

# AUDIT REPORT

Audit of Official  
Controls in Bottled  
Water Establishments

Environmental Health  
Service of the Health  
Service Executive

September 2023



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## 1. Glossary

|         |   |
|---------|---|
| CPD     | Continuing professional development   |
| EHIS    | Environmental Health Information System   |
| EHO     | Environmental Health Officer  |
| EHS     | Environmental Health Service  |
| EHSIAU  | Environmental Health Service Internal Audit Unit  |
| EHS KPI | Environmental Health Service Key Performance Indicators   |
| EU      | European Union  |
| FBO     | Food Business Operator  |
| FSAI    | Food Safety Authority of Ireland  |
| FSMS    | Food Safety Management System   |
| HSE     | Health Service Executive  |
| IAU     | Internal Audit Unit   |
| OCR     | Official Control Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended. |

|      |   |
|------|---|
| PAL  | Priority Action List  |
| PEHO | Principal Environmental Health Officer  |
| SEHO | Senior Environmental Health Officer   |
| SOP  | Standard Operating Procedure  |
| GN1  | Guidance Note 1 (Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 3))   |
| GN25 | Guidance Note 25 (Guidance for the assessment of compliance of legislation applicable to natural mineral waters, spring waters and other water (Revision 1) (2019)) |

## 2. Executive summary

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland. This is carried out through service contracts with official agencies. As part of its legal mandate, the FSAI is required to verify that the system of official controls is working effectively. For the purpose of assessing the delivery of official controls in the official agencies, the FSAI conducts an annual programme of audits.

The FSAI completed an audit of the official controls performed by the Environmental Health Service (EHS) of the Health Service Executive (HSE) in bottled water establishments across three regions of the HSE. The audit covered the organisation, planning, implementation, and review of official controls within the EHS at national and regional levels to confirm compliance with official control regulations, food law, service contract requirements and with procedures documented by the EHS. The scope of the audit included assessing the structure and organisation of official controls carried out by the EHS relating to bottled water establishments during 2021 and the relevant period of 2022. It also assessed whether the EHS were complying with the criteria against which the audit was carried out. The scope also included an assessment of compliance with relevant food law in selected bottled water establishments. The scope did not include the recognition of Natural Mineral Waters as these official controls are carried out by the National Standards Authority of Ireland.

There is a structured and organised system of official controls in place and undertaken by the EHS to verify requirements of food law pertaining to food businesses involved in the bottling and packaging of water. Those involved in official controls are suitably qualified and trained to perform this work. Environmental Health Officers of the EHS are duly authorised to perform official controls and other activities and the necessary legislation to enforce same is in place. Official controls across all aspects of the bottled water industry are carried out on a risk basis.

Records of official controls are maintained and made available to food business operators (FBOs). Documented procedures for carrying out official controls have been established in a series of protocols all of which are made available to staff electronically. Procedures are in place for the notification to the EHS by those who wish to register a food business. All food businesses have been issued with a unique identification number which is managed and maintained via the Environmental Health Inspection System (EHIS). Some findings relating to the structure, organisation and performance of official controls were identified by the audit team.

The audit team assessed compliance with relevant food law in five bottled water establishments. The size and complexity of bottled water establishments visited ranged from small-scale to large. In two small scale

bottled water establishments the audit team identified non-compliances regarding the ability of the food safety management systems and associated records to demonstrate compliance with food law. Where non-compliances with food law were established during the inspections of bottled water establishments, they were verbally notified to the food business operator at a closing meeting by the FSAI in agreement with the EHS. These non-compliances were followed up during subsequent official controls by the HSE.

## 3. Introduction

This audit was part of the planned programme of audits of official controls, undertaken by the FSAI in 2022. The opening meeting and initial audit of EHS structures and processes at a national level took place virtually, while the proceeding audits of EHS local areas and FBOs took place on-site and face-to-face. During the audit, there were 15 registered bottled water establishments located in HSE EHS operational regions; HSE West, HSE Dublin Northeast and HSE South. All three of these regions were visited as part of the audit. HSE local areas responsible for the supervision of bottled water establishments were selected for on-site activities. The closing meeting was conducted virtually.

The audit was carried out using documentation contained in the FSAI business management system i.e. The Audit Charter and FSAI Audit procedure. The FSAI team were at all times accompanied throughout the audit by representatives from the EHS.

The audit team acknowledge the challenges faced by the HSE while working through a global pandemic and the impact that COVID-19 has had on the delivery of the service. The pandemic was an unforeseen external challenge, and it is understood that as a direct result of this, work plans were reprioritised to accommodate additional functions assigned to the EHS. This is recognised through the agreement of revised EHS KPIs with the FSAI and the on-going engagement between the EHS and the FSAI throughout the pandemic to maintain food safety and consumer protection.

### 3.1 Audit objective

The overall objective of the audit was to evaluate official controls carried out by the Environmental Health Service (EHS) of the Health Service Executive (HSE) in food business operations. The primary objective was to assess the suitability and effectiveness of official controls carried out by the EHS in bottled water food business operations. The secondary objective was to assess the compliance of selected bottled water establishments with food law which related to their food business operation.

### 3.2 Audit scope

The scope of the audit included the structure and organisation of official controls carried out by the EHS relating to bottled water establishments during 2021 and the relevant period of 2022. It also assessed whether the EHS were complying with the audit criteria against which the audit was carried out. The scope also included an assessment of compliance with relevant food law in selected bottled water establishments.

The scope of the audit did not include the recognition of Natural Mineral Waters as these official controls are carried out by the National Standards Authority of Ireland.

The scope included:

- Legislation applicable to official controls
- Procedures documented to ensure that these controls are carried out uniformly and to a consistently high standard
- Inspection, sampling plans and reports of same
- Relevant Guidance Notes published by the FSAI applicable to bottled water
- FBO food safety management systems and related records.

### 3.3 Audit criteria and reference documents

[Food Safety Authority of Ireland Act 1998](#) (S.I. No 29 of 1998), as amended.

[Regulation 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority, as amended.

[Regulation 2017/625](#) on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended.

[Regulation 852/2004](#) on the hygiene of foodstuffs, as amended.

[S.I. No. 747 of 2007](#) European Communities (General Food Law) Regulations 2007.

[S.I. No. 369 of 2006](#) European Communities (Hygiene of Foodstuffs) Regulation 2006.

[S.I. No. 79 of 2020](#) European Union (Official Controls in relation to Food Legislation) Regulations 2020.

[Directive 2009/54/EC](#) on the exploitation and marketing of natural mineral waters.

[Commission Directive 2003/40/EC](#) establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters.

[Commission Regulation \(EU\) No 115/2010](#) laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters.

[Council Directive 98/83/EC](#) on the quality of water intended for human consumption.

[Council Regulation \(Euratom\) 2016/52](#) laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.

[Council Directive 2013/51/Euratom](#) laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

[S.I. No. 282 of 2016](#) European Union (Natural Mineral Water, Spring Waters and Other Waters in Bottles or Containers) Regulation 2016.



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[S.I. No. 55 of 2020](#) European Union (Natural Mineral Water, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulation 2020

[S.I. No. 122 of 2014](#) European Union (Drinking Water) Regulations 2014

[S.I. No. 160 of 2016](#) European Union (Radioactive Substances in Drinking Water) Regulations 2016

[Regulation \(EU\) No. 1169/2011](#) on the provision of food information to consumers

[S.I. No. 556/2014](#) European Union (Provision of food information to consumers)

[The FSAI HSE Service Contract 2021](#)

[The National Control Plan for Ireland 2018 - 2022](#)

EHS Operational Plans & data supplied to FSAI

EHS Documented Procedures and protocols

FSAI Guidance Notes / Codes of Practice

Other relevant legislation detailed in the [FSAI HSE Service Contract 2021](#)

### 3.4 Audit methodology

This audit was undertaken using documented procedures which are included in the FSAI Business Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI's audit obligations as set out in Section 48 (9) of the Food Safety Authority of Ireland Act 1998 as amended. They are also in accordance with the requirements of the EU Commission guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

To prepare, the audit team used information maintained in the FSAI which was supplemented by that contained in the pre-audit questionnaire completed by the EHS. The audit commenced with a virtual opening meeting and included a high-level overview and assessment of EHS structures and processes. This was followed by visits to five EHS local areas during which the audit team assessed compliance with the requirements of Regulation (EU) 2017/625 and other relevant legislation. This aspect of the audit consisted of two components. The first involved an assessment of official controls and their outcomes, performed by staff from these local areas. The second component consisted of an audit of selected bottled water establishments to verify the performance of official controls and to assess compliance with food law.

## 4. Audit findings

### 4.1 Service contract

Section 48 of the FSAI Act 1998 makes provision to allow the Authority for the purposes of carrying out its functions to enter a service contract with official agencies. For the purpose of this audit the service contract is between the Authority and the Health Service Executive.

Schedule 2, section 5.1 of the contract details how conformance with its requirements is monitored through liaison and review meetings. Such meetings shall be held according to an annual schedule developed by the Authority, in consultation with the HSE.

Preamble 4a(i) of the service contract sets out the requirement of the HSE to ensure compliance with food legislation. The service contract states that such compliance with food legislation is completed by means of 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.

Schedule 4, section 1.1 of the contracts states that the Official Agency will collect and store electronically, information generated from food related official controls and other official activities specified in Schedule 2 of

the service contract. 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.

### Findings

To verify that the HSE was adhering to the terms set out in preamble 4a(i) and schedule 4, section 1.1, the audit team reviewed information and records submitted by the HSE for 2021 and the relevant period of 2022. The minutes of the liaison meetings for this period were also reviewed. The audit team confirmed that the liaison meetings were taking place as per the schedule within the service contract and found that the minutes were detailed and contained information on the performance of all aspects of official controls including bottled water establishments.

The audit team verified that for the purposes of ensuring compliance with food legislation, the EHS carry out official controls on a risk basis in accordance with legislation, the service contract and related guidance notes. In particular Guidance Note 1 (Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 3) (GN1)) and Guidance Note 25 (Guidance for the assessment of compliance of legislation applicable to natural mineral waters, spring waters and other water (Revision 1) (2019) (GN25)) are used by the EHS in relation to official controls in bottled water establishments. In addition to GN1 and GN25, the EHS have implemented a suite of documented protocols to support the completion of official controls including sampling and inspection.

The EHS submit an annual report as required by section 48(8) of the FSAI Act and in addition to this a 6 monthly report is submitted to the FSAI. The annual and 6 monthly reports are intended to address the returns as outlined in schedule 4, section 1.1 of the service contract. The audit team verified that the annual and 6 monthly reports for 2021 were submitted to the FSAI as part of the service contract requirements.

The specific data to be provided to the Authority includes that specified in Schedule 4, section 1.1 (X), which states “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”. The operational plan developed by the EHS to meet this requirement for 2022 had been documented and submitted to the FSAI as part of the preparation for the audit in June 2022. The documented plan to meet this requirement for 2021 had not been electronically transmitted to the Authority during that calendar year. This plan was made available to the FSAI team during the course of the audit and was also sent to the FSAI enforcement policy division.

## 4.2 General obligations concerning the competent authorities and the official control authorities

Article 5 of Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended, requires competent authorities to have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities. Competent authorities shall also have the legal powers to perform official controls and other official activities and to take the action provided for within the Regulation. It is also a requirement that staff receive appropriate training for their area of competence.

### Findings

The audit team confirmed that the EHS have procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities in accordance with article 5 of the Official Control Regulation (OCR).

The audit team verified that there is a suite of documented protocols and procedures in place which are used to ensure the effectiveness and appropriateness of official controls applied, including Protocol 3 “Inspection of a food business” and Protocol 8 “Sampling of food and/or a relevant thing”.

The audit team verified that there are arrangements in place to ensure that all EHS staff performing official control activities are impartial and free from any conflict of interest. The EHS have put in place policies which incorporate requirements regarding impartiality and conflict of interest. In one local area the audit team assessed whether these requirements were being adhered to, and signed examples of these policies were provided. The audit team noted that all relevant EHS staff within that local area had not signed these policies at the time of the audit.

Prior to commencing employment with the EHS, it is a requirement that all Environmental Health Officers hold a BSc Degree in Environmental Health or equivalent as a minimum. All newly appointed / promoted / transferred / seconded Environmental Health staff receive induction training as detailed in the Environmental Health specific National Induction Checklist.

The audit team confirmed through the training records evaluated that staff carrying out official controls in bottled water establishments are qualified to do so and have received specialised training in “Natural mineral water”, “spring water” and “other water” legislative requirements. This specialised training on bottled water legislative requirements was carried out in the form of an FSAI workshop in 2019. The material used has

been made available via online shared platforms to all staff who attended or have subsequently commenced official controls in a bottled water establishment.

The EHS have developed Protocol 52 “Professional Development” to assess the learning and development needs of all staff against organisational goals including the Environmental Health Service operational plan. The protocol has been documented to establish a method for staff to receive appropriate training for their area of competence. At a national level the CPD (Continuing Professional Development) /Research Operational unit co-ordinate the development of the National CPD/Learning & Development Plan. In one local area visited, the Principal Environmental Health Officer (PEHO) provided to the audit team a copy of the completed local Learning and Development Needs Assessment form which had been submitted to the CPD / Research OU for collation and consideration within the National Plan. The approved National Learning and Development Plan which was issued to the service for 2021 and 2022 was reviewed by the audit team. It was noted that there was no specific training on bottled water requirements scheduled on the 2021/2022 National Plan, as specific training on bottled water requirements was carried out in 2019.

A Local Learning & Development Plan/Tracker is also in place to allow PEHOs identify any additional training needs for staff on their teams that is not provided in the national training plan. The audit team verified that this was appended to Protocol 52 and available to all PEHOs electronically through the EHIS. Section 6.4.1 of Protocol 52 states that “On an annual basis, the PEHO completes the Local Learning & Development Plan/Tracker”. In one local area visited, completion of the local learning and development tracker could not be demonstrated to the audit team for 2021 and for the relevant period of 2022 at the time of the audit. It was confirmed to the audit team that this local learning and development tracker was subsequently completed in quarter 4 2022.

During the onsite component of the audit, the FSAI team verified that authorised officers performing official controls have been issued with warrants or other documents to enforce legal powers. These legal powers are contained in Statutory Instruments which allow them to perform official controls and other official activities as set out in the OCR. SI 79 of 2020 European Union (Official Controls in Relation to Food Legislation) Regulations 2020 and SI 282 of 2016 European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles Or Containers) Regulations 2016 were confirmed as the principal legislation in place providing powers to the EHS to perform official controls and enforce bottled water regulations.

In one local area following an internal review by the PEHO, it was established that the application of official controls under the legal powers listed above in two bottled water establishments had not been appropriate and effective. GN 1 specifies how the outcomes of official controls are recorded. The documented outcomes of inspections in these two bottled water establishments as required by GN 1 did not reflect the actual level of compliance with food law. In subsequent inspections, significant non-compliances with food law were

detected which were acted upon by the PEHO and staff in the local area responsible for supervision of the two bottled water establishments concerned. The audit team were satisfied that the corrective action, taken following the internal review, was prompt and effective and that the issue identified had been addressed.

### 4.3 Internal audit

Article 6 of the OCR requires competent authorities to carry out internal audits or have audits carried out on themselves. It also requires the competent authorities to take appropriate measures considering the results of those audits. Such internal audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

#### Findings

The audit team verified that there is an established EHS internal audit function which carries out internal audits as required by Article 6 (1) of the OCR. Audits are undertaken using documented procedures namely the Environmental Health Service Internal Audit Unit (EHSIAU) Audit Charter and the EHSIAU Audit process. The objective of the EHSIAU is to verify EHS compliance with official legislation and to verify the effectiveness and suitability of planned arrangements. The EHSIAU is also responsible for carrying out internal audits on the other components of the work of the EHS outside food law.

It was established that the EHSIAU applies a risk universe assessment for the planning and prioritisation of audits relating to food law. A risk matrix is then applied, and a 5-year audit program is developed. An audit of official controls on natural mineral waters, spring waters and other bottled water plants was conducted by the EHSIAU in 2016. The audit team verified that all 3 national findings identified during the audit requiring corrective action were closed out and addressed. Further audits in relation to official controls in bottled water establishments are due to be scheduled in the 2022 – 2026 audit program. The audit team also verified that independent scrutiny of the internal audit process and function is completed routinely as required by Article 6.2 of the OCR.

### 4.4 General rules of official controls

Article 9 of the OCR requires competent authorities to perform official controls on all operators regularly, on a risk basis and with appropriate frequency. Official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out. Article 9 of the OCR also requires official controls to be carried out to identify possible intentional violations perpetrated through fraudulent or deceptive practices.

### Findings

The audit team verified that official controls are carried out by the EHS on a risk basis in accordance with official control regulations, the service contract, FSAI/HSE protocols and related guidance such as GN1 and GN25. GN1 is the documented procedure used by the EHS for the completion of risk profiling and the establishment of risk categorisation. One of the key purposes of GN1 is “to support the development of the HSE inspection program by setting out the process for risk categorisation of food premises to determine the frequency of scheduled inspections”. The EHIS has been designed to incorporate the risk profiling system outlined in GN1. The schedule for official control inspections is managed on EHIS for each FBO file. Once an official control inspection is uploaded to the EHIS, the next scheduled official control inspection date is populated. This is all based on the FBO risk category and frequency of inspection required.

The risk category assigned to an FBO determines the frequency and the prioritisation of official controls. The risk categories are numeric ranging from 1 to 6 in descending order as per GN1. Each risk category has a standard and a minimum frequency for planned inspections. Further to GN1, the EHS annual operational plan as agreed with the FSAI provides the final determination regarding the frequency of inspection, taking into account the key priorities of the service.

There were 15 registered bottled water establishments in operation at the time of the audit, 11 of which were determined to be a risk category 2, and 4 were determined to be a risk category 3. EHOs must carry out a risk profile for each new premises before they can record an official control against the premises. The risk category of a food premises is continuously assessed following each inspection and there is a process built into EHIS to reconfirm the risk category or edit the risk profile before the planned inspection/planned surveillance inspection can be saved. This ensures that any change to the risk profile is edited as necessary based on the findings at the time of the inspection and this may result in an overall increase or decrease in the score and in turn the risk category may change. The audit team noted that the EHIS, a tool used by the EHS as presented during the audit, was a robust system and provides structure to the EHS regarding its official control programmes. As the steps for risk profiling and risk categorisation are built into the EHIS, it provides reassurances that authorised officers cannot deviate from these steps.

Through demonstrations in local EHS offices, a detailed understanding of the EHIS, the recording of inspection reports and the issuing of correspondence issues to FBO's was developed by the FSAI team. The audit team confirmed that official control inspections of bottled water establishments were being carried out within each region and local area audited. As part of the audit process, the audit team assessed the risk categorisation and the resulting frequency of official control inspections performed on an average of two bottled water establishments within each local area office audited. This took into consideration the EHS protocol 3 “Inspection of a food business”, GN1 and the EHS annual business plans.

**Table 1** Planned official control inspection frequency for 2021

| Food Business Operator    | Risk Category <sup>1</sup> | Planned Inspection frequency as per 2021 EHS operational plan |           | Planned Surveillance frequency as per 2021 EHS operational plan |           |
|---------------------------|----------------------------|---|-----------|---|-----------|
|                           |                            | Planned   | Completed | Planned   | Completed |
| Food Business Operator 1  | 2                          | 1   | 1         | 1   | 1         |
| Food Business Operator 2  | 2                          | 1   | 1         | 1   | 1         |
| Food Business Operator 3  | 2                          | 1   | 1         | 1   | 0         |
| Food Business Operator 4  | 2                          | 1   | 1         | 1   | 0         |
| Food Business Operator 5  | 2                          | 1   | 0         | 1   | 2         |
| Food Business Operator 6  | 2                          | 1   | 1         | 1   | 0         |
| Food Business Operator 7  | 2                          | 1   | 0         | 1   | 1         |
| Food Business Operator 8  | 3                          | 1   | 0         | <sup>2</sup> N/A  | N/A       |
| Food Business Operator 9  | 3                          | 1   | 0         | N/A   | N/A       |
| Food Business Operator 10 | 3                          | 1   | 0         | N/A   | N/A       |

Table 1 collates the information collected by the audit team in relation to the 10 bottled water establishment files reviewed. It sets out the planned inspections and planned surveillance inspections in these bottled water establishments for 2021. Several bottled water establishments did not receive planned inspections or planned surveillance inspections as per the standard or minimum frequency outlined within the 2021 EHS operational plan. The EHS advised the audit team that inspection targets were not met in the timeframe for the scope of the audit due to the COVID-19 pandemic and the EHS involvement in activities directly related to the conduct of controls to minimise the risk of spread of the infection including contact tracing and

<sup>1</sup> Risk category 2 (1 Planned Inspection & 1 Planned Surveillance Inspection) Risk category 3 (1 planned inspection) for 2021 as per the 2021 EHS Operational Plan.

<sup>2</sup> Planned Surveillance Inspection not required as per the 2021 EHS Operational Plan



inspection checks. The FSAI HSE Service Contract (Schedule 2, 1.1) recognises and accepts the impact of external challenges. Section 6.9 of EHS protocol 3, states that “Where there is a deviation from the standard inspection frequency the PEHO must be informed and the reason and date for same must be recorded”. Evidence of this was not provided to the audit team at the time of the audit.

The FSAI/HSE protocol for routine official control sampling and analysis of bottled water 2022 in conjunction with GN25 is used by the EHS to provide information on routine official control sampling for bottled water and to ensure compliance with SI No. 282 of 2016. The audit team confirmed that sampling in relation to bottled water which is subject to full / partial monitoring and specialised chemical and physical testing had been carried out (where required) within each local area audited and robust official control sampling and analysis plans were in place. The sampling period for bottled water subject to full monitoring is agreed each year between the EHS and the laboratories.

The audit team noted that in one local area audited for the period of 2021 and 2022 to date, the full / partial monitoring did not include a test for the chemical parameter cyanide. Cyanide is listed as one of the chemical parameters within Annex I Part B of Council Directive 98/83/EC and within the FSAI/HSE protocol for routine official control sampling and analysis of bottled water 2022. While it is accepted that none of the Public Analysts Laboratories (PALs) are in a position to test for cyanide, this does not negate the responsibility to monitor its presence / absence levels as required by Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption by way of outsourced testing in an accredited and designated laboratory.

It was confirmed by the audit team that inspections are carried out in accordance with GN1. GN1 provides guidance regarding unannounced inspections and exceptions where prior notice may be necessary and duly justified. The audit team noted that there is no written or electronic confirmation maintained regarding the announced / unannounced nature of official control inspections and or the justification for the provision of prior notice. While there is currently no specific requirement within the OCR for this to be documented, verification of compliance with article 9(4) which states “official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out” cannot be determined from the current inspection report template. Confirmation of whether an official control was unannounced or announced is based exclusively on the ability of the inspecting officer to recall such from memory. In one local area, due to the size, scale and infrequent operation of certain bottled water establishments, it is routine practice for prior notice of official control inspections to be provided.

The documented procedure protocol 59 (Alleged Food Fraud Referral) is in place and used by the EHS to ensure that all alleged food fraud referrals and suspicions of food fraud are investigated. This is further strengthened by the annual operational plan which directs the EHS to carry out investigations on suspicion of

non-compliance as a result of intentional violation of food law. Inspection templates and e-sheets used during routine official controls are also deemed to form part of the controls in identifying possible violations of the rules referred to in Article 1(2) of the OCR, perpetrated through fraudulent or deceptive practices.

### 4.5 Operators, processes and activities subject to official controls

Article 10 of the OCR requires that to the extent necessary to ascertain compliance with the rules referred to in Article 1(2) of the Regulation, competent authorities shall perform official controls on animals and goods at any stage of production, processing, distribution, and use. The competent authority shall also draw up and keep up to date a list of operators.

#### Findings.

The audit team verified that the EHS has established a system of official controls in relation to bottled water establishments at all stages from extraction, processing, bottling, distribution, wholesale and retail. This system of official controls provides for an assessment of compliance with relevant legislation through inspection / auditing and sampling / monitoring programs. The audit team verified that there is a suite of protocols in place which outline the processes and steps to be taken when performing such official controls. These protocols are further supplemented by specific records such as “E-Sheets” and “visit records” which are utilised to document official controls performed and their outcomes.

In one bottled water establishment inspected, the audit team identified that during a recent planned official control inspection the FBO did not provide the EHS with updated details of the specific activities they carry out. The food business operator had commenced dispatching water in bulk tankers for further processing at another establishment. The planned official control did not identify this additional activity as part of the inspection process. As required by Article 6(2) of Regulation 852/2004 and Article 15(5) b of Regulation (EU) 2017/625, food business operators shall keep the competent authorities up-to-date with the specific activities they carry out. As a result, certain operator processes and activities were not subject to official controls.

The EHS operate a live list of establishments under its supervision which is maintained on a national register. It was verified by the audit team that any amendments in relation to the registration / approval and or removal of a food business results in an immediate update of the national register. The audit team verified in one local area that all 15 registered bottled water establishments were on the national register. The documented procedure Protocol 1 “Notification for registration of food business establishment” is in place and utilised by the EHS to ensure that notifications for registration of food business establishments are dealt

with in accordance with the relevant statute. This protocol also ensures that any significant changes in activities, change of ownership or cessation of existing establishments are recorded on the register.

### 4.6 Documented control procedures

Article 12 of the OCR requires competent authorities to perform official controls in accordance with documented procedures. They shall cover the subject areas for official controls, contain instructions for staff performing such official controls, take corrective action where shortcomings are identified and be updated as appropriate. Competent authorities shall have control verification procedures (arrangements put in place and actions performed by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective) in place.

#### Findings

The EHS has developed a suite of documented protocols which detail how official controls are carried out in respect of food business operations. Each protocol specifies related supporting documents and records under the headings “related documents” and “related records”. The audit team verified that all such protocols and records were available to all EHOs electronically.

The protocols listed below were the main protocols reviewed by the audit team to evaluate official controls carried out by the EHS. They have been documented not only to support the completion of official controls but also to ensure the effectiveness and appropriateness of those official controls. The main protocols reviewed by the audit team during this audit included:

- Protocol 1 – Notification for registration of food business establishment
- Protocol 3 – Inspection of a food business
- Protocol 8 – Sampling of food and / or a relevant thing
- Protocol 14 – Issuing of export certificates for food on non-animal origin
- Protocol 40 – Warrants
- Protocol 51 – Document control and change request
- Protocol 52 – Professional Development
- Protocol 59 – Alleged food fraud referral
- Protocol 62 – File review
- Shared FSAI/HSE protocol for routine official control sampling and analysis of bottled water 2022 (Survey Code 22NS1).

Protocol 51 “Document control and change request” is the overarching document control procedure in place. It is used to maintain and control all EHS documentation used during official controls activities. All protocols

are controlled by means of a protocol number, issue date, title, revision number, and approved by the Assistant National Director – Environmental Health-

In addition to the EHS protocols, there are several related records including forms, letter templates and E-sheets in place. The audit team noted that the following E-sheets and records were utilised as part of the recording of official controls in bottled water establishments:

- FR2 – FIC Other waters
- FR2 – FIC Spring waters
- FR2 – FIC Natural mineral waters
- FR3 – 852 Visit record

Section 6.5 of Protocol 51 states “To ensure document control on all related forms and letters, a revision number and issue date will be applied”. The audit team noted that there was no revision number present on the four forms above. In relation to the management of document control on forms / records, the EHS informed the audit team that the name of the form / record is a unique identifier. It has not been documented in Protocol 51 that the name of the form / record is a unique identifier.

The audit team verified that control verification procedures were in place to ensure that official controls performed by the EHS are effective, appropriate, and consistent. The Managing Quality Section of the Environmental Health Operational Plan 2021 states that “The EHS will finalise in 2021 Annex III and IV of the Guidance for all staff on the Verification of the Effectiveness of EHS Regulatory Control activities. This includes guidance on providing a quality regulatory service including the following elements:

- Risk-based targeting of controls.
- Documented procedures.
- Impartiality.
- Uniformity and consistency.
- Reliable detection and recording of non-compliance.
- Actions taken to improve compliance.
- Follow-up.”

In addition, the EHS has an Internal Audit Unit to provide assurance to management on the appropriate operation and effectiveness of service delivery.

Documentation forwarded to the FSAI in preparation for on-site activities included the EHS “position paper on effectiveness Version 2”. The position paper on effectiveness outlines the EHS perspective (position) on the interpretation of the high-level definition of effectiveness of official controls for the organisation as a

whole and outlines the control verification procedures at each level of the organisation. At the time of the audit, it was unclear the status of the position paper, as to whether it is the procedure to be implemented to determine the effectiveness of official controls or whether it is still in development.

As part of the audit process, the FSAI team assessed protocol 62 “File Review”. Section 6.1 of protocol 62 states “The PEHO shall plan a file review based on the EHS Business Plan.” The EHS business plan for 2021 states, “At least 3 food control files per SEHO/EHO shall be reviewed”. In two local areas audited, the audit team noted that only 1 file per S/EHO was reviewed and completed for 2021. It was stated by the EHS that this was due to the impact of the Covid 19 Pandemic.

### 4.7 Written records of official controls

Article 13 of the OCR requires that competent authorities shall draw up written or electronic records of every official control that they perform, and they shall contain a description of the purpose of the official controls, the control methods applied, the outcome of the official controls; and where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls. The operator shall be promptly informed in writing by the competent authorities of any case of non-compliance identified through the official controls.

#### Findings

The audit team verified that a combination of written and electronic records was in place for the completion of official controls in bottled water establishments. All records are appended to the relevant protocols and are available to all staff electronically.

Prior to the performance of official controls, the authorised officer completes a review of the FBO file and identifies the relevant records / E-sheets that apply to that business. The audit team verified that all relevant records / E-sheets for the recording of official controls in bottled water establishments were present on the EHIS and being utilised in each local area audited. The main records reviewed consisted of the following:

- FR2 – FIC Other waters
- FR2 – FIC Spring waters
- FR2 – FIC Natural mineral waters
- FR3 – 852 Visit record

A description of the purpose of the official control, the control method applied, and the outcome of the official control was evident on the records. In terms of official control methods, there are five different types of inspections which may be completed by the EHS:

- Planned inspection (Planned inspection / planned surveillance inspection),
- Enforcement inspection,
- Complaint-related inspection,
- Food incident or food alert inspection,
- Food legislation / other food hygiene inspection and visits.

The authorised officer records the inspection outcome as being compliant or non-compliant. Non-Compliant outcomes are further categorised as *Class I Non-compliance (s)* where the risk to food safety is of low magnitude and can be rectified and contained easily, *Class II Non-compliance(s)* which may or is likely to pose a significant risk but is not a grave and immediate danger to public health or *Class III Non-compliance(s)* where there may be a grave and immediate danger to public health. The outcome of the official controls is discussed with the FBO and the inspection record / E-sheet is completed, all of which is then uploaded on to the EHIS. Following an inspection where non-compliances are identified, correspondence in the form of standard template letters are issued to the FBO and a copy is maintained on file. Following a review of one 852 visit record regarding a planned surveillance inspection completed in 2021, the audit team noted that several fields had no text / commentary present, several fields stated “Satisfactory” without any supporting information and one section of the visit record was not selected as being satisfactory or non-compliant.

The audit team verified that procedures relating to written records were being adhered to and correspondence pertaining to official control outcomes had been issued by the authorised officer to the FBO in each of the local areas audited. The audit team also verified that during inspection of bottled water establishments that records pertaining to official controls were available on file.

### 4.8 Methods and techniques for official controls

Article 14 of the OCR specifies the methods and techniques to be used during official controls and may include the examination of the controls that operators have put in place and of the results obtained, inspection of equipment, cleaning and maintenance products and processes, traceability, labelling and controls on the hygiene conditions in the operators’ premises.

#### Findings

The standard “852 visit record” utilised by the EHS during official controls is based on Regulation (EC) No. 852/2004 and is maintained on the EHIS. This record requires the authorised officers to determine compliance with all relevant aspects of food law enforced through Regulation (EC) No. 852/2004. This record is broken down into key areas such as an inspection of prerequisite programs, the application of HACCP principles, and an inspection of management procedures. Additional inspection records are available to authorised officers which are selected for completion based on relevance to the food business operations.

The audit team confirmed that overall, the methods and techniques utilised by authorised officers during official controls were robust and were designed to incorporate all the relevant criteria outlined in Article 14 of the OCR.

### 4.9 Obligations of operators

Article 15 of the OCR requires competent authorities to the extent that this is necessary for the performance of official controls or of other official activities that operators shall, where required by the competent authorities, give staff of the competent authorities' access to premises and other places under their control, access to computerised information management systems, their documents, and any other relevant information.

#### Findings

The audit team were satisfied that during official controls conducted by authorised officers, that food business operators provided access to all areas of the food business and that the relevant information requested was provided by means of hard copy or electronic records. During the onsite verification part of the audit, the audit team were given full access to all relevant areas of the premise and of the food safety management systems used as part of their water bottling operations and the associated records.

## 5. Local area audits and food business operator findings

As part of the FSAI audit process five local area offices were audited within three HSE regions and five food businesses were audited to assess compliance with relevant food law. A range of bottled water establishments were selected for on-site inspections to take into consideration the three different types of water produced, i.e., natural mineral water, spring water and other water.

Five bottled water establishments were inspected during the audit. The size and complexity of bottled water establishments visited ranged from small scale to large. The three large scale establishments had detailed food safety management systems appropriate to the size of their operation in place. Procedures from these food safety management systems and associated records were reviewed by the audit team. Non-compliances were identified in all food business establishments. In the two small scale bottled water establishments the audit team identified significant non-compliances regarding the ability of the food safety management systems and associated records to demonstrate compliance with food law. The audit team noted that in one bottled water food business operation there was no such system or records available on

the day of inspection while in another, the availability of such documentation was limited. In one of these food businesses, packaging was being stored in an adjoining building which had not been notified to the HSE as being part of the food business. At the time of the inspection this building was unsuitable for the storage of packaging for bottled water products. Where non-compliances with food law were established during the inspections of bottled water establishments, they were verbally notified to the FBO at a closing meeting. These non-compliances were to be followed up and closed off during subsequent official controls by the HSE.

## 6. Conclusions

The audit team acknowledge the challenges faced by the HSE while working through a global pandemic and the impact that COVID-19 has had on the delivery of the service. The pandemic was an unforeseen external challenge, and it is understood that as a direct result of this, workplans were reprioritised to accommodate additional functions in the EHS. This is recognised through the agreement of revised EHS key performance indicators with the FSAI and on-going engagement between the EHS and the FSAI throughout the pandemic.

There is a structured and organised system of official controls in place for the supervision of FBOs involved in bottling water. Those involved in official controls are suitably qualified and trained to perform this work. Environmental Health Officers are duly authorised to perform official controls and the necessary legislation to enforce same is in place.

The EHS have procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities in accordance with Article 5 of the OCR. In one local area following an internal review, it was established that the application of official controls in two bottled water establishments had not been appropriate and effective. The audit team were satisfied that the corrective action taken by local management following the internal review was prompt and effective and that the issue identified had been addressed.

Official controls are carried out by the EHS on a risk basis in accordance with OCR requirements, the service contract and FSAI/HSE protocols. They are carried out on goods at all relevant stages of the food chain under the remit of the EHS and the outcome of official controls are recorded on specific official control records and uploaded on to the EHIS. The EHIS, a tool used by the EHS as presented during the audit, was found to be a robust system that provides structure to the EHS regarding its official control programmes. The EHIS also provides reassurances that authorised officers cannot deviate from the relevant steps established in line with GN1.



Records of official controls are maintained, as required and in all cases reviewed, the audit team found that the FBO was promptly informed in writing as to the outcome of official controls performed. Standard operating procedures for carrying out official controls have been documented in the form of protocols. EHS protocols have been developed at national level and made available to all regions and local offices via the EHIS. The audit team noted that EHS documented protocols reviewed were found to be comprehensive. There were instances identified during the audit where the requirements of certain protocols were not being complied with in full.

The audit team reviewed the control verification procedures that the EHS have put in place. The objective of these procedures is to ensure that official controls performed by the EHS are effective, appropriate, and consistent. Documentation forwarded to the FSAI in preparation for on-site activities included the EHS “position paper on effectiveness”. It was unclear the status of the position paper, as to whether it is the procedure to be implemented to determine the effectiveness of official controls or whether it is still in development.

Three large scale and two small scale bottled water establishments were audited as part of this audit program. While non-compliance with food law was identified within all five bottled water establishments audited, significant non-compliance with food law was identified within the two small scale establishments. This suggested that the application of official controls was more effective and appropriate within larger scale bottled water establishments than in the smaller scale establishments audited. Where non-compliances with food law were established during the inspections of bottled water establishments, they were verbally notified to the food business operator at a closing meeting. These non-compliances were followed up and closed out during subsequent official controls by the HSE and provide an opportunity to enhance the overall effectiveness of official controls.

## 7. Findings requiring corrective action

1. Ensure all service contract requirements are adhered to,
  - I. The specific data to be provided to the Authority includes that specified in Schedule 4, Section 1.1 (X), which states “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”. The documented plan to meet this requirement for 2021 had not been electronically transmitted to the Authority during that calendar year.
  
2. Ensure documented procedures developed by the EHS are adhered to,

- I. Section 6.4.1 of Protocol 52 states that “On an annual basis, the PEHO completes the Local Learning & Development Plan/Tracker”. In one local area office visited, completion of the local learning and development tracker could not be demonstrated to the audit team for 2021 and for the relevant period of 2022.
  - II. Section 6.9 of EHS protocol 3, states that “Where there is a deviation from the standard inspection frequency the PEHO must be informed and the reason and date for same must be recorded”. Evidence of this was not provided to the audit team at the time of the audit.
  - III. Section 6.5 of Protocol 51 states “To ensure document control on all related forms and letters, a revision number and issue date will be applied”. The audit team noted that there was no revision number present on the following four forms, FR2 FIC Other Waters, FR2 FIC Natural Mineral Waters, FR2 FIC Spring Waters and FR3 852 visit record.  
In relation to the management of document control on forms / records, the EHS informed the audit team that the name of the form / record is a unique identifier. It has not been documented in Protocol 51 that the name of the form / record is a unique identifier.
  - IV. Section 6.1 of protocol 62 states “The PEHO shall plan a file review based on the EHS Business Plan.” The EHS business plan for 2021 states, “At least 3 food control files per S/EHO shall be reviewed”. In two local areas audited, the audit team noted that only 1 file per S/EHO was reviewed and completed for 2021.
3. Ensure the status of the “position paper on effectiveness Version 2” is clear as to whether it is the procedure to be implemented to determine the effectiveness of official controls or whether it is still in development.
  4. Ensure that all non-compliances with food law identified during the inspection of bottled water establishments are closed out.



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

T +353 1 817 1300  
E [info@fsai.ie](mailto:info@fsai.ie)

 Join us on LinkedIn

 Follow us on Twitter @FSALinfo

 Say hi on Facebook

[www.fsai.ie](http://www.fsai.ie)