

¹ **Please note** that in some circumstances a second official analysis cannot be performed, because no other official laboratory in the EU or EEA has the expertise or equipment to perform the analysis in question. If this circumstance is known prior to sampling; this decision should be justified on the basis of an investigation using, for example, the mechanisms of administrative assistance and cooperation provided for in Articles 102 to 108 and/or available tools provided for by the Commission.

Appendix 3 Circumstances involving parameters for which sampling and analysis legislation already applies

Parameter	Sampling and Analysis Legislation
Erucic Acid	Commission Regulation (EU) 2015/705
<ul style="list-style-type: none"> • Lead • Cadmium • Mercury • Inorganic Tin • Inorganic Arsenic • 3-MCPD & 3-MCPD Fatty Acid Esters • Glycidyl Fatty Acid Esters • PAHs • Perchlorate • Acrylamide 	Commission Regulation (EC) No 333/2007
Mycotoxins	Commission Regulation (EC) No 401/2006
Nitrates (as contaminant only, not additives)	Commission Regulation (EC) No 1882/2006



Food Safety Authority of Ireland

The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300

E info@fsai.ie



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